UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2024

OR

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

For transition period from to

Commission File Number: 001-39186

ARCUTIS BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-2974255**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
3027 Townsgate Road Suite 300	**91361**
Westlake Village , California	**(Zip Code)**
(Address of Principal Executive Offices)	

(805) 418-5006

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001	**ARQT**	**The Nasdaq Global Select Market**

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 (§232.405 of this chapter) 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, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer”, “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The number of shares of the registrant’s Common Stock outstanding as of May 10, 2024 was 115,764,164 .

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q may be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “estimates,” “forecasts,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to statements regarding our future results of operations and financial position, industry and business trends, stock compensation, business strategy, plans, market growth, commercialization of approved products, and our objectives for future operations.

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. Forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed in Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q for the quarter ended March 31, 2024. The forward-looking statements in this Quarterly Report on Form 10-Q are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to this Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance, and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained in this Quarterly Report on Form 10-Q, whether as a result of any new information, future events, or otherwise.

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PART I. FINANCIAL INFORMATION

aItem 1. Financial Statements

ARCUTIS BIOTHERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and par value)

	March 31, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 190,097	$ 88,398
Restricted cash	617	925
Marketable securities	213,769	183,463
Trade receivables, net	37,154	25,807
Inventories	13,247	13,134
Prepaid expenses and other current assets	13,178	18,704
Total current assets	468,062	330,431
Property, plant, and equipment, net	1,369	1,539
Intangible assets, net	6,250	6,438
Operating lease right-of-use asset	2,264	2,361
Other assets	596	596
Total assets	$ 478,541	$ 341,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,969	$ 11,992
Accrued liabilities	33,584	33,941
Operating lease liability	756	735
Total current liabilities	47,309	46,668
Operating lease liability, noncurrent	3,181	3,382
Long-term debt, net	202,803	201,799
Other long-term liabilities	306	849
Total liabilities	253,599	252,698
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $ 0.0001 par value; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, $ 0.0001 par value; 300,000,000 shares authorized at March 31, 2024 and December 31, 2023; 115,505,437 and 96,787,343 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	12	9
Additional paid-in capital	1,242,349	1,070,558
Accumulated other comprehensive loss	(133)	4
Accumulated deficit	(1,017,286)	(981,904)
Total stockholders' equity	224,942	88,667
Total liabilities and stockholders' equity	$ 478,541	$ 341,365

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

ARCUTIS BIOTHERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Revenues:		
Product revenue, net	$ 21,569	$ 2,781
Other revenue	28,000	—
Total revenues	49,569	2,781
Operating expenses:		
Cost of sales	3,256	783
Research and development	23,141	35,345
Selling, general, and administrative	54,794	42,918
Total operating expenses	81,191	79,046
Loss from operations	(31,622)	(76,265)
Other income (expense):		
Other income, net	4,044	3,207
Interest expense	(7,480)	(7,042)
Loss before income taxes	(35,058)	(80,100)
Provision for income taxes	324	—
Net loss	$ (35,382)	$ (80,100)
Other comprehensive income (loss):		
Unrealized income (loss) on marketable securities	(116)	724
Foreign currency translation adjustment	(21)	(52)
Total other comprehensive income (loss)	$ (137)	$ 672
Comprehensive loss	$ (35,519)	$ (79,428)
Per share information:		
Net loss per share, basic and diluted	$ (0.32)	$ (1.31)
Weighted-average shares used in computing net loss per share, basic and diluted	111,048,525	61,169,089

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

ARCUTIS BIOTHERAPEUTICS, INC.

Condensed Consolidated Statements of Changes in Stockholders' Equity
(In thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2023	96,787,349	$ 9	$ 1,070,558	$ 4	$ (981,904)	$ 88,667
Issuance of shares of common stock net of discount and issuance costs of $ 10,820	18,157,895	3	161,679	—	—	161,682
Issuance of common stock upon the exercise of stock options	21,863	—	82	—	—	82
Issuance of common stock upon the vesting of restricted stock units	538,330	—	—	—	—	—
Stock-based compensation expense	—	—	10,030	—	—	10,030
Unrealized loss on marketable securities	—	—	—	(116)	—	(116)
Foreign currency translation adjustment	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	(35,382)	(35,382)
Balance—March 31, 2024	115,505,437	$ 12	$ 1,242,349	$ (133)	$ (1,017,286)	$ 224,942

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2022	61,037,403	$ 6	$ 930,425	$ (1,086)	$ (719,764)	$ 209,581
Issuance of common stock upon the exercise of stock options	31,497	—	63	—	—	63
Issuance of common stock upon the vesting of restricted stock units	285,314	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	3,718	—	37	—	—	37
Stock-based compensation expense	—	—	9,479	—	—	9,479
Unrealized gain on marketable securities	—	—	—	724	—	724
Foreign currency translation adjustment	—	—	—	(52)	—	(52)
Net loss	—	—	—	—	(80,100)	(80,100)
Balance—March 31, 2023	61,357,932	$ 6	$ 940,004	$ (414)	$ (799,864)	$ 139,732

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

ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Three Months Ended March 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (35,382)	$ (80,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	170	175
Non-cash lease expense	97	87
Amortization of intangible assets	188	188
Net accretion on marketable securities	(1,725)	(2,161)
Non-cash interest expense	1,004	994
Stock-based compensation expense	10,030	9,479
Changes in fair value of embedded derivative instrument	(543)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(11,347)	(4,311)
Inventories	(113)	(1,037)
Prepaid expenses and other current assets	5,538	(2,415)
Accounts payable	992	3,376
Accrued liabilities	(332)	(4,459)
Operating lease liabilities	(180)	(160)
Net cash used in operating activities	(31,603)	(80,344)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(105,952)	(39,667)
Proceeds from maturities of marketable securities	77,255	147,500
Purchases of property and equipment	—	(82)
Net cash provided by (used in) investing activities	(28,697)	107,751
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon exercise of stock options	82	100
Proceeds from issuance of common stock, net of issuance costs	161,682	—
Net cash provided by financing activities	161,764	100
Effect of exchange rate changes on cash	(73)	(52)
Net increase in cash, cash equivalents, and restricted cash	101,391	27,455
Cash, cash equivalents, and restricted cash at beginning of period	89,323	54,875
Cash, cash equivalents, and restricted cash at end of period	$ 190,714	$ 82,330
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Interest expense paid in cash	$ 6,512	$ 5,999

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

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Organization and Description of Business

Arcutis Biotherapeutics, Inc., or the Company, is a commercial-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. The Company's strategy is to focus on validated biological targets and to use its drug development platform and deep dermatology expertise to develop differentiated products that have the potential to address the major shortcomings of existing therapies in its targeted indications.

The Company received U.S. Food and Drug Administration ("FDA") approval of its first product, ZORYVE ® (roflumilast) cream 0.3% ("ZORYVE cream"), on July 29, 2022, for the treatment of plaque psoriasis, including intertriginous psoriasis, in individuals 12 years of age and older (subsequently approved down to 6 years old), and began U.S. commercialization in August 2022. The Company also received Health Canada approval of ZORYVE cream in plaque psoriasis on April 28, 2023 and began Canadian commercialization in June 2023. The Company received FDA approval of ZORYVE® (roflumilast) topical foam 0.3% ("ZORYVE foam"), on December 15, 2023, for the treatment of seborrheic dermatitis in individuals 9 years of age and older, and began U.S. commercialization in late January 2024.

Initial Public Offering and Follow-On Financings

On February 4, 2020, the Company closed an initial public offering ("IPO") issuing and selling shares of its common stock receiving aggregate net proceeds of approximately $ 167.2 million. The company completed subsequent public sales of its common stock in October 2020, February 2021, August 2022 and October 2023, receiving aggregate net proceeds of $ 93.4 million, $ 207.5 million, $ 161.6 million and $ 95.8 million, respectively.

In addition to the sale of common stock, the offering completed in October 2023 consisted of prefunded warrants to purchase 7,500,000 shares of the Company's common stock at $ 2.4999 per underlying share of common stock. The exercise price of the warrants is $ 0.0001 per underlying share of common stock. The prefunded warrants are exercisable at any time on or after their original issuance, and were not exercised as of March 31, 2024.

On February 28, 2024, the Company completed an offering relating to the sale of 15,789,474 shares of the Company's common stock at $ 9.50 per share. The Company also granted the underwriters an option to purchase up to an additional 2,368,421 shares at $ 9.50 per share, which the underwriters exercised in full on February 29, 2024. The aggregate net proceeds to the Company was $ 161.7 million after deducting underwriting discounts, commissions, and estimated offering expenses payable by the Company.

At-the-Market ("ATM") Offerings

On May 6, 2021, the Company entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC ("Cowen"), under which the Company may from time to time issue and sell shares of its common stock through ATM offerings for an aggregate offering price of up to $ 100.0 million. Cowen will act as the Company's sales agent for the ATM program and is entitled to compensation for its services equal to 3 % of the gross proceeds of any shares of common stock sold under the Sales Agreement. In March 2022, the Company sold 882,353 shares under the ATM for $ 17.00 per share and received $ 14.5 million in net proceeds. In December 2023, the Company sold 1,250,000 shares under the ATM for $ 2.60 per share and received $ 3.1 million in net proceeds.

In January 2024, the Company amended and restated its Sales Agreement with Cowen, to reset the shares available for sale, from time to time, through the Company's ATM equity offering program to such number of shares as would generate aggregate gross sales proceeds of up to $ 100.0 million. All terms are substantially the same as the original Sales Agreement entered into in May 2021. The Company has not yet issued or sold any common stock under the amended and restated Sales Agreement.

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $ 1,017.3 million and $ 981.9 million as of March 31, 2024 and December 31, 2023, respectively. Management expects to continue to incur operating losses. The Company had cash, cash equivalents, restricted cash, and marketable securities of $ 404.5 million and $ 272.8 million as of March 31, 2024 and December 31, 2023, respectively. The Company has $ 200.0 million outstanding under the Loan Agreement as of March 31, 2024. See Note 7.

The Company believes that its existing capital resources will be sufficient to meet the projected operating requirements for at least 12 months from the date of issuance of its financial statements. If the Company's available cash and marketable securities and anticipated future cash flows from operations are insufficient to satisfy its liquidity requirements, the Company may need to raise additional capital to fund its operations. No assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, the Company may be required to curtail certain planned activities. Failure to manage discretionary spending or raise additional financing, as needed, may adversely impact the Company's ability to achieve its intended business objectives and have an adverse effect on its results of operations and future prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The condensed consolidated financial statements include the Company's wholly-owned subsidiaries. All material intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, management evaluates such estimates and assumptions for continued reasonableness. In particular, management makes estimates with respect to revenue recognition, accruals for research and development activities, stock-based compensation expense, and income taxes. Appropriate adjustments, if any, to the estimates used are made prospectively based upon such periodic evaluation. Actual results could differ from those estimates.

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated balance sheet as of March 31, 2024, the interim condensed consolidated statements of operations and comprehensive loss, and the condensed consolidated changes in convertible preferred stock and stockholders' equity (deficit) and cash flows for the three months ended March 31, 2024 and 2023 are unaudited. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's audited annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair statement of the Company's financial information. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the three month periods are also unaudited. The condensed consolidated results of operations for the three months ended March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2023 included herein was derived from the audited financial statements as of that date. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Therefore, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2023.

Significant Accounting Policies

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

There have been no significant changes to the accounting policies during the three months ended March 31, 2024, as compared to the significant accounting policies described in Note 2 Company's audited financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2023.

Restricted Cash

As of March 31, 2024 and December 31, 2023, the Company held $ 0.6 million and $ 0.9 million, respectively, of restricted cash as collateral for a letter of credit related to the Company's amended office space lease.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities, and accounts receivable. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company is exposed to credit risk in the event of a default by either the financial institutions holding its cash or by its customers owing trade receivables to the extent recorded on the condensed consolidated balance sheets. To manage accounts receivable credit risk, the Company continuously evaluates the creditworthiness of its customers and the need for an allowance for potential credit losses.

Fair Value Measurement

The Company's financial instruments, in addition to those presented in Note 4, include cash equivalents, accounts receivable, accounts payable, accrued liabilities, and long-term debt. The carrying amount of cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate their fair values due to their short maturities. As the long-term debt is subject to variable interest rates that are based on market rates which regularly reset, the Company believes that the carrying value of the long-term debt approximates its fair value.

Assets and liabilities recorded at fair value on a recurring basis on the condensed consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active;

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07，*Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-07.

ARCUTIS BIOTHERAPEUTICS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

3. Revenue

Revenues are recognized under guidance within ASC 606, Revenue from Contracts with Customers. The following table presents the Company's disaggregated revenue for the periods presented (in thousands):

	Three Months Ended March 31,	
	2024	2023
ZORYVE cream	$ 15,026	$ 2,781
ZORYVE foam	6,543	—
Total product revenue, net	21,569	2,781
Other revenue	28,000	—
Total revenues	$ 49,569	$ 2,781

Other revenue relates to the Sato and Huadong licensing agreements. See Note 6.

4. Fair Value Measurements

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	March 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[(1)]	$ 169,927	$ —	$ —	$ 169,927
Commercial paper	—	6,958	—	6,958
Corporate debt securities	—	96,400	—	96,400
U.S. Treasury securities	130,581	—	—	130,581
Total assets	$ 300,508	$ 103,358	$ —	$ 403,866

(1) This balance includes cash requirements settled on a nightly basis.

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[(1)]	$ 73,544	$ —	$ —	$ 73,544
Commercial paper	—	11,806	—	11,806
Corporate debt securities	—	59,954	—	59,954
U.S. Treasury securities	126,557	—	—	126,557
Total assets	$ 200,101	$ 71,760	$ —	$ 271,861

(1) This balance includes cash requirements settled on a nightly basis.

Money market funds and U.S. Treasury securities are valued based on quoted market prices in active markets, with no valuation adjustment.

Commercial paper and corporate debt securities are valued taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

The following table summarizes the estimated value of the Company's cash, cash equivalents and marketable securities, and the gross unrealized holding gains and losses (in thousands):

	March 31, 2024			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 169,927	$ —	$ —	$ 169,927
Corporate debt securities	10,276	—	—	10,276
U.S. Treasury securities	9,894	—	—	9,894
Total cash and cash equivalents	$ 190,097	$ —	$ —	$ 190,097
Marketable securities:				
Commercial paper	$ 6,962	$ —	$ (4)	$ 6,958
Corporate debt securities	86,131	18	(25)	86,124
U.S. Treasury securities	120,692	7	(12)	120,687
Total marketable securities	$ 213,785	$ 25	$ (41)	$ 213,769

(1) This balance includes cash requirements settled on a nightly basis.

	December 31, 2023			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 73,544	$ —	$ —	$ 73,544
Corporate debt securities	14,851	3	—	14,854
Total cash and cash equivalents	$ 88,395	$ 3	$ —	$ 88,398
Marketable securities:				
Commercial paper	$ 11,817	$ 1	$ (12)	$ 11,806
Corporate debt securities	45,056	45	(1)	45,100
U.S. Treasury securities	126,492	82	(17)	126,557
Total marketable securities	$ 183,365	$ 128	$ (30)	$ 183,463

(1) This balance includes cash requirements settled on a nightly basis.

Realized gains or losses on investments for the three months ended March 31, 2024 and 2023 were no t material. As of March 31, 2024, it was determined that no credit losses exist, because the change in market value of those securities resulted from fluctuations in market interest rates since the time of purchase, rather than a deterioration of the credit worthiness of the issuers. As of March 31, 2024 and December 31, 2023, all securities have a maturity of 18 months or less and all securities with gross unrealized losses have been in a continuous loss position for less than one year. The Company generally holds its marketable securities until maturity and does not intend to sell, and is not required to sell, the investments that are in an unrealized loss position before the recovery of their amortized cost basis.

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

The following table summarizes the change in the fair value of the embedded derivative instrument for the three months ended March 31, 2024 (in thousands). There was no activity for the three months ended March 31, 2023.

	March 31, 2024
Beginning balance	$ 849
Gain from changes in fair value	(543)
Ending balance	$ 306

The fair value of the Company's embedded derivative instrument is based on significant inputs not observed in the market, and thus represents a Level 3 measurement. Refer to Note 7 for further discussion on the embedded derivative instrument.

5. Balance Sheet Components

Inventories

The components of inventory are summarized as follows (in thousands):

	March 31, 2024	December 31, 2023
Raw materials	$ 8,202	$ 9,951
Work in progress	2,303	486
Finished goods	2,742	2,697
Total inventories	$ 13,247	$ 13,134

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	March 31, 2024	December 31, 2023
Prepaid insurance	$ 1,953	$ 864
Prepaid clinical trial costs	1,533	1,024
Prepaid co-pay assistance program	—	8,608
Other prepaid expenses and current assets	9,692	8,208
Total prepaid expenses and other current assets	$ 13,178	$ 18,704

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2024	December 31, 2023
Accrued sales deductions	$ 16,651	$ 11,578
Accrued compensation	7,476	14,872
Clinical trial accruals	3,425	4,192
Accrued expenses and other current liabilities	6,032	3,299
Total accrued liabilities	$ 33,584	$ 33,941

6. License Agreements & Acquisition

Sato License Agreement

On February 27, 2024, the Company entered into a License Agreement with Sato Pharmaceutical Co., Ltd. ("Sato"). Pursuant to the terms of the License Agreement, the Company grants to Sato an exclusive, sublicensable

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(under certain circumstances) license under certain patent rights and know-how controlled by the Company for Sato to develop, conduct medical affairs activities for, manufacture, commercialize, and otherwise exploit roflumilast formulations (the “Licensed Products”) for all therapeutic uses for certain dermatological indications in humans (the “Field”) in Japan (the "Territory").

The License Agreement sets forth each party’s respective obligations with respect to the development, medical affairs activities, manufacture and supply, and commercialization of the Licensed Products. Pursuant to the terms of the License Agreement, Sato will, at its expense, develop, obtain regulatory approval for, commercialize, and conduct medical affairs activities related to the Licensed Products in the Field in Japan, subject to certain of the Company’s approval and oversight rights.

Pursuant to the terms of the License Agreement, the Company received an upfront payment of $ 25.0 million and will potentially receive additional payments (i) up to an aggregate amount of $ 10.0 million upon the achievement of certain regulatory milestones and (ii) up to an aggregate amount of $ 30.0 million upon the achievement of certain sales milestones. In addition, on a Licensed Product-by-Licensed Product basis, commencing from the first commercial sale of such Licensed Product in Japan until the latest of (i) the expiration of the last valid claim in the intellectual property rights licensed by the Company to Sato under the License Agreement covering such Licensed Product in Japan, (ii) the expiration of regulatory exclusivity for such Licensed Product in Japan, or (iii) ten years after the first commercial sale of such Licensed Product in Japan, the Company will receive low double-digit to mid-teen double-digit percentage royalties on Sato’s, its affiliates’ and sublicensees’ total annual net sales of all Licensed Products, subject to certain royalty reductions.

The term of the License Agreement continues until, on a Licensed Product-by-Licensed Product basis, the expiration of the Royalty Term. The License Agreement may be terminated by either party in its entirety if the other party commits a material breach, subject to a cure period, or if the other party becomes insolvent. Sato may terminate the License Agreement at-will in its entirety upon 90 days’ written notice. Unless unenforceable under applicable law, the Company may terminate the License Agreement in its entirety if Sato, its affiliate or sublicensee contests or assists a third party in contesting the scope, validity or enforceability of any patent or patent application licensed by the Company to Sato. The Company may also terminate the License Agreement if Sato or any director, officers, employee, agent, affiliate, sublicensee, or subcontractor is charged by a governmental authority for a violation of any anti-corruption, anti-money laundering, sanctions or export or import control laws or regulations, or, subject to the terms of the License Agreement, if Sato, its affiliates and sublicensees do not conduct any material development or commercialization activities of a Licensed Product in Japan for a certain period of time.

Other revenue under the Sato agreement was $ 25.0 million for the three months ended March 31, 2024.

Huadong License and Collaboration Agreement

In August 2023, the Company entered into a license and collaboration agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd (“Huadong”), a wholly owned subsidiary of Huadong Medicine Co., Ltd. Pursuant to the terms of the agreement, the Company granted to Huadong an exclusive, sublicensable (under certain circumstances) license under certain patent rights and know-how controlled by the Company for Huadong to develop, conduct medical affairs activities for, manufacture, commercialize, and otherwise exploit both cream and foam topical roflumilast for all therapeutic uses for certain dermatological indications ("Huadong Licensed Products") in Greater China (mainland China, Hong Kong, Macau, and Taiwan) and Southeast Asia (Indonesia, Singapore, The Philippines, Thailand, Myanmar, Brunei, Cambodia, Laos, Malaysia, and Vietnam) ("Huadong Territories").

Huadong will, at its expense, develop, obtain regulatory approval for, commercialize, and conduct medical affairs activities for the Huadong Licensed Products, subject to certain of the Company’s approval and oversight rights. The Company will retain exclusive rights for the development, manufacture and commercialization of topical roflumilast outside the Huadong Territories.

As consideration for the rights granted under the Huadong Agreement, Huadong paid the Company a non-refundable upfront fee pursuant to the terms of the agreement, upon closing in September 2023. The Company received a net payment of $ 27.0 million, which consisted of a $ 30.0 million upfront payment less the applicable tax withholding obligation in China of $ 3.0 million. In addition, the Company received a payment of $ 3.0 million in March 2024 related to the achievement of a development and regulatory milestone. The Company may also potentially receive additional payments: (i) up to an aggregate amount of $ 21.0 million upon the achievement of

certain development and regulatory milestones, (ii) up to an aggregate amount of $ 40.3 million upon the achievement of certain sales milestones, and (iii) low double-digit to high-teen double-digit tiered percentage royalties on net sales of the Huadong Licensed Products.

The term of the Huadong Agreement continues on a Licensed Product-by-Licensed Product and country or region-by-country or region basis, until the expiration of the Royalty Term, which is: (i) the date of expiration of the last valid patent claim related to the Huadong Licensed Products, (ii) ten years after the first commercial sale of a the Huadong Licensed Product and (iii) the expiration of any regulatory exclusivity as to a Huadong Licensed Product. The License Agreement may be terminated by both parties under certain circumstances.

For the three months ended March 31, 2024, the Company recognized $ 3.0 million of Other revenue and $ 0.3 million of income tax expense related to the achievement of a development and regulatory milestone. No milestones were achieved for the three months ended March 31, 2023.

7. Long-term debt

On December 22, 2021, the Company entered into a loan and security agreement, or Loan Agreement, with SLR Investment Corp. ("SLR") and the lenders party thereto. The Loan Agreement was amended and restated on January 10, 2023 to include Arcutis Canada, Inc. as a borrower and party to the Loan Agreement. The lenders agreed to extend term loans to the Company in an aggregate principal amount of up to $ 225.0 million, comprised of (i) a tranche A term loan of $ 75.0 million, (ii) a tranche B-1 term loan of $ 50.0 million, (iii) a tranche B-2 term loan of up to $ 75.0 million, available in minimum increments of $ 15.0 million, and (iv) a tranche C term loan of up to $ 25.0 million (Term Loans). As security for the obligations under the Loan Agreement, the Company granted SLR, for the benefit of the lenders, a continuing security interest in substantially all of the Company's assets, including its intellectual property, subject to certain exceptions.

On November 1, 2023, the Company entered into an amendment to the Loan Agreement with SLR. Pursuant to the amendment, the terms of the Loan Agreement were revised to, among others, (i) eliminate the undrawn tranche C term loan of up to $ 25.0 million, (ii) modify the financial covenant relating to minimum net product revenue, and (iii) include an additional minimum financing covenant.

The tranche A term loan under the Loan Agreement was funded on December 22, 2021 in the amount of $ 75.0 million. With the approval of ZORYVE cream on July 29, 2022, the tranche B term loans were funded and the Company received $ 125.0 million on August 2, 2022. The amended Loan Agreement provides for term loans to the Company in aggregate principal amount of up to $ 200.0 million, which amounts were fully drawn as of December 31, 2023.

Principal amounts outstanding under the Term Loans will accrue interest at a floating rate equal to the applicable rate in effect from time to time, as determined by SLR on the third business day prior to the funding date of the applicable Term Loan and on the first business day of the month prior to each payment date of each Term Loan. The applicable rate is a per annum interest rate equal to 7.45 % plus the greater of (a) 0.10 % and (b) the per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (or on any successor or substitute published rate) for a term of one month, subject to a replacement with an alternate benchmark rate and spread in certain circumstances. Starting in July 2023, the Secured Overnight Financing Rate (SOFR) for a term of one month was substituted for the benchmark rate. On March 31, 2024, the rate was 12.87 %. The maturity date for each term loan is January 1, 2027.

Commencing on February 1, 2022, interest payments are payable monthly following the funding of any Term Loan. Any principal amounts outstanding under the Term Loans, if not repaid sooner, are due and payable on January 1, 2027, or the Maturity Date. The Company may voluntarily prepay principal amounts outstanding under the Term Loans in minimum increments of $ 5.0 million, subject to a prepayment premium of 1.0 % of the principal amount of such Term Loan so prepaid after December 22, 2023 and prior to December 22, 2025.

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If the Term Loans are accelerated due to, among others, the occurrence of a bankruptcy or insolvency event, the Company is required to make mandatory prepayments of (i) all principal amounts outstanding under the Term Loans, plus accrued and unpaid interest thereon through the prepayment date, (ii) any fees applicable by reason of such prepayment, (iii) the prepayment premiums set forth in the paragraph above, plus (iv) all other obligations that are due and payable, including expenses and interest at the Default Rate (as defined below) with respect to any past due amounts.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on the Company's ability to dispose of its business or property, to change its line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on its property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock or to redeem capital stock. The Company also agreed to a financial covenant whereby, beginning with the month ending December 31, 2023, the Company must generate net product revenue in excess of specified amounts for applicable measuring periods pursuant to the Loan Agreement.

In addition, the Loan Agreement contains customary events of default that entitle the lenders to cause any indebtedness under the Loan Agreement to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the Term Loans. Under the Loan Agreement, an event of default will occur if, among other things, the Company fails to make payments under the Loan Agreement, the Company breaches any of the covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches, the lenders determine that a material adverse change has occurred, or the Company or the Company's assets become subject to certain legal proceedings, such as bankruptcy proceedings. Upon the occurrence and for the duration of an event of default, an additional default interest rate, or the Default Rate, equal to 4.0 % per annum will apply to all obligations owed under the Loan Agreement. The prepayment upon default and other potential additional interest provisions under the Loan Agreement were determined to be a compound embedded derivative instrument to be bifurcated from the loan and accounted for as a separate liability for accounting purposes under the guidance in ASC 815, *Derivatives and Hedging*. At the inception of the Loan Agreement, the fair value of the embedded derivative was determined to be immaterial. The embedded derivative instrument is remeasured at fair value each reporting period with any future changes in fair value reported in Other income, net in the condensed consolidated statement of operations and comprehensive loss. During the three months ended March 31, 2024, the Company recognized $ 0.5 million gain in Other income, net related to the change in fair value of the embedded derivative instrument. The fair value of the embedded derivative instrument as of March 31, 2024 and December 31, 2023 was a liability of $ 0.3 million and $ 0.8 million, respectively, and is included in Other-long term liabilities in the accompanying condensed consolidated balance sheets. See Note 4.

In connection with the Loan Agreement, the Company paid a closing fee of $ 1.0 million on December 22, 2021, and is further obligated to pay (i) a final fee equal to 6.95 % of the aggregate original principal amount of the Term Loans funded upon the earliest to occur of the Maturity Date, the acceleration of any Term Loan and the prepayment, refinancing, substitution, or replacement of any Term Loan and (ii) a certain amount of lenders' expenses incurred in connection with the execution of the Loan Agreement. Additionally, in connection with the Loan Agreement, the Company entered into an Exit Fee Agreement, whereby the Company agreed to pay an exit fee in the amount of 3.0 % of each Term Loan funded upon (i) any change of control transaction or (ii) a revenue milestone, calculated on a trailing six month basis. Notwithstanding the prepayment or termination of the Term Loan, the exit fee will expire 10 years from the date of the Loan Agreement.

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Pursuant to the amendment, the modified financial covenant requires the Company to generate a minimum net product revenue equal to 75 % of its projected net product revenue as set forth in the Company's annual plan for the respective period, tested on a trailing 12 month basis for the month ending December 31, 2023 and then tested on a trailing six month basis, as of the end of each month, for the month ending January 31, 2024 and each month thereafter. Pursuant to the amendment, each annual plan shall be approved by the Company's board of directors and SLR, in its capacity as collateral agent, in its reasonable discretion. Any failure by the Company to deliver such annual plan on or before December 15 of the prior year shall be an immediate event of default. In addition, the Company agreed to raise at least $ 31.0 million in net cash proceeds, during the period commencing on November 1, 2023 and ending on April 1, 2024, from (a) the sale or issuance of the Company's equity interests, (b) business development or collaboration agreements (including upfront, milestone, royalty, and other payments), or (c) subordinated debt, in each case as permitted pursuant to the terms of the Loan Agreement. The Company raised the required capital during the first quarter of 2024 and was in compliance with all financing covenants under the Loan Agreement as of March 31, 2024.

The debt issuance costs have been recorded as a debt discount which are being accreted to interest expense through the maturity date of the term loan. Interest expense is calculated using the effective interest method, and is inclusive of non-cash amortization of debt issuance costs. The final maturity payment of $ 13.7 million is recognized over the life of the term loan through interest expense. At March 31, 2024 and December 31, 2023, the effective interest rate was 14.79 % and 13.79 %, respectively. Interest expense relating to the term loan for the three months ended March 31, 2024 and 2023 was $ 7.5 million and $ 7.0 million, respectively.

The following summarizes additional information related to the Company's long-term debt (in thousands):

	March 31, 2024	December 31, 2023
Long-term debt, gross	$ 200,000	$ 200,000
Accrued final fee	5,625	4,876
Unamortized debt issuance costs	(2,822)	(3,077)
Long-term debt, net	$ 202,803	$ 201,799

Upon the contractual maturity of the Company's long term debt, a payment of principal and final fees of $ 213.9 million is due on January 1, 2027.

8. Stock-Based Compensation

Stock Option Exchange Program

On January 16, 2024, the Company commenced an offer to certain eligible employees and consultants to exchange certain outstanding eligible options to purchase shares of the Company's common stock for a lesser number of RSUs pursuant to an option exchange program (the "Option Exchange"). The Option Exchange expired on February 12, 2024. Pursuant to the Option Exchange, eligible option holders elected to exchange, and the Company accepted for cancellation, eligible options to purchase an aggregate of 5,059,129 shares of the Company's common stock, representing approximately 98 % of the total shares of common stock underlying the eligible options. On February 13, 2024, immediately following the expiration of the Option Exchange, the Company granted 2,129,594 shares of Replacement RSU Awards, pursuant to the terms of the Option Exchange. The Replacement RSU Awards will vest based on continued service with the Company over a period of either 1 , 2 or 3 years, depending on the grant date of the exchanged options.

The exchange of stock options was treated as a modification for accounting purposes, which requires an incremental expense of $ 8.6 million to be recognized for the Replacement RSU Awards over their new service

periods (1 - 3 years). In addition, any unamortized expense remaining on the exchanged options as of the modification will be recognized over their original remaining service period.

Stock Option Activity

The following summarizes option activity:

	Number of Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($, in thousands)
Balance—December 31, 2023	7,919,699	$ 18.52	7.35	$ 1,435
Granted	2,904,500	3.84		
Exercised	(21,863)	3.82		
Forfeited[1]	(5,157,144)	23.15		
Expired	(171,428)	23.21		
Balance—March 31, 2024	5,473,764	$ 6.28	8.08	$ 28,716
Exercisable—March 31, 2024[2]	1,936,138	$ 9.39	5.20	$ 8,798

(1) The number of stock options forfeited includes those exchanged in the Option Exchange as described above.

(2) Options exercisable includes early exercisable options.

The aggregate intrinsic value is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of March 31, 2024. The intrinsic value of options exercised for the three months ended March 31, 2024 and 2023 was $ 0.1 million and $ 0.4 million, respectively.

The total grant-date fair value of the options vested during the three months ended March 31, 2024 and 2023 was $ 0.5 million and $ 6.2 million, respectively. The weighted-average grant-date fair value of employee options granted during the three months ended March 31, 2024 and 2023 was $ 2.71 and $ 10.93 , respectively.

Restricted Stock Unit Activity

The following table summarizes information regarding the Company's RSUs:

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2023	2,929,602	$ 15.24
Granted[1]	4,715,094	4.03
Vested	(538,955)	17.71
Forfeited	(292,235)	11.08
Unvested Balance—March 31, 2024	6,813,506	$ 7.46

(1) The number of RSU's granted includes those in association with the Option Exchange as described above.

The grant date fair value of an RSU equals the closing price of the Company's common stock on the grant date. RSUs generally vest equally over four years .

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Stock-Based Compensation Expense

Stock-based compensation expense included in the condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 3,657	$ 3,688
Selling, general, and administrative	6,373	5,791
Total stock-based compensation expense	$ 10,030	$ 9,479

As of March 31, 2024, there was $ 37.3 million of total unrecognized compensation cost related to unvested options that are expected to vest, which is expected to be recognized over a weighted-average period of 2.4 years. As of March 31, 2024, there was $ 45.8 million of total unrecognized compensation cost related to RSUs that is expected to vest, which is expected to be recognized over a weighted-average period of 2.7 years.

The fair value of stock option awards granted was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31, 2024	Year Ended December 31, 2023
Expected term (in years)	6.0 – 6.1	5.0 – 6.1
Expected volatility	79.1 – 80.8 %	75.2 – 78.4 %
Risk-free interest rate	3.9 – 4.2 %	3.5 – 4.7 %
Dividend yield	— %	— %

9. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average common shares outstanding. Pre-funded warrants to purchase 7,500,000 shares of the Company's stock were included in the weighted-average common shares outstanding used in calculating net loss per share for the three months ended March 31, 2024.

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	As of March 31,	
	2024	2023
Stock options to purchase common stock	5,473,764	8,343,760
Early exercised options subject to future vesting	—	11,135
RSUs subject to future vesting	6,813,506	2,807,215
ESPP shares subject to future issuance	359,184	98,670
Total	12,646,454	11,260,780

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated *financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, and the audited financial statements and notes thereto as of and for the year ended December 31, 2023 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2023, which has been filed with the Securities and Exchange Commission ("SEC"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans, objectives, expectations, projections, and strategy for our business, includes forward-looking statements that involve risks and uncertainties. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties, and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. As a result of many factors, including those factors identified below and those set forth in the "Risk Factors" section of our Annual Report on Form 10-K, our actual results and the timing of selected events could differ materially from the forward-looking statements contained in the following discussion and analysis.*

Overview

We are a commercial-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. Our current portfolio is comprised of highly differentiated topical and systemic treatments with significant potential to treat immune-mediated dermatological diseases and conditions. We believe we have built the industry's leading platform for dermatologic product development and commercialization. Our strategy is to focus on validated biological targets, and to use our drug development platform and deep dermatology expertise to develop and commercialize differentiated products that have the potential to address the major shortcomings of existing therapies in our targeted indications. We believe this strategy uniquely positions us to rapidly advance our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

We launched our lead product, ZORYVE® (roflumilast) cream 0.3% ("ZORYVE cream"), in August 2022 after obtaining our initial U.S. Food and Drug Administration ("FDA") approval for the treatment of plaque psoriasis, including psoriasis in the intertriginous areas (e.g. groin or axillae), in individuals 12 years of age or older. ZORYVE cream is approved for once-daily treatment of mild, moderate, and severe plaque psoriasis with no limitations on location or duration of use. In October 2023, we received FDA approval for an expanded indication in plaque psoriasis down to 6 years of age. We are currently working with the FDA to potentially further expand this indication in plaque psoriasis down to 2 years of age following the generation of additional clinical data. In April 2023, we had our first commercial launch outside of the United States following Health Canada approval of ZORYVE cream for the treatment of plaque psoriasis in individuals 12 years or age or older. ZORYVE cream is a once-daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase-4 ("PDE4") inhibitor. PDE4 is an established biological target in dermatology, with multiple PDE4 inhibitors approved by the FDA for the treatment of dermatological conditions.

In December 2023, we received FDA approval for ZORYVE® (roflumilast) topical foam 0.3% ("ZORYVE foam") for the treatment of seborrheic dermatitis in individuals aged 9 years and older, with no limitation on severity, location, or duration of use. ZORYVE foam has been shown to provide rapid disease clearance and significant reduction in itch in clinical trials. In a pivotal Phase 3 study, 80% of individuals treated with ZORYVE foam achieved the primary efficacy endpoint of IGA Success, defined as an IGA score of "clear" or "almost clear" plus a 2-point improvement at Week 8, and just over 50% of individuals achieved an IGA score of clear at Week 8. In addition, individuals treated with ZORYVE foam reported reductions in itch from baseline within 48 hours of first application. ZORYVE foam is a once-daily steroid-free foam and, as a PDE4 inhibitor, is the first drug approved for the treatment of seborrheic dermatitis with a new mechanism of action in over two decades. ZORYVE foam became commercially available in late January 2024. Seborrheic dermatitis is estimated to occur in as many as 10 million people in the United States, and is associated with a substantial psychosocial burden for those suffering from the disease.

In addition to the approval of ZORYVE cream for plaque psoriasis and ZORYVE foam for seborrheic dermatitis (collectively, "ZORYVE"), we are also developing ZORYVE cream for the treatment of atopic dermatitis. In

atopic dermatitis, we have successfully completed three pivotal Phase 3 clinical trials: INTEGUMENT-1 and -2 enrolled subjects 6 years of age or older and INTEGUMENT-PED enrolled subjects between the ages of 2 and 5 years. We are also conducting INTEGUMENT-OLE, an open label extension study of the long-term safety of ZORYVE cream 0.15% in individuals 6 years of age or older and ZORYVE cream 0.05% in subjects between the ages 2 and 5 years. In the fourth quarter of 2022, we announced positive topline data from both INTEGUMENT-1 and -2 in atopic dermatitis, and in September 2023, we announced positive topline data from INTEGUMENT-PED and positive interim results from INTEGUMENT-OLE. In September 2023, we submitted a supplemental new drug application (“sNDA”) for ZORYVE cream 0.15% for the treatment of mild to moderate atopic dermatitis in individuals 6 years of age or older, which was accepted by the FDA and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of July 7, 2024. Based on the positive results from the INTEGUMENT-PED study in September 2023, we expect to submit a subsequent sNDA for topical ZORYVE cream 0.05% for children ages 2 to 5 years of age if our current sNDA for ZORYVE cream 0.15% is approved for the treatment of mild to moderate atopic dermatitis in individuals 6 years of age or older.

Beyond seborrheic dermatitis, we are also developing ZORYVE foam for scalp and body psoriasis and have successfully completed our pivotal Phase 3 clinical trial. We announced positive topline data in September 2022, and we plan to submit an sNDA in the third quarter of 2024.

Beyond ZORYVE, we are developing ARQ-255, a deep-penetrating topical formulation of ivarmacitinib, a potent and highly selective topical Janus kinase type 1 ("JAK1") inhibitor, designed to preferentially deliver the drug deep into the hair follicle, the site of inflammation in alopecia areata, in order to potentially develop the first topical treatment for this disease. In December 2022, we announced that the first subject had been enrolled in a Phase 1b study evaluating ARQ-255 for the treatment of alopecia areata. The first subject in the alopecia areata cohort enrolled in the second quarter of 2023.

In September 2022, we acquired Ducentis BioTherapeutics LTD ("Ducentis") and its lead asset, DS-234 (now ARQ-234), a fusion protein that is a potent and highly selective checkpoint agonist of the CD200 Receptor (CD200R). Currently in the preclinical stage, we plan to develop ARQ-234 in atopic dermatitis, where we believe it could be a potentially highly complementary biologic treatment option to ZORYVE cream in that indication, if approved. ARQ-234 could potentially be used to treat other inflammatory conditions as well.

We have incurred net losses in each year since inception, including net losses of net losses of $35.4 million and $80.1 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $1,017.3 million and cash, cash equivalents, restricted cash, and marketable securities of $404.5 million. As of March 31, 2024, we had $200.0 million outstanding under the Loan Agreement.

We expect to continue to incur losses and significant expenses as we commercialize ZORYVE cream in psoriasis and ZORYVE foam in seborrheic dermatitis, and as we advance our product candidates and label extensions through clinical trials, regulatory submissions, and commercialization. We expect to incur significant and prioritized commercialization expenses related to the sales, marketing, manufacturing, and distribution of ZORYVE cream and foam, while we focus our clinical development spend on ARQ-234, ARQ-255, and ZORYVE label extensions, if we obtain regulatory approval for them. If our available cash and marketable securities balances, amounts available under the Loan Agreement, and anticipated future cash flows from operations are insufficient to cover these expenses, we may need to fund our operations through equity or debt financings or other sources, such as future potential collaboration agreements. Adequate funding may not be available to us on acceptable terms, or at all. Any failure to obtain sufficient funds on acceptable terms as and when needed could have a material adverse effect on our business, results of operations, and financial condition. See “Liquidity, Capital Resources, and Requirements” below and Note 1 to the condensed consolidated financial statements for additional information.

We rely on third parties in the conduct of our nonclinical studies and clinical trials and for manufacturing and supply of our product candidates. We have no internal manufacturing capabilities, and we will continue to rely on third parties, many of whom are single source suppliers, for our nonclinical and clinical trial materials, as well as the commercial supply of our products.

Components of Our Results of Operations

Revenue

Product Revenue, Net

In August 2022, in conjunction with the launch of our first FDA approved product, ZORYVE cream, we began to recognize revenue from product sales, net of rebates, chargebacks, discounts, and other adjustments. Additionally, in June 2023, we began recognizing revenue net of deductions for ZORYVE cream in Canada and, in January 2024, for ZORYVE foam. We will continue to evaluate trends related to revenue for ZORYVE. Additionally, if our development efforts for our other product candidates and ZORYVE label extensions are successful and result in regulatory approval, we may generate additional revenue in the future from product sales.

Other Revenue

Other revenue relates to the Sato License Agreement and the Huadong License and Collaboration Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Cost of Sales

Cost of sales includes direct and indirect costs related to the manufacturing and distribution of ZORYVE cream, including raw materials, third-party manufacturing costs, packaging services, and freight-in, as well as third-party royalties payable on our net product sales and amortization of intangible assets associated with ZORYVE.

Our cost of sales will reflect a lower average per unit cost of materials until inventory that was previously expensed is sold, which is expected to occur over the next eighteen months. As of March 31, 2024 and December 31, 2023, the value of this inventory, mostly at the raw materials stage, was approximately $8.7 million and $8.7 million, respectively.

Operating Expenses

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including conducting nonclinical studies and clinical trials, manufacturing development efforts, and activities related to regulatory filings for our product candidates. Research and development costs are expensed as incurred. These costs include direct program expenses, which are payments made to third parties that specifically relate to our research and development, such as payments to clinical research organizations, clinical investigators, manufacturing of clinical material, nonclinical testing, and consultants. In addition, employee costs, including salaries, payroll taxes, benefits, stock-based compensation, and travel for employees contributing to research and development activities are classified as research and development costs. We allocate direct external costs on a program specific basis (topical roflumilast program, topical JAK inhibitor program, and early stage programs). Our internal costs are primarily related to personnel or professional services and apply across programs, and thus are not allocable on a program specific basis.

We expect to continue to incur research and development expenses in the future as we develop our product candidates. In particular, we expect to incur research and development expenses for the pediatric and open label extension Phase 3 trials of ZORYVE cream for atopic dermatitis, phase 1 ARQ-255 study for alopecia areata, and early development of ARQ-234 for atopic dermatitis.

We have entered, and may continue to enter, into license agreements to access and utilize certain molecules for the treatment of dermatological diseases and disorders. We evaluate if the license agreement is an acquisition of an asset or a business. To date, none of our license agreements have been considered to be an acquisition of a business. For asset acquisitions, the upfront payments, as well as any future milestone payments made before product approval, are immediately recognized as research and development expense when due, provided there is no alternative future use of the rights in other research and development projects.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing, or costs required to complete the remaining development of ZORYVE cream, ZORYVE foam, ARQ-255, and ARQ-234 or any other product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates. See “Risk Factors” for a discussion of the risks and uncertainties associated with the development of our product candidates.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of salaries and related costs, including payroll taxes, benefits, stock-based compensation, and travel, and costs related to sales and marketing of ZORYVE cream. Other selling, general and administrative expenses include legal costs of pursuing patent protection of our intellectual property, insurance, and professional services fees for auditing, tax, and general legal services. We expect our selling, general and administrative expenses to continue to increase in the future as we continue to commercialize ZORYVE and potentially other product candidates and support our operations, including increased expenses related to legal, accounting, insurance, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, directors and officers liability insurance premiums, and investor relations activities.

Other Income, Net

Other income, net primarily consists of interest income earned on our cash, cash equivalents, and marketable securities, as well as changes in the fair value of the derivative related to our debt. See Note 7 to the condensed consolidated financial statements for additional information.

Interest Expense

Interest expense is related to interest incurred on our long term debt.

Provision for Income Taxes

Provision for income taxes is related to the Huadong License and Collaboration Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table sets forth our results of operations for the periods indicated:

	Three Months Ended March 31,		Change	
	2024	2023	$	%
	(in thousands)			
Revenues:				
Product revenue, net	$ 21,569	$ 2,781	$ 18,788	676 %
Other revenue	28,000	—	28,000	*
Total revenues	49,569	2,781	46,788	1682 %
Operating expenses:				
Cost of sales	3,256	783	2,473	316 %
Research and development	23,141	35,345	(12,204)	(35) %
Selling, general, and administrative	54,794	42,918	11,876	28 %
Total operating expenses	81,191	79,046	2,145	3 %
Loss from operations	(31,622)	(76,265)	44,643	(59) %
Other income (expense):				
Other income, net	4,044	3,207	837	26 %
Interest expense	(7,480)	(7,042)	(438)	6 %
Loss before income taxes	(35,058)	(80,100)	45,042	(56) %
Provision for income taxes	324	—	324	*
Net loss	$ (35,382)	$ (80,100)	$ 44,718	(56) %

*Not applicable

Product revenue, net

We began recording U.S. product revenue in the third quarter of 2022 following the FDA approval and subsequent commercial launch of ZORYVE cream in August 2022, Canada product revenue in the second quarter of 2023 following the Health Canada approval and subsequent commercial launch of ZORYVE in June 2023, and additional U.S. revenue in the first quarter of 2024 following the FDA approval and subsequent commercial launch of ZORYVE foam in January 2024.

	Three Months Ended March 31,		Change	
	2024	2023	$	%
	(in thousands)			
Product revenue, net				
ZORYVE cream	$ 15,026	$ 2,781	$ 12,245	440 %
ZORYVE foam	6,543	—	6,543	*
Total product revenue, net	$ 21,569	$ 2,781	$ 18,788	676 %

*Not applicable

Product revenue, net, for ZORYVE cream increased by $12.2 million for the three months ended March 31, 2024 compared to three months ended March 31, 2023, primarily driven by higher end customer demand for ZORYVE cream in the United States and the commercial launch of ZORYVE cream in Canada in June 2023.

Product revenue, net, for ZORYVE foam increased by $6.5 million for the three months ended March 31, 2024 compared to three months ended March 31, 2023, driven by its commercial launch in January 2024.

Other revenue

Other revenue in the first quarter of 2024 includes $25.0 million received as an upfront payment in connection with the Sato Agreement and a $3.0 milestone payment received in connection with the Huadong Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Cost of Sales

Cost of sales increased by $2.5 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023. The increase is related primarily to additional ZORYVE cream and foam product costs incurred. Prior to the dates on which the initial regulatory approvals were received for each product, costs of raw materials were recorded as research and development expense. Therefore, cost of sales will reflect a lower average per unit cost until the related inventory is sold, which is expected to occur over the next eighteen months. See Note 5 to the condensed consolidated financial statements for additional information.

Research and Development Expenses

	Three Months Ended March 31,		Change	
	2024	2023	$	%
	(in thousands)			
Direct external costs:				
Topical roflumilast program	$ 3,588	$ 16,186	$ (12,598)	(78) %
Topical JAK inhibitor program	667	1,172	(505)	(43) %
Other early stage programs	4,133	1,132	3,001	265 %
Indirect costs:				
Compensation and personnel-related	10,378	10,835	(457)	(4) %
Other	4,375	6,020	(1,645)	(27) %
Total research and development expense	$ 23,141	$ 35,345	$ (12,204)	(35) %

Research and development expenses decreased by $12.2 million, or 35%, for the three months ended March 31, 2024 compared to the three months ended March 31, 2023. The decrease was primarily due to the completion of Phase 3 studies of roflumilast cream in atopic dermatitis and roflumilast foam in seborrheic dermatitis and scalp and body psoriasis, partially offset by manufacturing costs incurred related to the development of early stage programs.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by $11.9 million, or 28%, for the three months ended March 31, 2024 compared to the three months ended March 31, 2023. The increase was primarily due to an increase in sales and marketing expenses of $6.2 million and an increase in compensation and personnel-related expenses of $5.3 million. These increases were primarily due to our continued commercialization efforts for ZORYVE.

Other Income, Net

Other income, net increased by $0.8 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023, primarily due to the change in fair value of the derivative related to our debt, as well as the impact of higher interest rates. See Note 7 to the condensed consolidated financial statements for additional information.

Interest Expense

Interest expense increased by $0.4 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023, due to the impact of higher interest rates. See Note 7 to the condensed consolidated financial statements for additional information.

Provision for Income Taxes

Income tax expense of $0.3 million for the three months ended March 31, 2024 was primarily due to withholding tax on the Huadong License and Collaboration Agreement.

Liquidity, Capital Resources, and Requirements

Sources of Liquidity

Our primary sources of capital to date have been private placements of preferred stock, our IPO completed in January 2020, our follow-on financings in October 2020, February 2021, August 2022, October 2023, and March 2024, our Loan Agreement, our ATM, and revenue from the sale of ZORYVE cream and foam. We have incurred operating losses since our inception and have an accumulated deficit as a result of ongoing efforts to develop and commercialize our products and product candidates, including conducting nonclinical and clinical trials and providing selling, general and administrative support for these operations. As of March 31, 2024, we had cash, cash equivalents, restricted cash, and marketable securities of $404.5 million, and an accumulated deficit of $1,017.3 million. We maintain cash balances with financial institutions in excess of insured limits. In March 2024, we completed a public offering of shares of our common stock and received $161.7 million in net proceeds. In March 2024, we received an upfront payment of $25.0 million related to the Sato Agreement and a milestone payment $2.7 million related to the Huadong Agreement. As of March 31, 2024, we had $200.0 million outstanding under the Loan Agreement.

If our capital resources are insufficient to satisfy our requirements, we may need to fund our operations through the sale of our equity securities, accessing or incurring additional debt, entering into licensing or collaboration agreements with partners, grants, or other sources of financing. There can be no assurance that sufficient funds will be available to us at all or on attractive terms when needed from these sources. If we are unable to obtain additional funding from these or other sources when needed it may be necessary to significantly reduce our current rate of spending through, among other things, reductions in staff and delaying, scaling back, or stopping certain research and development programs, nonclinical studies, clinical trials or other development activities, and commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. In addition, market conditions impacting financial institutions could impact our ability to access some or all of our cash, cash equivalents and marketable securities, and we may be unable to obtain alternative funding when and as needed on acceptable terms, if at all.

We have based our projected operating requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development, and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Any future funding requirements will depend on many factors, including, but not limited to:

- the timing, receipt, and amount of sales of any current and future products;
- the scope, progress, results, and costs of researching and developing our lead product candidates or any future product candidates, and conducting nonclinical studies and clinical trials, in particular our planned or ongoing development activities of ZORYVE cream in plaque psoriasis and atopic dermatitis, ZORYVE foam in seborrheic dermatitis and scalp psoriasis, ARQ-255 in alopecia areata, and our formulation and nonclinical efforts for ARQ-234;
- suspensions or delays in the enrollment or changes to the number of subjects we decide to enroll in our ongoing clinical trials;
- the number and scope of clinical programs we decide to pursue, and the number and characteristics of any product candidates we develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing ZORYVE or any future product candidates and any products we successfully commercialize, including costs associated with building out our supply chain;
- the cost of commercialization activities for ZORYVE or any future product candidates that are approved for sale, including marketing, sales and distribution costs, and any discounts or rebates to obtain access;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the costs related to milestone payments to AstraZeneca, Hengrui, or any future collaborator or licensing partner, upon the achievement of predetermined milestones;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio; and
- costs associated with any adverse market conditions or other macroeconomic factors.

Indebtedness

On December 22, 2021 we entered into a loan and security agreement, or Loan Agreement, with SLR and the lenders party thereto. The Loan Agreement was amended and restated on January 10, 2023 to include Arcutis Canada, Inc. as a borrower and party to the Loan Agreement. The lenders agreed to extend term loans to us in an aggregate principal amount of up to $225.0 million, comprised of: (i) a tranche A term loan of $75.0 million, (ii) a tranche B-1 term loan of $50.0 million, (iii) a tranche B-2 term loan of up to $75.0 million, available in minimum increments of $15.0 million, and (iv) a tranche C term loan of up to $25.0 million. We refer to the tranche A, tranche B, and tranche C term loans together as our Term Loans. As security for the obligations under the Loan Agreement, we granted SLR, for the benefit of the lenders, a continuing security interest in substantially all of our assets, including our intellectual property, subject to certain exceptions.

On November 1, 2023, we entered into an amendment to the Loan Agreement. Pursuant to the amendment, the terms of the Loan Agreement were revised to, among others, (i) eliminate the undrawn tranche C term loan of up to $25.0 million, (ii) modify the financial covenant relating to minimum net product revenue and remove the market capitalization threshold, and (iii) include an additional minimum financing covenant. The modified financial covenant requires us to generate a minimum net product revenue equal to 75% of our projected net product revenue as set forth in our annual plan for the respective period, tested on a trailing 12 month basis for the month ending December 31, 2023 and then tested on a trailing six month basis, as of the end of each month, for the month ending January 31, 2024 and each month thereafter. Pursuant to the amendment, each annual plan shall be approved by our board of directors and SLR, in its capacity as collateral agent, in its reasonable discretion. Any failure by us to deliver such annual plan on or before December 15 of the prior year shall be an immediate event of default. In addition, we agreed to raise at least $31.0 million in net cash proceeds, during the period commencing on November 1, 2023 and ending on April 1, 2024, from (a) the sale or issuance of the our equity interests, (b) business development or collaboration agreements (including upfront, milestone, royalty and other payments), or (c) subordinated debt, in each case as permitted pursuant to the terms of the Loan Agreement. We raised the required capital during the first quarter of 2024 and were in compliance with all covenants under the Loan Agreement as of March 31, 2024.

The tranche A term loan was funded on December 22, 2021. Following the approval of ZORYVE, we drew down $125.0 million on the tranche B term loans, which we received in August 2022. As amended, the Loan Agreement provides for term loans to us in an aggregate principal amount of up to $200.0 million, which amounts were fully drawn as of March 31, 2024.

Principal amounts outstanding under the Term Loans will accrue interest at a floating rate equal to the applicable rate in effect from time to time, as determined by SLR on the third business day prior to the funding date of the applicable Term Loan and on the first business day of the month prior to each payment date of each Term Loan. The applicable rate is a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (or on any successor or substitute published rate) for a term of one month, subject to a replacement with an alternate benchmark rate and spread in certain circumstances. Starting in July 2023, the Secured Overnight Financing Rate ("SOFR") for a term of one month was substituted for the benchmark rate. On March 31, 2024, the rate was 12.87%.

Interest payments are payable monthly following the funding of any Term Loan. Any principal amounts outstanding under the Term Loans, if not repaid sooner, are due and payable on January 1, 2027, or the Maturity Date. We may voluntarily prepay principal amounts outstanding under the Term Loans in minimum increments of $5.0 million, subject to a prepayment premium of (i) 3.0% of the principal amount of such Term Loan so prepaid prior to December 22, 2022, (ii) 2.0% of the principal amount of such Term Loan so prepaid after December 22, 2022 and prior to December 22, 2023, or (iii) 1.0% of the principal amount of such Term Loan so prepaid after December 22, 2023 and prior to December 22, 2025.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on our ability to dispose of its business or property, to change its line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on its property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock or to redeem capital stock. We also agreed to a financial covenant whereby, beginning with the month ending December 31, 2023, we must generate net product revenue in excess of specified amounts for applicable measuring periods pursuant to the Loan Agreement.

If the Term Loans are accelerated due to, among others, the occurrence of a bankruptcy or insolvency event, we are required to make certain mandatory prepayments, including fees applicable by reason of such prepayment.

In addition, the Loan Agreement contains customary events of default that entitle the lenders to cause any indebtedness under the Loan Agreement to become immediately due and payable, and to exercise remedies against us and the collateral securing the Term Loans. Upon the occurrence and for the duration of an event of default, an additional default interest rate, or the Default Rate, equal to 4.0% per annum will apply to all obligations owed under the Loan Agreement.

In connection with the Loan Agreement, we are obligated to pay (i) a final fee equal to 6.95% of the aggregate original principal amount of the Term Loans funded upon the earliest to occur of the Maturity Date, the acceleration of any Term Loan and the prepayment, refinancing, substitution or replacement of any Term Loan and (ii) a certain amount of lenders' expenses incurred in connection with the execution of the Loan Agreement. Additionally, in connection with the Loan Agreement, we entered into an Exit Fee Agreement, whereby we agreed to pay an exit fee in the amount of 3.0% of each Term Loan funded upon (i) any change of control transaction or (ii) a revenue milestone, calculated on a trailing six month basis. Notwithstanding the prepayment or termination of the Term Loan, the exit fee will expire 10 years from the date of the Loan Agreement.

We were in compliance with all covenants under the Loan Agreement as of March 31, 2024.

Cash Flows

The following table sets forth our cash flows for the periods indicated:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (31,603)	$ (80,344)
Cash provided by (used in) investing activities	(28,697)	107,751
Cash provided by financing activities	161,764	100
Effect of exchange rate changes on cash	(73)	(52)
Net increase in cash, cash equivalents, and restricted cash	$ 101,391	$ 27,455

Net Cash Used in Operating Activities

During the three months ended March 31, 2024, net cash used in operating activities was $31.6 million, which consisted of a net loss of $35.4 million and a change in net operating assets and liabilities of $5.4 million, partially offset by net non-cash charges of $9.2 million. The net non-cash charges were primarily related to stock-based compensation expense of $10.0 million.

During the three months ended March 31, 2023, net cash used in operating activities was $80.3 million, which consisted of a net loss of $80.1 million and a change in net operating assets and liabilities of $9.0 million, partially offset by net non-cash charges of $8.8 million. The net non-cash charges were primarily related to stock-based compensation expense of $9.5 million.

Net Cash Provided by (Used in) Investing Activities

During the three months ended March 31, 2024, net cash used in investing activities was $28.7 million, which was comprised primarily by purchases of marketable securities of $106.0 million, offset by proceeds from the maturities of marketable securities of $77.3 million.

During the three months ended March 31, 2023, net cash provided by investing activities was $107.8 million, which was comprised primarily of proceeds from the maturities of marketable securities of $147.5 million, partially offset by purchases of marketable securities of $39.7 million.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2024, net cash provided by financing activities was $161.8 million, which was comprised primarily of $161.7 million of net proceeds from our February 2024 public stock offering.

During the three months ended March 31, 2023, net cash provided by financing activities was $0.1 million, which related to proceeds from the issuance of common stock upon the exercise of stock options.

Contractual Obligations and Contingent Liabilities

There have been no material changes outside the ordinary course of business to our contractual obligations and commitments as described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2023.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of March 31, 2024, we had cash and cash equivalents of $190.1 million, restricted cash of $0.6 million, and marketable securities of $213.8 million; which consist of bank deposits, money market funds, commercial paper, government securities, and corporate debt securities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

In addition, as of March 31, 2024, we had $200.0 million outstanding under our Loan Agreement. Amounts outstanding under our Loan Agreement bear interest at a floating rate equal a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (or on any successor or substitute published rate) for a term of one month, subject to a replacement with an alternate benchmark rate and spread in certain circumstances. Starting in July 2023, the Secured Overnight Financing Rate ("SOFR") for a term of one month was substituted for the benchmark rate. As a result, we are exposed to risks related to our indebtedness from changes in interest rates. Based on the amount outstanding under our Loan Agreement as of March 31, 2024, for every 100 basis point increase in the interest rates, we would incur approximately $2.0 million of additional annual interest expense. We do not currently engage in hedging transactions to manage our exposure to interest rate risk, but higher interest expense would be offset in part by higher earnings on our cash and marketable securities. We may in the future use swaps, caps, collars, structured collars or other common derivative financial instruments to reduce interest rate risk. It is difficult to predict the effect that future hedging activities would have on our operating results.

We are exposed to foreign currency exchange risk as our Canadian subsidiary operates with the Canadian dollar as its functional currency. The majority of our transactions occur in U.S. dollars. The fluctuation in the value of the U.S. dollar against the Canadian dollar affects the reported amounts of expenses, assets and liabilities. If we expand our international operations our exposure to exchange rate fluctuations will increase. At March 31, 2024 we had cash balances denominated in Canadian dollars of $5.5 million. We currently do not hedge any foreign currency exposure. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have a material impact on our condensed consolidated financial statements.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2024, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such required information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Management Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an assessment of the effectiveness of our internal control over financial reporting based our assessment on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of our assessment, our management concluded that our internal control over financial reporting was effective as of March 31, 2024.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Arcutis Biotherapeutics, Inc. filed a lawsuit against Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, Padagis) in the U.S. District Court for the District of New Jersey and the U.S. District Court for the District of Delaware on March 26, 2024 and March 27, 2024, respectively, based on the submission to the FDA of an ANDA seeking approval to market and sell a generic version of Arcutis's ZORYVE® 0.3% cream for the treatment of plaque psoriasis. The complaint asserts infringement of the following six patents, which are listed in the FDA's Orange Book for Arcutis' ZORYVE® 0.3% cream: 9,884,050; 9,907,788; 10,940,142; 11,129,818; 11,793,796; and 11,819,496 (collectively, Asserted Patents). Arcutis seeks a judgment that Padagis has infringed or will infringe one or more claims of each of the Asserted Patents and based on that judgment, a permanent injunction prohibiting the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Padagis's proposed generic product before expiration of each of the Asserted Patents found to infringe.

On April 23, 2024, Padagis responded to the complaint in the District Court of Delaware, denying infringement and asserting counterclaims seeking a declaratory judgement that the asserted patents are not infringed, invalid and/or unenforceable.

Item 1A. RISK FACTORS

For a discussion of our potential risks and uncertainties, see the information in Part I, "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023. There have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

Issuer Purchases of Equity Securities

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Trading Plans

During the three months ended March 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document	Incorporated by Reference			Filed/Furnished Herewith
		Form	Date	Number	
3.1	Restated Certificate of Incorporation.	10-Q	5/12/20	3.1	
3.2	Restated Bylaws.	10-Q	5/12/20	3.2	
4.1	Form of Common Stock Certificate.	S-1/A	1/21/20	4.1	
4.2^	Amended and Restated Investors' Rights Agreement, dated October 8, 2019, by and among the Registrant and certain of its stockholders.	S-1/A	1/21/20	4.2	
10.1	Amended and Restated Sales Agreement, dated January 31, 2024, by and between Registrant and Cowen and Company, LLC.	S-3	1/31/24	1.2	
10.2	Amendment Employment Agreement, dated February 22, 2024, by and between the Registrant and Matthew R. Moore.	10-K	2/22/24	10.35	
10.3†	License Agreement, dated as of February 27, 2024, by and between the Registrant and Sato Pharmaceutical Co., Ltd.				X
10.4	First Amendment to the License Agreement, dated February 18, 2024, by and between the Registrant and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				X

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^ Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

* The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of Arcutis Biopharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

ARCUTIS BIOTHERAPEUTICS, INC.

Date: May 14, 2024

By: /s/ Todd Franklin Watanabe

Todd Franklin Watanabe
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 14, 2024

By: /s/ David Topper

David Topper
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.3

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and is the type that the registrant treats as private or confidential.

LICENSE AGREEMENT

by and between

Arcutis Biotherapeutics, Inc.,

and

Sato Pharmaceutical Co., Ltd.

Dated as of February 27, 2024

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Schedules

LICENSE AGREEMENT

This LICENSE AGREEMENT (this "**Agreement**") is made as of February 27, 2024 (the "**Effective Date**") by and among Arcutis Biotherapeutics, Inc., having its principal place of business at 3027 Townsgate Road, Suite 300, Westlake Village, CA 91361 ("**Licensor**"), Sato Pharmaceutical Co., Ltd., having its principal place of business at 1-5-27, Moto-Akasaka, Minato-ku, Tokyo 107-0051, Japan ("**Licensee**"). Licensor and Licensee are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Licensor is a pharmaceutical company with expertise in the development and commercialization of pharmaceutical products, including the Licensed Products;

WHEREAS, Licensor Controls certain Know-How and Patent Rights relating to the Licensed Products;

WHEREAS, Licensee is a pharmaceutical company engaged in the research, development, manufacture, sale and commercialization of pharmaceutical products in Japan; and

WHEREAS, the Parties desire to enter into a license agreement pursuant to which Licensee would together, with Licensor, Exploit Licensed Products in Japan, all in accordance with the terms and conditions set forth herein.

NOW, **THEREFORE**, in consideration of the foregoing and the mutual agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms will have the respective meanings set forth below, whether used in the singular or plural:

1.1 "**Accounting Standards**" means GAAP or IFRS (as applicable to a Party).

1.2 "**Acquired Party**" has the meaning set forth in Section 1.25 (Change of Control).

1.3 "**Affiliate**" means any Person which, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with a Party. For purposes of this Section 1.3 (Affiliate) only, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person means: (a) direct or indirect ownership of 50% or more of the voting securities or other voting interest of any Person (including attribution from related parties) or (b) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management and policies of such Person, whether through ownership of voting securities, by contract, as a general partner, as a manager, or otherwise.

1.4 "**Agreement**" has the meaning set forth in the preamble of this Agreement.

1.5 "**Alliance Manager**" has the meaning set forth in Section 3.1 (Alliance Managers).

1.6 "**Amounts**" has the meaning set forth in Section 10.10 (Financial Records and Audits).

1.7 "**Annual Net Sales**" means, with respect to a Licensed Product, the total Net Sales of such Licensed Product in a particular Calendar Year.

1.8 "**Anti-Corruption Laws**" means all local or other laws, regulations, or orders prohibiting or regulating public or private-sector corruption, bribery, kickbacks, speed or facilitation payments, ethical business conduct, money laundering, embezzlement, political contributions, gifts, gratuities, expenses, entertainment, hospitalities, agency relationships, commissions, lobbying, books and records, and financial controls, including the United States Foreign Corrupt Practices Act, the U.S. Travel Act, the Japanese Unfair Competition Prevention Act, the Japanese Act on Prevention of Unjust Acts by Organized Crime Group Members and any other laws that prohibit the corrupt payment, offer, promise, or authorization of the payment or transfer of anything of value (including gifts or entertainment), directly or indirectly, to any Public Official, commercial entity, or any other Person to obtain an improper business, in each case, as amended.

1.9 "**Anti-Corruption Violation**" has the meaning set forth in Section 15.2.5 (Termination for Anti-Corruption Violation).

1.10 "**Anti-Money Laundering Laws**" means laws, regulations, rules, or guidelines relating to money laundering, including financial recordkeeping and reporting requirements, such as the U.S. Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107-56, the U.S. Currency and Foreign Transaction Reporting Act of 1970, as amended, the U.S. Money Laundering Control Act of 1986, as amended, the Japanese Act on Prevention of Transfer of Criminal Proceeds, and all money laundering-related laws of other countries or jurisdictions where Licensee or its Affiliates, Sublicensees, or Subcontractors, as applicable, conduct business or own assets, and any related or similar law issued, administered, or enforced by any Governmental Entity.

1.11 "**Applicable Law**" means collectively all laws, rules, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit, or similar right granted under any of the foregoing), and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party, including all Anti-Corruption Laws, Anti Money Laundering Laws, Global Trade Laws and Regulations, GCP, GLP, and cGMP, all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder. It is understood and agreed that the Applicable Law of Japan shall be preferentially applied, where applicable, in terms of Development, performing Medical Affairs, Manufacturing, Commercialization and otherwise Exploitation of Licensed Products in the Field in the territory of Japan.

1.12 "**ARQ-151**" means ZORYVE™ cream, a topical form of Roflumilast formulated as a cream, in the formulation set forth in Schedule 1.12 (ARQ-151) and in (a) the concentration(s)

set forth in Schedule 1.12 (ARQ-151), (b) any concentration for which Licensor or its Affiliates obtains Regulatory Approval outside Japan, and (c) any concentration(s) and formulation(s) approved by Licensor under Section 4.8 (Development of New Formulations, Concentrations, or Indications).

1.13 "**ARQ-154**" means topical Roflumilast foam, a topical form of Roflumilast formulated as a foam, in the formulation set forth in Schedule 1.13 (ARQ-154) and in (a) the concentration(s) set forth in Schedule 1.13 (ARQ-154), (b) any concentration for which Licensor or its Affiliates obtains Regulatory Approval outside Japan, and (c) any concentration(s) and formulation(s) approved by Licensor under Section 4.8 (Development of New Formulations, Concentrations, or Indications).

1.14 "**Auditor**" has the meaning set forth in Section 10.10 (Financial Records and Audits).

1.15 "**AZ Confidential Information**" means any information deemed Confidential Information (as such term is defined in the AZ License) under the AZ License.

1.16 "**AZ License**" means that certain License Agreement between Licensor and AstraZeneca AB dated as of July 23, 2018, as amended.

1.17 "**Breach Notification**" has the meaning set forth in Section 15.2.3 (Termination for Material Breach).

1.18 "**Business Day**" means any day other than (a) a Saturday or Sunday, or (b) a bank or public holiday in California, United States or Tokyo, Japan.

1.19 "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, and December 31.

1.20 "**Calendar Year**" means the respective periods of 12 months ending on December 31.

1.21 "**CBP**" has the meaning set forth in Section 1.70 (Global Trade Laws and Regulations).

1.22 "**cGLP**" or "**GLP**" means the applicable then-current good laboratory practice standards as are required by applicable Regulatory Authorities or Applicable Law in the relevant country or jurisdiction.

1.23 "**cGCP**" or "**GCP**" means the applicable then-current ethical and scientific quality standards for designing, conducting, recording and reporting Clinical Trials as are required by applicable Regulatory Authorities or Applicable Law in the relevant country or jurisdiction.

1.24 "**cGMP**" or "**GMP**" means all current good manufacturing practices and regulations applicable to the Manufacture of the Licensed Product that are promulgated by any applicable Regulatory Authority having jurisdiction over the Manufacture of the Licensed Product, including, as applicable, as promulgated under and in accordance with (a) the principles detailed

in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the International Conference on Harmonization's Q7 Guideline, and (d) the equivalent Applicable Law in any relevant country or region (including Japan), each as may be amended and applicable from time to time.

1.25 "**Change of Control**" means, with respect to a Party (an "**Acquired Party**"), the occurrence of any of the following events from and after the Effective Date: (a) any Person or group of Persons becomes the beneficial owner (directly or indirectly) of more than 50% of the voting shares of such Acquired Party; (b) such Acquired Party consolidates with or merges into or with another Person pursuant to a transaction in which more than 50% of the voting shares of the acquiring or resulting entity outstanding immediately after such consolidation or merger is not held by the holders of the outstanding voting shares of such Acquired Party immediately preceding such consolidation or merger; or (c) that Acquired Party sells or transfers to another Person all or substantially all of its assets.

1.26 "**Clinical Data**" has the meaning set forth in Section 4.7 (Licensee Data Disclosure and Use).

1.27 "**Clinical Development**" has the meaning set forth in Section 1.50 (Development).

1.28 "**Clinical Trial**" means any clinical trial in humans that is conducted in accordance with cGCP and is designed to generate data (a) under an IND, (b) to address a commitment or requirement under a Regulatory Approval or Reimbursement Approval (as applicable), or (c) to support an expansion of a Regulatory Approval for an indication.

1.29 "**Clinical Trial Issue**" means that there has occurred, or Licensor determines in its reasonable discretion that deficiencies in trial conduct have arisen, that have the potential to significantly affect trial participant's rights, safety, well-being, or significantly impact the reliability of trial results, or that there is likely to occur any failure to comply with the terms of the AZ License, this Agreement, the applicable Japanese Clinical Development Plan, cGLP, cGMP, cGCP, or Applicable Law.

1.30 "**CMO**" means a contract manufacturing organization.

1.31 "**Code**" has the meaning set forth in Section 15.2.7(b) (Section 365(n) Rights).

1.32 "**Commercialization**" means with respect to any product, any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, import, export, offering for sale, and sale of such product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or jurisdiction for such product regarding the foregoing, including seeking and maintaining any required Reimbursement Approval, but excluding any activities directed to Manufacturing, Development, or Medical Affairs. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed pursuant to this section.

1.33 "**Commercialization Report**" has the meaning set forth in Section 8.2 (Commercialization Reports).

1.34 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by any Person with respect to any objective, reasonable, diligent and good faith efforts to accomplish such objective. With respect to Licensee's obligations set forth in Article 9 (Diligence), that measure of efforts and resources that is consistent with the efforts and resources that [***] Developing, Manufacturing, Commercializing, or performing Medical Affairs activities with respect to [***] Development, life cycle, and commercial potential, but excluding from consideration any financial obligations of Licensee to Licensor under this Agreement.

1.35 "**Competing Product**" means any (a) topically delivered product being Developed or that has received Regulatory Approval for the treatment of any Indication and (b) any topically delivered selective phosphodiesterase-4 inhibitor being Developed or that has received Regulatory Approval for any indication.

1.36 "**Competitive Activities**" has the meaning set forth in Section 2.7.2 (Business Combinations).

1.37 "**Competitive Infringement**" means any infringement of the Licensor Prosecuted Patent Rights that arises as a result of the making, using, offering to sell, selling, or importing of a product in the Field in Japan that is competitive with the Commercialization of a Licensed Product in the Field in Japan.

1.38 "**Compliance Breach**" means a finding by a Regulatory Authority that Licensee or any of its Representatives, Affiliates, Sublicensees, or Subcontractors has committed a violation of Applicable Law in connection with its activities under this Agreement.

1.39 "**Compliance Finding**" means any findings in an audit conducted by or on behalf of Licensor in accordance with Section 12.8.2 (Compliance Audits), or information otherwise learned by Licensor, which findings or information reasonably indicate that there has been or will reasonably likely be a violation or a pattern of violations by Licensee or its Representatives, Affiliates, Sublicensees, or Subcontractors of either (i) Applicable Law or (ii) the covenants set forth in Sections 12.4.4 through 12.4.7 or 12.6 (Export Controls).

1.40 "**Confidential Information**" means, with respect to a Party, except as otherwise expressly provided in this Agreement, all information (including chemical or biological materials, chemical structures correspondence, customer lists, data, formulae, improvements, inventions, Know-How, processes, Regulatory Approvals, Regulatory Submissions and other regulatory filings, reports, strategies, techniques or other information) that is disclosed by or on behalf of such Party or any of its Affiliates to the other Party or any of its Affiliates pursuant to this Agreement or the Confidentiality Disclosure Agreement, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other Party by or on behalf of the Disclosing Party in oral, written, visual, graphic or electronic form.

1.41 "**Confidentiality Disclosure Agreement**" means the Mutual Nondiclosure Disclosure Agreement by and between the Parties dated May 31, 2022 (as amended from time to time).

1.42 "**Control**" or "**Controlled**" means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to a license granted under this Agreement) of,

(a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, license, or sublicense and without being required to make any payment to any Third Party or incurring any payment obligations under any such arrangement or agreement, other than payment obligations pursuant to the AZ License or if Licensor determines, in its sole discretion, that Licensee need not be responsible for any costs associated with the grant of a sublicense thereunder or Licensee agrees to reimburse Licensor for all payments made by Licensor arising out of Licensee's or its Affiliates' or Sublicensees' exercise of such rights and other reasonably allocated payments under any such arrangement or agreement with a Third Party and Licensee agrees to all obligations applicable to a sublicensee thereunder, and (c) with respect to any product, the legal authority or right to grant an exclusive license or sublicense under Patent Rights that Cover such product or Know-How that relates to such product as described in clause (b). Notwithstanding anything in this Agreement to the contrary, in the event that a Party undergoes a Change of Control, such Party and its Affiliates will be deemed to not Control any Patent Rights or Know-How that are owned or controlled by the Third Party described in the definition of "Change of Control," or such Third Party's Affiliates (other than any such Affiliate of such Third Party that was an Affiliate of such Party prior to the Change of Control), (a) prior to the closing of such Change of Control, except to the extent that any such Patents Rights or Know-How (i) were discovered, developed, invented or created by such Third Party or its Affiliates prior to such Change of Control using or incorporating such Party's or its pre-existing Affiliate's Know-How or Patent Rights or (ii) are used or practiced by or on behalf of such Party or any of its Affiliates in the performance of activities under this Agreement, or (b) after the closing of such Change of Control to the extent that such Patent Rights or Know-How (i) are discovered, developed, invented, created, acquired or in-licensed by such Third Party or its Affiliates (other than such Party or its pre-existing Affiliates) after the closing of such Change of Control without using or incorporating such Party's or its pre-existing Affiliates' Know-How or Patent Rights or any Confidential Information of either Party, and (ii) are not used or practiced by or on behalf of such Party or any of its Affiliates in the performance of activities under this Agreement.

1.43 "**Cover**" means, with respect to a particular subject matter at issue and a relevant Patent Right, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in such Patent Right.

1.44 "**CREATE Act**" has the meaning set forth in Section 14.3 (CREATE Act).

1.45 "**Critical Findings**" means any evidence of non-compliance, including documented in an audit, that meets any of the following criteria: (a) is evaluated as 'critical', (b) significantly affects or has the potential to significantly affect trial participant's rights, safety / well-being, or significantly impacts the reliability of trial results, (c) where the sponsor has notified the Regulatory Authority or IRB/IEC, or (d) if an investigator site is terminated for noncompliance.

1.46 "**Data Breach**" has the meaning set forth in Section 12.4.5 (Covenants of Licensee).

1.47 "**Debarred/Excluded**" means any Person becoming debarred or suspended under 21 U.S.C. §335(a) or (b), the subject of a conviction described in Section 306 of the FD&C Act, excluded, or having previously been excluded, from a federal or governmental health care program, debarred from federal contracting, convicted of or pled *nolo contendere* to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, the subject to OFAC sanctions or on the OFAC list of specially designated nationals, or the subject of any similar sanction of any Governmental Authority in Japan.

1.48 "**Deficient Site**" has the meaning set forth in Section 4.4.2 (Deficient Sublicensees/Subcontractors or Sites and Replacement).

1.49 "**Deficient Sublicensee/Subcontractor**" has the meaning set forth in Section 4.4.2 (Deficient Sublicensees/Subcontractors or Sites and Replacement).

1.50 "**Development**" means, with respect to any product, any and all internal and external research, development, and regulatory activities regarding such product, including (a) research, process development, non-clinical testing, toxicology, non-clinical activities, GLP toxicology and other preclinical studies, and Clinical Trials and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of such product (the conduct of Clinical Trials and the conduct of those regulatory activities described in the foregoing clause (b), to the extent related to the conduct of Clinical Trials, "**Clinical Development**"), but excluding any activities directed to Manufacturing, Medical Affairs, or Commercialization. Development will include research, development, and regulatory activities for additional presentations or indications for a product after receipt of Regulatory Approval of such product, including Clinical Trials commenced following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication (such as post-Regulatory Approval studies and observational studies, if required by any Regulatory Authority in Japan to support or maintain Regulatory Approval for a product) in Japan. "**Develop**," "**Developing**," and "**Developed**" will be construed pursuant to this section.

1.51 "**Development Activities**" has the meaning set forth in Section 4.1 (Development Responsibilities).

1.52 "**Development Data**" has the meaning set forth in Section 4.7 (Licensee Data Disclosure and Use).

1.53 "**Development Report**" has the meaning set forth in Section 4.6 (Development Reports).

1.54 "**Disclosing Party**" has the meaning set forth in Section 11.1.1 (Duty of Confidence).

1.55 "**Dispute**" has the meaning set forth in Section 16.1 (Exclusive Dispute Resolution Mechanism).

1.56 "**Dollar**" means the U.S. dollar, and "$" will be interpreted accordingly.

1.57 "**Effective Date**" has the meaning set forth in the Preamble.

1.58 "**Entity**" has the meaning set forth in Section 10.11.5 (No Partnership).

1.59 "**Executive Officers**" has the meaning set forth in Section 3.4.2 (Decisions of the JSC).

1.60 "**Existing Generic**" means[***].

1.61 "**Exploit**" means to make, have made, use, import, export, offer to sell, sell, Develop, Manufacture, perform Medical Affairs activities for, Commercialize, or otherwise exploit. "**Exploitation**" will be construed accordingly.

1.62 "**FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.63 "**Field**" means the treatment of the Indications in humans.

1.64 "**First Commercial Sale**" means, with respect to an applicable product in a country, the first sale in an arm's length transaction to a Third Party by or on behalf of a Party or any of its Affiliates or sublicensees in the Field, in such country following Regulatory Approval of such product in such country. For the avoidance of doubt, a first sale for compassionate use or named patent program sales prior to Regulatory Approval will not constitute a First Commercial Sale for purposes of this Agreement.

1.65 "**FTE**" means a qualified full-time person, or more than one person working the equivalent of a full-time person, where "full time" is based upon a total of [***] working hours per Calendar Year of scientific or technical work carried out by one or more duly qualified employees. Overtime, and work on weekends, holidays, and the like will not be counted with any multiplier (*e.g.* time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution.

1.66 "**FTE Rate**" means $[***] per FTE per annum, *provided* that such rate will increase or decrease on January 1 of each Calendar Year starting with January 1, 2024 in accordance with the percentage year-over-year increase or decrease in the Consumer Price Index – Urban Wage Earners and Clerical Workers, US City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) over the 12 month period preceding each such January 1. The FTE Rate includes (a) all wages and salaries, employee benefits, bonus, travel and entertainment, supplies and other direct expenses and (b) indirect allocations, including all general and administrative expenses, human resources, finance, occupancy and depreciation.

1.67 "**GAAP**" means United States or Japan generally accepted accounting principles, consistently applied.

1.68 "**Generic Product**" means, with respect to a given Licensed Product in Japan, a product that (a) (i) contains the same active pharmaceutical ingredient as such Licensed Product and is approved in reliance, in whole or in part, on a prior Regulatory Approval of such Licensed Product, (ii) is otherwise approved under any then-existing laws and regulations in Japan pertaining to approval of generic products, as a "generic" version of such Licensed Product, which approval relies, in whole or in part, on a prior Regulatory Approval of such Licensed Product or (iii) is otherwise recognized by the applicable Regulatory Authority as an interchangeable product to such Licensed Product, and (b) is sold or marketed for sale in Japan by a Third Party that has not obtained the rights to market or sell such product as a Sublicensee, Subcontractor, or Third Party distributor of Licensee or any of its Affiliates, Sublicensees, or Subcontractors with respect to such Licensed Product.

1.69 "**Global Brand Elements**" has the meaning set forth in Section 14.10.1 (Global Brand Elements).

1.70 "**Global Trade Laws and Regulations**" means the U.S. Export Administration Regulations; the U.S. International Traffic in Arms Regulations; the import laws administered by U.S. Customs and Border Protection or any successor agency thereto ("**CBP**"); the economic sanctions rules and regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control or any successor agency thereto ("**OFAC**"); the anti-boycott laws and regulations administered by the U.S. Departments of Commerce and Treasury or any successor agency thereto; the Japanese Foreign Exchange and Foreign Trade Act; all relevant regulations made under any of the foregoing; and other similar economic and trade sanctions or export or import control laws.

1.71 "**Governmental Authority**" means any: (a) federal, state, local, municipal, foreign, or other government; (b) governmental or quasi-governmental authority of any nature (including any agency, board, body, branch, bureau, commission, council, department, entity, governmental division, instrumentality, office, officer, official, organization, representative, subdivision, unit, and any court or other tribunal); (c) multinational governmental organization or body; or (d) entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military, or taxing authority or power of any nature (including any arbiter).

1.72 "**Governmental Entity"** means any: (a) national, federal, state, county, local, municipal, foreign, or other government; (b) governmental or quasigovernmental authority of any nature (including any agency, board, body, branch, bureau, commission, council, department, entity, governmental division, instrumentality, office, officer, official, organization, representative, subdivision, unit, political subdivision of any government, entity or organization described in the foregoing clauses (a) or (b), and any court or other tribunal); (c) public international or multinational governmental organization or body; (d) entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature (including any arbiter) or administrative functions of or pertaining to government; or (e) any company, business, enterprise, or other entity owned, in whole

or in part, or controlled by any government, entity, organization, or other Person described in the foregoing clauses (a), (b), (c), or (d) of this definition; or (f) any political party.

1.73 "**ICH**" means the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

1.74 "**IFRS**" means International Financial Reporting Standards, consistently applied.

1.75 "**Indemnified Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

1.76 "**Indemnifying Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

1.77 "**Indications**" mean (a) plaque psoriasis, (b) atopic dermatitis, (c) scalp psoriasis, (d) seborrheic dermatitis, and (e) any additional indication for which the Parties reach agreement on terms to be licensed to Licensee pursuant to Section 2.8 (Negotiation for Product Improvements) or for which Licensee develops a Licensed Product pursuant to Section 4.8 (Development of New Formulations, Concentrations, or Indications).

1.78 "**Indirect Taxes**" has the meaning set forth in Section 10.11.4 (Indirect Taxes).

1.79 "**Invoicing Entity**" has the meaning set forth in Section 1.120 (Net Sales).

1.80 "**IRS**" has the meaning set forth in Section 10.11.3 (Tax Cooperation).

1.81 "**Japanese Clinical Development Plan**" has the meaning set forth in Section 4.2 (Japanese Clinical Development Plans).

1.82 "**Japanese Medical Affairs Plan**" has the meaning set forth in Section 7.1 (Japanese Medical Affairs Plans).

1.83 "**Joint IP**" has the meaning set forth in Section 14.1.2(c) (Ownership of Arising Intellectual Property).

1.84 "**JSC**" has the meaning set forth in Section 3.2.1 (Formation and Purpose of JSC).

1.85 "**JSC Chairperson**" has the meaning set forth in Section 3.2.1 (Formation and Purpose of JSC).

1.86 "**Know-How**" means algorithms, data, information, inventions, knowledge, methods (including methods of use or administration or dosing), practices, results, software, techniques, technology and trade secrets, including analytical and quality control data, analytical methods (including applicable reference standards), assays, batch records, chemical structures and formulations, compositions of matter, formulae, manufacturing data, pharmacological, toxicological and clinical test data and results, processes, reports, research data, research tools, sequences, standard operating procedures and techniques, in each case, whether patentable or not, and, in each case, tangible manifestations thereof.

1.87 "**Knowledge**" means, with respect to a Party, the actual knowledge of those Persons listed for such Party on Schedule 1.87 (Knowledge) after due inquiry of such Person's direct reports.

1.88 "**Launch Quarter**" has the meaning set forth in Section 10.3.3(b) (Generic Competition).

1.89 "**Licensed Product**" means either (a) ARQ-151 or (b) ARQ-154.

1.90 "**Licensed Product Improvement**" has the meaning set forth in Section 2.8 (Right of First Negotiation).

1.91 "**Licensee**" has the meaning set forth in the Preamble.

1.92 "**Licensee Collaboration Know-How**" means any Know-How, other than Licensor Product-Related Program IP and Joint IP, conceived, discovered, developed, generated, invented, or otherwise made in the performance of activities under this Agreement during the Term by Licensee or Representatives of Licensee or its Affiliates or its or their licensees, Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Know-How to Licensee or any Affiliate of Licensee.

1.93 "**Licensee Collaboration Patent Right**" means any Patent Right that (a) has a priority date on or after the Effective Date and (b) Covers any invention included in the Licensee Collaboration Know-How.

1.94 "**Licensee Collaboration Technology**" means the Licensee Collaboration Know-How and Licensee Collaboration Patent Rights.

1.95 "**Licensee Indemnitee(s)**" has the meaning set forth in Section 13.2 (By Licensor).

1.96 "**Licensee Manufacturer**" has the meaning set forth in Section 6.2 (Commercial Supply).

1.97 "**Licensee Program IP**" has the meaning set forth in Section 14.1.2(b) (Ownership of Arising Intellectual Property).

1.98 "**Licensee ROFN Negotiation Notice**" has the meaning set forth in Section 2.8.2 (Right of First Negotiation).

1.99 "**Licensee ROFN Negotiation Period**" has the meaning set forth in Section 2.8.2 (Right of First Negotiation).

1.100 "**Licensee ROFN Trigger Notice**" has the meaning set forth in Section 2.8.2 (Right of First Negotiation).

1.101 "**Licensor**" has the meaning set forth in the Preamble.

1.102 "**Licensor Indemnitee(s)**" has the meaning set forth in Section 13.1 (By Licensee).

1.103 "**Licensor Know-How**" means any Know-How that is (a) Controlled by Licensor or any of its Affiliates as of the Effective Date, and (b) necessary or reasonably useful to Develop in accordance with the applicable Japanese Clinical Development Plan, perform Medical Affairs with respect to in accordance with the Japanese Medical Affairs Plan, Manufacture, Commercialize or otherwise Exploit one or more Licensed Products in Japan in the Field.

1.104 "**Licensor Patent Rights**" means any Patent Right that is (a) Controlled by Licensor or any of its Affiliates as of the Effective Date, and (b) is necessary or reasonably useful (or, with respect to patent applications, would be necessary or reasonably useful if such patent applications were to issue as patents) to Develop in accordance with the applicable Japanese Clinical Development Plan, perform Medical Affairs with respect to in accordance with the Japanese Medical Affairs Plan, Manufacture, Commercialize or otherwise Exploit, one or more Licensed Products in Japan in the Field. Schedule 1.104 (Licensor Patent Rights) sets forth the Licensor Patent Rights existing as of the Effective Date in Japan. For the avoidance of doubt, if a Patent Right exists outside Japan as of the Effective Date but has not been filed in Japan as of the Effective Date, any Patent Right in Japan, to the extent claiming priority to such Patent Right outside Japan and otherwise captured by this definition, shall be a Licensor Patent Right hereunder.

1.105 "**Licensor Patent Right Infringement**" has the meaning set forth in Section 14.5.1 (Notice).

1.106 "**Licensor Product-Related Program IP**" has the meaning set forth in Section 14.1.2(a) (Ownership of Arising Intellectual Property).

1.107 "**Licensor Prosecuted Patent Rights**" has the meaning set forth in Section 14.4.1 (Licensor-Prosecuted Patent Rights)

1.108 "**Licensor Program IP**" has the meaning set forth in Section 14.1.2(a) (Ownership of Arising Intellectual Property).

1.109 "**Licensor Technology**" means the Licensor Know-How and Licensor Patent Rights.

1.110 "**Listing Patent Rights**" has the meaning set forth in Section 14.7 (Patent Listings).

1.111 "**Losses**" means all losses, costs, claims, damages, judgments, liabilities, Taxes, and expenses (including reasonable attorneys' fees and other reasonable out-of-pocket costs in connection therewith).

1.112 "**Manufacture**" means with respect to any product, any and all activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, supply, or storage of such product (or any components or process steps involving such product), as the case may be, including qualification, validation, and scale-up, preclinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding any activities directed to Development, Medical Affairs, or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed pursuant to this section.

1.113 "**Marketing Authorization**" or "**MA**" has the meaning set forth in Section 1.143 (Regulatory Approval).

1.114 "**Marketing Authorization Application**" or "**MAA**" means any new drug application, biologics license application, or other marketing authorization application, in each case, filed pursuant to the Japan New Drug Application Marketing Authorization, which application is required to commercially market or sell a pharmaceutical or biologic product (and any amendments thereto).

1.115 "**Marketing Authorization Holder**" or "**MAH**" means the holder of the relevant MAA(s) or issued marketing authorization(s) with respect to a Licensed Product and all supplements, amendments, and revisions thereto.

1.116 "**Material Adverse Impact**" means, with respect to any matter, that such matter (a) could have an adverse impact on the Development, Manufacture, Medical Affairs, or Commercialization of any Licensed Product outside of Japan (including any concern related to product integrity (including counterfeiting and diversion), quality, safety, toxicity, or side effects) or (b) is inconsistent with Licensor's global regulatory strategy for any Licensed Product.

1.117 "**Medical Affairs**" means activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, a product, including by way of example: (a) activities of medical scientific liaisons who, among their other functions, may (i) conduct service-based medical activities including providing input and assistance with consultancy meetings, recommend investigators for Clinical Trials and provide input in the design of such trials and other research related activities and (ii) deliver non-promotional communications and conduct non-promotional activities including presenting new Clinical Trial and other scientific information; (b) grants to support continuing medical education, symposia, or Third Party research related to a product; (c) development, publication, and dissemination of publications relating to a product; (d) medical information services provided in response to scientific inquiries from healthcare providers (HCPs), communicated via sales representatives or received directly from an HCP by letter, phone call, or email; (e) the conduct of scientific advisory board meetings or other consultant programs; (f) the support of investigator-initiated trials, post-approval studies, and health economics and outcomes research; and (g) the implementation of risk, evaluation and mitigation strategies (REMS). Medical Affairs excludes any activities directed to Manufacturing, Development, or Commercialization.

1.118 "**Medical Affairs Report**" has the meaning set forth in Section 7.2 (Medical Affairs Reports).

1.119 "**Negotiation Period**" has the meaning set forth in Section 2.8.2.

1.120 "**Net Sales**" means the gross amount invoiced for sale or other disposition of the Licensed Products by Licensee, its Affiliates, Sublicensees, and any Affiliates of such Sublicensees (in each case, the "**Invoicing Entity**") to Third Party end users, distributors, or wholesalers (for the purposes of commercial distribution), less the following deductions accounted for in accordance with applicable Accounting Standards:

(a) sales returns and allowances actually paid, granted, or accrued on the Licensed Product, including trade quantity, prompt pay and cash discounts, and any other adjustments, including those granted on account of price adjustments or billing errors;

(b) credits or allowances given or made for rejection, recall, return, or wastage replacement of the Licensed Product or for rebates or retroactive price reductions;

(c) price reductions, discounts, rebates, and chargeback payments granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers (including Medicare, Medicaid, managed care, and similar types of rebates and chargebacks);

(d) to the extent included as part of gross sales, costs of freight, insurance, and other transportation charges, as well as any administration fees or other fees for services provided by wholesalers, distributors, warehousing chains, and other Third Parties related to the distribution of the Licensed Product;

(e) to the extent included as part of gross sales, Taxes, duties, or other governmental charges required to be accounted for to a Governmental Authority (including any Tax such as a value added or similar Tax, other than any Taxes based on income) relating to the sale of the Licensed Product, as adjusted for rebates and refunds; and

(f) any invoiced amounts for the Licensed Product that are not collected by such Invoicing Entity, including provision for bad debts (*provided* that any such amounts subsequently collected will be included in Net Sales for the period in which collected),

to the extent such deductions: (i) are applicable and in accordance with standard allocation procedures, (ii) have not already been deducted or excluded, and (iii) are incurred in the ordinary course of business in type and amount consistent with good industry practice.

Net Sales will not be imputed to transfers of a Licensed Product without consideration or for nominal consideration for use in any clinical trial, or for any bona fide charitable, compassionate use, or indigent patient program purpose or as a sample. For the avoidance of doubt, in the case of any transfer of a Licensed Product between or among Invoicing Entities for resale, Net Sales will be determined based on the sale made by such Invoicing Entity to a Third Party (other than another Invoicing Entity). In the case of any sale for value, such as barter or counter-trade, of a Licensed Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales will be deemed to be the Net Sales at which substantially similar quantities of such Licensed Product are sold for cash in an arm's length transaction in Japan or in the absence of such sales, the fair market value of the Licensed Product as determined by the Invoicing Entity in good faith.

In the event that discounts, allowances, credits, rebates, or other deductions are provided with respect to multiple products, including both Licensed Products and non-Licensed Products (or discounts are provided with respect to Licensed Products to induce customers to purchase both Licensed Products and non-Licensed Products), such discounts, allowances, credits, rebates, or other deductions will be fairly and equitably allocated to the Licensed Products and other products.

1.121 "**New License Agreement**" has the meaning set forth in Section 2.5.2 (Sublicense Survival).

1.122 "**NHI**" has the meaning set forth in Section 6.2 (Commercial Supply).

1.123 "**OFAC**" has the meaning set forth in Section 1.70 (Global Trade Laws and Regulations).

1.124 "**Offered Product**" has the meaning set forth in Section 2.8.1.

1.125 "**Offered Product Transaction**" has the meaning set forth in Section 2.8.1.

1.126 "**Party**" or "**Parties**" has the meaning set forth in the Preamble.

1.127 "**Patent Challenge**" has the meaning set forth in Section 15.2.4 (Termination for Patent Challenge).

1.128 "**Patent Prosecution**" means activities directed to (a) preparing, filing, and prosecuting applications (of all types) for any Patent Right, (b) maintaining any Patent Right, and (c) deciding whether to abandon or maintain any Patent Right.

1.129 "**Patent Rights**" means: (a) any patent or patent application in any country or supranational jurisdiction worldwide; (b) any substitution, divisional, continuation, continuation-in-part, reissue, renewal, registration, confirmation or the like of any such patent or patent application; or (c) any extension or restoration by existing or future extension or restoration mechanism, including revalidation, reissue, re-examination or extension, including any supplementary protection certificate of any of the foregoing.

1.130 "**Patent Term Adjustment**" has the meaning set forth in Section 14.8 (Patent Term Extensions).

1.131 "**Patent Term Extension**" has the meaning set forth in Section 14.8 (Patent Term Extensions).

1.132 "**Person**" means any individual, partnership (general or limited), joint venture, limited liability company, corporation, firm, trust, association, enterprise, unincorporated organization, Governmental Authority, or any other entity not specifically listed herein.

1.133 "**Personal Information**" means information related to a reasonably identifiable natural person.

1.134 "**PMDA**" means the Pharmaceuticals and Medical Devices Agency in Japan or any successor thereto that conducts scientific reviews of marketing authorization applications for pharmaceuticals and monitoring of their post-marketing safety in Japan.

1.135 "**Post-Change of Control Party**" has the meaning set forth in Section 2.7.2 (Business Combinations).

1.136 "**Privacy Laws**" has the meaning set forth in Section 12.4.5 (Covenants of Licensee).

1.137 "**Product Marks**" has the meaning set forth in Section 14.10.2 (Product Marks in Japan).

1.138 "**Program IP**" has the meaning set forth in Section 14.1.2 (Ownership of Arising Intellectual Property).

1.139 "**Prohibited Activities**" has the meaning set forth in Section 2.8.2 (Right of First Negotiation).

1.140 "**Public Official**" means (a) any official, officer, employee, or representative of, or any Person acting in an official capacity for or on behalf of, any regional, federal, state, provincial, county, or municipal government or government department, agency, or other division, or any other Governmental Entity; (b) 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; (c) any officer, employee, or representative of any public international organization, such as the International Monetary Fund, the United Nations, or the World Bank; (d) any political party or party official or candidate for political office; or (e) any person acting in an official capacity for any government or Governmental Entity, or other government entity, enterprise, or organization identified above.

1.141 "**Publication**" has the meaning set forth in Section 11.5 (Publications).

1.142 "**Receiving Party**" has the meaning set forth in Section 11.1.1 (Duty of Confidence).

1.143 "**Regulatory Approval**" means, (a) with respect to Japan, approval by the PMDA of the Japan New Drug Application Marketing Authorization ("**MA**") and (b) with respect to any other particular country or other regulatory jurisdiction, any approval of a MAA or other approval, product, or establishment license, registration, or authorization of any Regulatory Authority necessary for the commercial marketing or sale of a pharmaceutical or biologic product in such country or other regulatory jurisdiction, excluding, in each case, Reimbursement Approval.

1.144 "**Regulatory Authority**" means any applicable Governmental Authority with jurisdiction or authority over the Development, Manufacture, Commercialization, or other Exploitation (including Regulatory Approval or Reimbursement Approval) of pharmaceutical or biologic products in a particular country or other regulatory jurisdiction, including the PDMA, the Japanese Ministry of Healthy, Labor and Welfare, the FDA, the European Medicines Agency, and any corresponding national or regional regulatory authorities.

1.145 "**Regulatory Exclusivity**" means any exclusive marketing rights or exclusivity rights or protection conferred by any Regulatory Authority with respect to a pharmaceutical or biologic product in Japan, but in all cases excluding Patent Rights and Patent Term Extensions.

1.146 "**Regulatory Milestone Event**" has the meaning set forth in Section 10.2.1 (Regulatory Milestones).

1.147 "**Regulatory Milestone Payment**" has the meaning set forth in Section 10.2.1 (Regulatory Milestones).

1.148 "**Regulatory Submissions**" means any registration, filing, application, or submission with any Regulatory Authority in support of Developing, Manufacturing, or Commercializing a pharmaceutical or biologic product (including to obtain, support, or maintain Regulatory Approval from that Regulatory Authority), and all correspondence or communication with or from the relevant Regulatory Authority, including notifications and reports, as well as minutes of any substantive meetings, telephone conferences, or discussions with the relevant Regulatory Authority, and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files. Regulatory Submissions include all MAAs and other applications for Regulatory Approval and their equivalents (for clarity, as applications, but not the approvals with respect thereto).

1.149 "**Reimbursement Approval**" means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end-users for pharmaceutical or biologic products at which a particular pharmaceutical or biologic product will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in Japan.

1.150 "**Replacement Site**" has the meaning set forth in Section 4.4.2 (Deficient Sublicensees/Subcontractors or Sites and Replacement).

1.151 "**Representatives**" has the meaning set forth in Section 12.1.6 (Representations and Warranties of Each Party).

1.152 "**Restricted Country**" means any country or geographic region subject to comprehensive economic sanctions administered by OFAC, which as of the Effective Date includes: Crimea, Donetsk, Luhansk, Russia, Cuba, Iran, North Korea, and Syria.

1.153 "**Restricted Party**" means (a) any Person included on one or more of the Restricted Party Lists, (b) any Person owned by or acting on behalf of a Person included on one or more of the Restricted Party Lists, or (c) a Person ordinarily resident in or an entity that is located in or organized under the laws of a Restricted Country.

1.154 "**Restricted Party Lists**" includes the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals and Blocked Persons List, the Foreign Sanctions Evaders List, and the Sectoral Sanctions Identifications List, all administered by OFAC; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the consolidated list of Persons, Groups and Entities subject to EU Financial Sanctions, as implemented by the EU Common Foreign & Security Policy; and similar lists of restricted parties maintained by other applicable Governmental Authorities.

1.155 "**Review Period**" has the meaning set forth in Section 11.5 (Publications).

1.156 "**Roflumilast**" means 3-cyclopropylmethoxy-*N*-(3,5-dichloropyridin-4-yl)-4-(difluoromethoxy) benzamide, as set forth in Schedule 1.156 (Roflumilast).

1.157 "**Right of First Negotiation**" has the meaning set forth in Section 2.8.1.

1.158 "**Royalties**" has the meaning set forth in Section 10.3.1 (Royalty Rates).

1.159 "**Royalty Term**" means, on a Licensed Product-by-Licensed Product basis, the period of time that commences upon the First Commercial Sale of such Licensed Product in Japan and ends upon the latest of: (a) the expiration of the last Valid Claim in the Licensor Patent Rights covering such Licensed Product in Japan, (b) the expiration of Regulatory Exclusivity for such Licensed Product in Japan or (c) 10 years after the First Commercial Sale of such Licensed Product in Japan.

1.160 "**Safety Data Exchange Agreement**" has the meaning set forth in Section 5.6.1 (Safety Data Exchange Agreement).

1.161 "**Sales Milestone Event**" has the meaning set forth in Section 10.2.2(a) (Sales Milestone Payments).

1.162 "**Sales Milestone Payments**" has the meaning set forth in Section 10.2.2(a) (Sales Milestone Payments).

1.163 "**Subcontractor**" means a Third Party contractor engaged by a Party to perform certain obligations or exercise certain rights of such Party under this Agreement on a fee-for-service basis (including CROs, CMOs, and CSOs). Any Third Party distributor will be deemed a Subcontractor of Licensor or its Affiliates or Sublicensees, as applicable. A Subcontractor of Licensee may be deemed a Sublicensee for purposes of this Agreement if such Subcontractor receives a sublicense under the rights granted to Licensee in Section 2.1 (License Grant to Licensee) to perform the applicable activities for which they were engaged.

1.164 "**Sublicense**" has the meaning set forth in Section 2.5.1 (Right to Sublicense).

1.165 "**Sublicensee**" means any Person to whom Licensee grants a sublicense of, or other authorization or permission granted under, the rights granted to Licensee in Section 2.1 (License Grant to Licensee) or any option to receive such a sublicense, authorization or permission, including any Subcontractor (to the extent such Subcontractor requires a sublicense under the rights granted to Licensee in Section 2.1 (License Grant to Licensee) to perform the applicable activities for which they were engaged).

1.166 "**Suspension Notice**" has the meaning set forth in Section 12.8.3(b) (Remediation).

1.167 "**Tax**" or "**Taxes**" means taxes of any kind including, but not limited to those measured on, measured by or referred to as, income, alternative or add-on minimum, gross receipts, escheat, capital, capital gains, sales, use, ad valorem, franchise, profits, license, privilege, transfer, withholding, payroll, employment, social security, excise, severance, stamp, occupation, premium, value added, turnover, property, environmental or windfall profits taxes, customs duties or similar fees, assessments or charges of any kind whatsoever, including any contractual obligation to indemnify another Person for Taxes, together with any interest and any penalties, additions to tax or additional amounts imposed by any Governmental Authority.

1.168 "**Term**" has the meaning set forth in Section 15.1 (Term).

1.169 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.170 "**Third Party Claims**" means collectively, any and all Third Party demands, claims, actions, suits, and proceedings (whether criminal or civil or in contract, tort, or otherwise).

1.171 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

1.172 "**Valid Claim**" means: (a) a claim of an issued and unexpired patent (as may be extended through supplementary protection certificate or patent term extension or the like) that has not been revoked, held invalid, or unenforceable by a patent office or other Governmental Authority of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and which claim has not been disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination, or disclaimer or otherwise; or (b) a pending claim of an unissued, pending patent application, which application has not been pending for more than [***] years since the date of the first response on the merits received from the relevant patent office regarding such application; *provided* that such [***] year period will be tolled for the duration of any adverse proceeding (*e.g.*, Third Party oppositions or any appeal of an adverse determination against the Valid Claim) with respect to the patent application at issue.

1.173 "**Withheld Amount**" has the meaning set forth in Section 10.11.2 (Withholding Tax).

ARTICLE 2
LICENSES; EXCLUSIVITY; RIGHT OF FIRST NEGOTIATION

2.1 License Grant to Licensee. Subject to the terms of this Agreement, Licensor hereby grants to Licensee an exclusive (subject to Licensor's retained rights under Section 2.4 (No Implied Licenses; Retained Rights)), royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.5 (Sublicensing and Subcontractors), under its interest in (a) the Licensor Technology, and (b) the Joint IP, in each case ((a) and (b)) to Develop, perform Medical Affairs with respect to, Manufacture, Commercialize and otherwise Exploit Licensed Products in the Field in the territory of Japan solely in accordance with the terms of this Agreement, including the terms of each Japanese Clinical Development Plan and Japanese Medical Affairs Plan.

2.2 Affiliate Rights. The rights licensed to Licensee under Section 2.1 (License Grant to Licensee) may be extended by Licensee to Affiliates of Licensee, *provided* that:

(a) such rights will be extended only for so long as such Affiliate remains an Affiliate;

(b) each such Affiliate agrees in writing to be bound by the terms and conditions of this Agreement as if it were Licensee hereunder;

(c) any act or omission by each such Affiliate will be deemed an act or omission by Licensee hereunder, and Licensee will be responsible for each such Affiliate complying with all obligations of Licensee under this Agreement (including all restrictions placed on Licensee herein);

(d) any assumption of rights or obligations by each such Affiliate under this Agreement will not relieve Licensee of any of its obligations under this Agreement; and

(e) each such Affiliate is not in violation of any Applicable Law.

2.3 License Grant to Licensor. Subject to the terms of this Agreement, Licensee hereby grants to Licensor and its Affiliates a non-exclusive, royalty-free, fully paid-up, perpetual, irrevocable, worldwide, transferable license, with the right to grant sublicenses through multiple tiers, under the Licensee Collaboration Technology to Develop, perform Medical Affairs with respect to, Manufacture, Commercialize and otherwise Exploit Licensed Products in all fields and indications other than in the Field in Japan during the Term.

2.4 No Implied Licenses; Retained Rights. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party, including Licensor Technology or Licensee Collaboration Technology, in each case, that are not expressly granted herein, whether by implication, estoppel, or otherwise. Any rights not expressly granted to Licensor by Licensee under this Agreement are hereby retained by Licensee. Any rights not expressly granted to Licensee by Licensor under this Agreement are hereby retained by Licensor. Notwithstanding any provision to the contrary set forth in this Agreement, Licensor hereby retains (a) on behalf of itself and its Affiliates, licensees, sublicensees (other than Licensee and its Affiliates and Sublicensees), and Subcontractors, the right under the Licensor Technology to Develop Licensed Products in the Field in Japan for seeking and obtaining Regulatory Approval and for Commercialization outside of Japan and, subject to the terms of this Agreement, outside of the Field in the territory of Japan, and (b) on behalf of itself and its Affiliates and Subcontractors, the right under the Licensor Technology to Manufacture Licensed Products in the Field in Japan for Development worldwide and for seeking and obtaining Regulatory Approval and for Commercialization outside of Japan and, subject to the terms of this Agreement, outside of the Field in Japan. Licensee will not practice the Licensor Technology other than as expressly licensed and permitted under this Agreement or otherwise agreed by the Parties in writing.

2.5 Sublicensing and Subcontractors.

2.5.1 Right to Sublicense. Subject to the terms of this Agreement, Licensee will have the right to grant sublicenses of the rights granted under Section 2.1 (License Grant to Licensee) to Third Parties (each a "**Sublicense**") with the prior written consent of Licensor, which consent may not be unreasonably withheld, conditioned, or delayed. Within [***] days of entering into any Sublicense, Licensee will provide a notice to Licensor of such Sublicense, which notice will identify the applicable Sublicensee and summarize the scope of each such Sublicense. Except as provided in Section 2.5.2 (Sublicense Survival), each Sublicensee will hold its rights contingent on the rights licensed to Licensee under the terms of this Agreement, and any termination of the licenses granted to Licensee under Section 2.1 (License Grant to Licensee) as a result of a

termination of this Agreement with respect to one or more Licensed Products or in its entirety will cause the Sublicensees to automatically lose the same rights under any sublicense.

2.5.2 Sublicense Survival. Upon the termination of this Agreement for any reason, at the written request of any Sublicensee who is not then in breach of its sublicense agreement or the terms of this Agreement, Licensor will enter into a direct license agreement with such Sublicensee on the same terms as this Agreement, taking into account any difference in license scope, territory, and duration of the applicable sublicense grant (each a "**New License Agreement**"). Under any New License Agreement between Licensor and a former Sublicensee, such Sublicensee will be required to pay to Licensor the same amounts in consideration for such direct grant as Licensor would have otherwise received from Licensee pursuant to this Agreement on account of such Sublicensee's Exploitation of the relevant Licensed Products had this Agreement not been terminated. Under such New License Agreement, Licensor will not be bound by any grant of rights broader than, and will not be required to perform any obligation other than those rights and obligations contained in, this Agreement and all applicable rights of Licensor set forth in this Agreement will be included in such New License Agreement.

2.5.3 Terms of Sublicenses to Third Parties. Within [***] days of granting any Sublicense, Licensee will provide an unredacted copy of such Sublicense. Each sublicense to a Third Party will be granted under a written agreement that is consistent with and subject to the terms of this Agreement and that:

(a) requires each such Sublicensee to comply with the terms of this Agreement that are applicable to such Sublicensee (including the record keeping and audit requirements set forth under Section 4.4 (Clinical Trial Audit Rights), Section 4.5 (Development Records), and Section 10.10 (Financial Records and Audits), a right of reference to Licensee and Licensor under any Regulatory Approvals and Regulatory Submissions Controlled by such Sublicensee or its Affiliate with respect to any Licensed Product, consistent in scope with the right of reference granted to each Party under Section 5.5 (Right of Reference), confidentiality and non-use provisions that are at least as stringent as those set forth in Article 11 (Confidentiality; Publication), the anti-corruption, export restrictions, privacy and data protection covenants set forth in Section 12.4 (Covenants of Licensee), 12.6 (Export Controls) and 12.8 (Compliance), and the intellectual property provisions set forth in Article 14 (Intellectual Property) including a license or present assignment(s) back to Licensee of all Licensee Collaboration Know-How and Licensee Collaboration Patent Rights conceived, discovered, developed, generated, invented, or otherwise made by or on behalf of the Sublicensee such that Licensee can grant Licensor the license set forth in Section 2.3 (License Grant to Licensor) with respect to such Licensee Collaboration Know-How and Licensee Collaboration Patent Rights);

(b) contains a right for Licensee to terminate for a Patent Challenge by such Sublicensee consistent with that set forth in Section 15.2.4 (Termination for Patent Challenge);

(c) requires that each such Sublicensee performs the activities that they are sublicensed or engaged to perform (as applicable) in accordance with the terms of the AZ License, cGLP, cGMP, and cGCP, as applicable, and otherwise in compliance with Applicable Law;

(d) includes Licensor as an intended third party beneficiary under the sublicense with the right to enforce the applicable terms of such sublicense (including the provision described in clause (e));

(e) prohibits such Third Party from engaging in, independently or for or with any other Third Party, any Exploitation of any Competing Product in Japan during the applicable exclusivity period under Section 2.7.1 (Licensee Exclusivity) (which provision Licensee will enforce against all Sublicensees); and

(f) is subject in all respects to the AZ License under which Licensor is granted any right that will be sublicensed under such proposed sublicense.

2.5.4 Right to Subcontract. Subject to the terms of this Agreement, Licensee will have the right to engage Subcontractors for the sole purpose of performing Licensee's obligations with respect to the Development, performance of Medical Affairs activities with respect to, or Commercialization of the Licensed Products in Japan in accordance with the terms of this Agreement. Licensee will require that each Subcontractor comply with the terms of this Agreement that are applicable to such Subcontractor (including containing the record keeping and audit requirements set forth under Section 4.4 (Clinical Trial Audit Rights) and Section 4.5 (Development Records), a right of reference to Licensee and Licensor under any Regulatory Approvals and Regulatory Submissions Controlled by such Subcontractor or its Affiliate with respect to any Licensed Product, consistent in scope with the right of reference granted to each Party under Section 5.5 (Right of Reference), confidentiality and non-use provisions that are at least as stringent as those set forth in Article 11 (Confidentiality; Publication), the anti-corruption, export restrictions, privacy and data protection covenants set forth in Section 12.4 (Covenants of Licensee), 12.6 (Export Controls) and 12.8 (Compliance), and the intellectual property provisions set forth in Article 14 (Intellectual Property) including a license or present assignment(s) back to Licensee of all Licensee Collaboration Know-How and Licensee Collaboration Patent Rights conceived, discovered, developed, generated, invented, or otherwise made by or on behalf of the Subcontractor, as applicable, such that Licensee can grant Licensor the license set forth in Section 2.3 (License Grant to Licensor) with respect to such Licensee Collaboration Know-How and Licensee Collaboration Patent Rights). Licensee will conduct appropriate risk-based due diligence to assess the capabilities, compliance, and reputation of Subcontractors that it engages. Licensee will not engage or propose the engagement of any Subcontractor that is Debarred/Excluded.

2.5.5 Responsibility for Sublicensees and Subcontractors. Notwithstanding any sublicensing or subcontracting, Licensee will remain primarily liable to Licensor for the performance of all of its obligations under, and Licensee's and its Sublicensees' and Subcontractors' compliance with all provisions of, this Agreement. Licensee will be fully responsible and liable for any breach of the terms of this Agreement by any of its Sublicensees or Subcontractors to the same extent as if Licensee itself has committed any such breach, and Licensee will terminate promptly the agreement with any Sublicensee or Subcontractor if such Sublicensee or Subcontractor is in material breach of this Agreement and does not cure such breach in a timely manner.

2.6 AZ License. Licensee stipulates and agrees that (a) the rights and licenses granted to Licensee under this Agreement are subject and subordinate to the applicable terms of the AZ

License with respect to the Licensor Technology that is being sublicensed thereunder, (b) Licensor's obligation to comply with its obligations, and grant rights and licenses to Licensee, under this Agreement are limited by any and all requirements and restrictions imposed on Licensor under the AZ License with respect to the Licensor Technology that is being sublicensed by Licensor under the AZ License, and (c) Licensor will not be required to take any action or inaction that would cause Licensor to be in breach of the AZ License or to grant any rights to Licensee hereunder that are in violation of, or inconsistent with, the AZ License. Licensee will abide by the applicable terms of the AZ License.

2.7 Exclusivity Covenants.

2.7.1 Licensee Exclusivity. On a Licensed Product-by-Licensed Product basis, Licensee will not, and will cause its Affiliates and Sublicensees not to, directly or indirectly, [***] unless and until this Agreement is terminated in its entirety or with respect to the applicable Licensed Product.

2.7.2 Business Combinations. Licensee will not be in breach of the restrictions set forth in this Section 2.7 (Exclusivity Covenants) if Licensee or any of its Affiliates undergoes a Change of Control with a Third Party (together with such Third Party and its Affiliates following the closing of the applicable Change of Control transaction, the "**Post-Change of Control Party**") that (either directly or through an Affiliate, or in collaboration with any other Third Party) (a) is performing, at the closing of the Change of Control transaction, any activity that would be in breach of Section 2.7.1 (Licensee Exclusivity) if performed by Licensee (such prohibited activities, "**Competitive Activities**") or (b) commences any Competitive Activities after the closing of the Change of Control transaction; and such Post-Change of Control Party may perform such Competitive Activities in Japan, as long as (i) no Licensor Technology is used by or on behalf of such Post-Change of Control Party or its Affiliates in connection with the performance of any Competitive Activities and (ii) such Post-Change of Control Party institutes commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (i) are met, including by creating "firewalls" between the personnel performing any Competitive Activities and the personnel charged with Exploiting any Licensed Product or having access to data from activities performed under this Agreement or Confidential Information of the Parties.

2.7.3 Acquisition of a Competing Product. Licensee will not be in breach of the restrictions set forth in this Section 2.7 (Exclusivity Covenants) if Licensee or any of its Affiliates acquires a Competing Product that is being Exploited in Japan in a manner that would breach Section 2.7 (Exclusivity Covenants) if conducted by Licensee through an acquisition of, or a merger with, the whole or substantially the whole of a business or assets of another Person, so long as Licensee or the applicable Affiliate (a) enters into a definitive agreement with a Third Party to divest (whether by exclusive out-license or otherwise) such Competing Product in Japan and closes such transaction within [***] days after the closing of such acquisition or merger or (b) terminates the further Exploitation of such Competing Product in Japan within [***] days after the closing of such acquisition or merger, and, until the completion of such divestiture or termination, (i) no Licensor Technology or Licensee Collaboration Technology is used by or on behalf of Licensee or its Affiliates in connection with any subsequent Exploitation of such Competing Products in Japan and (ii) Licensee and its Affiliates institute commercially reasonable technical and

administrative safeguards to ensure the requirements set forth in the foregoing clause (i) are met, including by creating "firewalls" between the personnel Exploiting such Competing Products and the personnel charged with Exploiting any Licensed Product or having access to data from activities performed under this Agreement or Confidential Information of the Parties.

2.8 Right of First Negotiation. During the Term, if Licensor obtains Regulatory Approval in any country (or if Regulatory Approval is not required, Commercializes or otherwise makes use of as part of the Manufacture or Commercialization in any country) for, or otherwise Controls any intellectual property relating to, any new formulations, upgrades, improvements or line extensions to a Licensed Product, including any new indications that are not Indications hereunder, (each a "**Licensed Product Improvement**"), then, if Licensor intends to enter into an Offered Product Transaction, Licensee will have the right to negotiate a definitive license agreement with respect to each Licensed Product Improvement in Japan on the terms set forth in this Section 2.8 (Right of First Negotiation).

2.8.1 On a product by product basis, in the event that Licensor or any of its Affiliates intends, directly or indirectly, to enter into any license, co-development, co-commercialization, co-promotion or any other arrangement or amendment to such arrangement, pursuant to which Licensor would grant to any Third Party any rights, or any option to Develop, Manufacture, Commercialize or otherwise Exploit one or more Licensed Product Improvements in the Field in Japan (the "**Offered Product**"), either under a new agreement or under an amendment to any then existing agreement with a Third Party (each an "**Offered Product Transaction**"), Licensee shall have the rights with respect to such Offered Product set forth in Sections 2.8.2 to 2.8.3 (the "**Right of First Negotiation**").

2.8.2 Prior to entering into any discussions, negotiations, solicitations of interest or other interaction with any Third Party regarding an Offered Product Transaction (the "**Prohibited Activities**") or entering into any Offered Product Transaction, Licensor shall provide notice to Licensee identifying the Offered Product (the "**Licensee ROFN Trigger Notice**"). If, within [***] Business Days following its receipt of a Licensee ROFN Trigger Notice (the "**Licensee ROFN Negotiation Period**"), Licensee provides a written notice to Licensor exercising the Right of First Negotiation with respect to the Offered Product that is subject to the Licensee ROFN Trigger Notice (each such notice from Licensee to Licensor a "**Licensee ROFN Negotiation Notice**") then, from the period commencing on the date of Licensor's receipt of the Licensee ROFN Negotiation Notice and ending on the [***] day thereafter, or such longer period as agreed to by the Parties (the "**Negotiation Period**"), Licensee and Licensor shall exclusively negotiate in good faith the terms of a definitive license agreement (or at the Parties' election, an amendment to this Agreement) pursuant to which Licensor would grant Licensee the right to Develop and Commercialize the applicable Offered Product in the Field in Japan. Licensor may not engage in any Prohibited Activities regarding the applicable Offered Product during the Negotiation Period but may, for the avoidance of doubt, engage in discussions regarding the grant of rights to the Offered Product outside of Japan or outside of the Field in Japan.

2.8.3 If (a) Licensee does not deliver a Licensee ROFN Negotiation Notice to Licensor during the applicable Licensee ROFN Negotiation Period or (b) Licensee delivers a Licensee ROFN Negotiation Notice to Licensor during the applicable Licensee ROFN Negotiation Period, but the Parties fail to enter into a definitive license agreement (or amendment to this Agreement)

with respect to the applicable Offered Product during the applicable Negotiation Period, then in each case ((a) or (b)), Licensor shall be free to negotiate any transaction with respect to the applicable Offered Product with any Third Party in Japan in the Field and shall have no further obligation to enter into an agreement with Licensee with respect to such Offered Product, *provided* if Licensee had delivered a Licensee ROFN Negotiation Notice for such Offered Product, during the [***] months following the expiry of the Licensee ROFN Negotiation Period, Licensor may only license such Offered Product to Third Parties on terms that Licensor reasonably believes are no less favorable to Licensor in the aggregate than the terms last offered to Licensee during the Negotiation Period.

ARTICLE 3
GOVERNANCE

3.1 Alliance Managers. Each Party will appoint an individual to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (each an "**Alliance Manager**"). The Alliance Managers will: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties; (c) facilitate the prompt resolution of any Disputes; and (d) attend JSC meetings as a non-voting member. An Alliance Manager may also bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will use reasonable efforts to keep an appropriate level of continuity but may replace its Alliance Manager at any time upon prior written notice to the other Party.

3.2 Joint Steering Committee.

3.2.1 Formation and Purpose of JSC. No later than [***] days after the Effective Date, the Parties will establish a joint steering committee (the "**JSC**") to coordinate and oversee the Development and Commercialization of, and performance of Medical Affairs with respect to, the Licensed Products in Japan. The JSC will be composed of an equal number of representatives from each Party and a minimum of three representatives of each Party who are fluent in English and who have the appropriate and direct knowledge and expertise and requisite decision-making authority. Each Party may replace any of its representatives on the JSC and appoint a Person to fill the vacancy arising from each such replacement upon written notice to the other Party. Both Parties will use reasonable efforts to keep an appropriate level of continuity in representation. A representative of Licensor will chair the JSC (the "**JSC Chairperson**"). Each Party's representatives on the JSC will inform and coordinate within their respective organization to enable each Party to fulfill its obligations under this Agreement, including within the time frames set forth hereunder.

3.2.2 Meeting Agendas. Each Party will disclose to the other Party the proposed agenda items along with appropriate information at least [***] Business Days in advance of each meeting of the JSC; *provided* that under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a shorter period of time in advance of a meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party

consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.

3.2.3 Meetings. The JSC will hold meetings at such times as it elects to do so, but will meet no less frequently than quarterly, unless otherwise agreed by the Parties. All meetings will be conducted in English. The JSC may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communication method. Each Party will bear its own expenses related to the attendance of the JSC meetings by its representatives. Each Party may also call for special meetings to resolve particular matters requested by such Party upon [***] Business Days' prior written notice to the other Party. The JSC Chairperson or their designee will keep minutes of each JSC meeting that record in writing all decisions made, action items assigned or completed, and other appropriate matters. The JSC Chairperson or his or her designee will send meeting minutes to all members of the JSC for review within [***] Business Days after each meeting. Each member will have [***] Business Days from receipt in which to approve or provide comments to the minutes (such approval not to be unreasonably withheld, conditioned, or delayed). If a member, within such time period, does not notify the JSC Chairperson that he or she does not approve of the minutes, then the minutes will be deemed to have been approved by such member. Each Party's JSC members may designate another staff member of such Party, which could be the Alliance Manager, to coordinate the administrative work surrounding the JSC, including sending notices for JSC meetings, creating the draft of minutes, or distributing the minutes.

3.2.4 Subcommittees. The JSC may establish and delegate specifically-defined duties to any other operational committees, *ad hoc* subcommittees, or working groups on an "as needed" basis to oversee particular projects or activities. Each such operational committee, *ad hoc* subcommittee, or working group and its activities will be subject to the oversight of, and will report to, the JSC. The membership, meeting, and decision-making terms applicable to the JSC (as set forth in this Article 3 (Governance)) will apply to each such operational committee, *ad hoc* subcommittee, or working group, *mutatis mutandis*, unless otherwise agreed by the Parties. No such operational committee, *ad hoc* subcommittee, or working group may exceed the authorities specified for the JSC in this Article 3 (Governance).

3.2.5 JSC Roles and Responsibilities. The responsibilities of the JSC will be to:

(a) provide a forum for the discussion of the Parties' activities under this Agreement;

(b) review, discuss, and determine whether to approve any amendment to a Japanese Clinical Development Plan, as described in Section 4.2 (Japanese Clinical Development Plans);

(c) review, discuss, and determine whether to approve any Clinical Trials, as described in Section 4.3 (Clinical Trial Design; Protocols);

(d) review, discuss, and determine whether to approve any remediation plan, as described in Section 4.4.1 (Conduct of Audits);

(e) discuss the status, progress, and results of all Development Activities described in each Development Report;

(f) discuss all Development Data and Clinical Data generated by or on behalf of Licensee;

(g) review, discuss, and determine whether to approve any Proposed New Formulations, Concentrations, or Indications, as described in Section 4.8 (Development of New Formulations, Concentrations, or Indications);

(h) discuss any regulatory developments related to the Licensed Products in Japan;

(i) review, discuss, and determine whether to approve any Japanese Medical Affairs Plan or amendment thereto, as described in Section 7.1 (Japanese Medical Affairs Plans);

(j) as and when requested by Licensor, discuss the coordination of Medical Affairs activities inside and outside Japan;

(k) discuss any Commercialization insights or materials provided by Licensor pursuant to Section 8.3 (Licensor Commercialization Insights);

(l) discuss the Product Marks, as described in Section 14.10.2 (Product Marks in Japan)

(m) form and delegate specifically defined responsibilities to such other operational committees, *ad hoc* subcommittees, and working groups as the JSC may deem appropriate, as described in Section 3.2.4 (Subcommittees); and

(n) perform such other functions as expressly set forth in this Agreement or allocated to the JSC by the Parties' written agreement.

3.3 Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives (which may include legal counsel), to attend a meeting of the JSC (in a non-voting capacity), if such participants have expertise that is relevant to the planned agenda for such JSC meeting; *provided* that if either Party intends to have any Third Party (including any consultant) attend such a meeting, then such Party will provide prior written notice to the other Party reasonably in advance of such meeting and will ensure that such Third Party is bound by obligations of confidentiality and non-use at least as stringent as those set forth in Article 11 (Confidentiality; Publication). Notwithstanding any provision to the contrary set forth in this Agreement, if the other Party objects in good faith to the participation of such Third Party in such meeting due to a *bona fide* concern regarding competitively sensitive information that is reasonably likely to be discussed at such meeting (*i.e.*, a consultant that also provides services to a Third Party with a Competing Product), then such Third Party will not be permitted to participate in such meeting (or the portion thereof during which such competitively sensitive information is reasonably likely to be discussed).

3.4 Decision-Making.

3.4.1 General Process. The JSC will have only the powers expressly assigned to it in this Article 3 (Governance) and explicitly elsewhere in this Agreement and will not have the

authority to (a) modify or amend the terms of this Agreement or (b) waive either Party's compliance with the terms of this Agreement. Other than with respect to those matters that are expressly assigned to the JSC under this Agreement, the committee decision-making process set forth in this Article 3 (Governance) is not intended to govern the day-to-day activities necessary for each Party to perform its obligations under any then-current Japanese Clinical Development Plan or Japanese Medical Affairs Plan so long as such actions are consistent with the activities assigned to such Party under each applicable plan. All decisions of the JSC will be made by unanimous vote, with each Party's representatives having one vote (*i.e.*, one vote per Party). No action taken at any meeting of the JSC will be effective unless there is a quorum at such meeting, and at all such meetings, a quorum will be reached if two voting representatives of each Party are present or participating in such meeting and no Party will unreasonably fail to cause a quorum of its representatives to attend any meeting of the JSC. Except as otherwise expressly set forth in this Agreement, the phrases "determine," "designate," "confirm," "approve," or "determine whether to approve" by the JSC and similar phrases used in this Agreement will mean approval in accordance with this Section 3.4 (Decision-Making), including the escalation and tie-breaking provisions herein. For the avoidance of doubt, matters that are specified in Section 3.2.5 (JSC Roles and Responsibilities) to be reviewed and discussed (as opposed to reviewed, discussed, and approved) do not require any agreement or decision by either Party and are not subject to the voting and decision-making procedures set forth in this Section 3.4 (Decision-Making) or in Section 3.5 (Resolution of JSC Disputes).

3.4.2 Decisions of the JSC. The JSC will use good faith efforts, in compliance with this Section 3.4.2 (Decisions of the JSC), to promptly resolve any such matter for which it has authority. If, after the use of good faith efforts, the JSC is unable to resolve any matter that is within the scope of its authority, including, any other disagreement between the Parties that may be referred to the JSC, within a period of [***] days (or such other period as the Parties may agree in writing), then a Party may refer such matter for resolution in accordance with Section 3.5.1 (Referral to Executive Officers) to the Chief Executive Officer of Licensor (or an executive officer of Licensor designated by the Chief Executive Officer of Licensor who has the power and authority to resolve such matter) and the Chief Executive Officer of Licensee (or an executive officer of Licensee designated by the Chief Executive Officer of Licensee who has the power and authority to resolve such matter) (collectively, the "**Executive Officers**").

3.5 Resolution of JSC Disputes.

3.5.1 Referral to Executive Officers. If a Party makes an election under Section 3.4.2 (Decisions of the JSC) to refer a matter on which the JSC cannot reach a consensus decision for resolution by the Executive Officers, then the JSC will submit in writing the respective positions of the Parties to their respective Executive Officers. The Executive Officers will use good faith efforts to resolve any such matter so referred to them as soon as practicable, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties. For the avoidance of doubt, the Parties will continue to perform activities required under this Agreement pending resolution of a dispute escalated to the Executive Officers pursuant to this Section 3.5.1 (Referral to Executive Officers).

3.5.2 Final Decision-Making Authority. If the Executive Officers are unable to reach agreement on any such matter referred to them within [***] days after such matter is so referred (or such longer period as the Executive Officers may agree upon), then:

(a) **Licensor Final Decision-Making Authority**. Except as set forth in Section 3.5.2(b) (No Change; Status Quo), Licensor will have final decision-making authority over [***].

(b) **No Change; Status Quo**. Neither Party will have final decision-making authority over [***] and all such matters must be decided by unanimous agreement in order to take any action or adopt any change from the then-current status quo.

(c) **Licensee Final Decision-Making Authority**. For the avoidance of doubt, while not within the decision-making authority of the JSC, Licensee will have final decision-making authority over matters [***].

3.5.3 Limitations on Decision-Making. Notwithstanding any provision to the contrary set forth in this Agreement, without the other Party's prior written consent, neither Party (in the exercise of a Party's final decision-making authority), the JSC, nor a Party's Executive Officer, in each case, may make a decision that could reasonably be expected to require the other Party to take any action that such other Party reasonably believes would require such other Party to violate any Applicable Law (including cGLP, cGMP, or cGCP, as applicable).

3.6 Discontinuation of JSC and Subcommittees. The JSC will continue to exist until the Parties agree to disband the JSC. Once the JSC is disbanded, the JSC will have no further obligations under this Agreement and, thereafter, the Alliance Managers will be the points of contact for the exchange of information between the Parties under this Agreement and any references in this Agreement to decisions of the JSC will automatically become references to decisions by and between the Parties in writing, subject to the other terms of this Agreement and consistent with the terms of Section 3.5 (Resolution of JSC Disputes). Upon the disbandment of the JSC, any other operational committee, *ad hoc* subcommittee, or working group established under Section 3.2.4 (Subcommittees) will automatically disband.

ARTICLE 4
DEVELOPMENT ACTIVITIES

4.1 Development Responsibilities. Subject to the terms and conditions of this Agreement, as between the Parties, Licensee will be solely responsible for and will conduct all activities under the Japanese Clinical Development Plan ("**Development Activities**") at its sole cost.

4.2 Japanese Clinical Development Plans. All Development Activities conducted by or on behalf of Licensee with respect to any Licensed Product will be conducted only pursuant to a written development plan approved by the JSC (each such plan with respect to a Licensed Product, as such plan may be updated from time to time in accordance with this Section 4.2 (Japanese Clinical Development Plans), a "**Japanese Clinical Development Plan**"). The initial high-level Japanese Clinical Development Plan for each Licensed Product is set forth on Schedule 4.2 (Japanese Clinical Development Plans) attached hereto. Licensee shall use Commercially Reasonable Efforts to initiate consultation with the PMDA within [***] days of the Effective Date

and, in any event, as soon as practicable following the Effective Date, and the Parties will use reasonable efforts through the JSC to develop and approve a more detailed Japanese Clinical Development Plan for each Licensed Product complying with the terms of this Section 4.2 (Japanese Clinical Development Plans) within [***] days of receipt of official meeting minutes from the PMDA after such consultation with the PMDA, or such longer period as mutually agreed by the Parties in writing. Each Japanese Clinical Development Plan and all updates thereto will contain in reasonable detail (a) a description of the scope and breadth of initial Development and regulatory activities for the applicable Licensed Product in the Field in the territory of Japan, including Clinical Development activities and regulatory meetings or consultations reasonably necessary to support Regulatory Approval of such Licensed Product in the Field in the territory of Japan, including a description of all protocols of planned Clinical Trials (including estimated study size, clinical sites, treatment assumptions, etc.), (b) the allocation of such activities between Licensee, its Affiliates, and its and their Subcontractors and Sublicensees, (c) the target timelines for performing and completing such activities, (d) a forecast of Clinical Trial material demand and details on importation requirements, and (e) an estimated timeline for submission of MAAs for the applicable Licensed Product in Japan. From time to time during the Term, but at least [***], the JSC will discuss the status of activities under each Japanese Clinical Development Plan. The JSC will review, discuss, and determine whether to approve any and all updates to a Japanese Clinical Development Plan. Once approved by the JSC, each update to a Japanese Clinical Development Plan will become effective and supersede the then-current Japanese Clinical Development Plan for such Licensed Product.

4.3 Clinical Trial Design; Protocols. Licensee will not conduct any Clinical Trials pursuant to this Agreement without the prior approval of the JSC. On a Clinical Trial-by-Clinical Trial basis, prior to the initiation of such Clinical Trial to be conducted pursuant to a Japanese Clinical Development Plan, Licensee will provide a synopsis of such Clinical Trial to the JSC for the JSC's approval. For the purposes of this Section 4.3 (Clinical Trial Design; Protocols), "synopsis" means the part of any clinical trial template with key elements including, but not limited to, background, eligibility criteria, objectives, study size, study design and methodology, treatment, and assessments to be performed in the Clinical Trial. Licensee will additionally provide the JSC such other information and documentation concerning such Clinical Trial as Licensor may request from time to time, including the full study protocol for such Clinical Trial and details on any active agents that will be used in combination with a Licensed Product in any such Clinical Trial.

4.4 Clinical Trial Audit Rights.

4.4.1 Conduct of Audits. In the event Licensee conducts an audit of its or its applicable Affiliates', Sublicensees', or Subcontractors' Clinical Trial sites engaged by Licensee or such applicable Affiliates, Sublicensees, or Subcontractors to perform Licensee's obligations under any Japanese Clinical Development Plan, conducted under ICH guidelines (with respect to such obligations and Clinical Trials), that results in a discovery of a Clinical Trial Issue, then Licensee shall prepare, or cause to be prepared, an audit report. After preparing or receiving an audit report, Licensee shall provide Licensor with a written summary of Licensee's findings, or at the request of Licensor, the full audit report (in the original language), including any material deficiencies from such standards or other areas of remediation that Licensee identifies during any such audit, which shall be discussed at the JSC to determine if any material deficiencies exist and require

remediation. Notwithstanding any provision to the contrary in this Agreement, Licensor may provide any such summaries or reports to the counterparty to the AZ License. Licensee shall remediate any such deficiencies no later than [***] days after Licensor's receipt of such report, at Licensee's cost and expense or, if such remediation is anticipated to take longer than [***] days, then Licensee shall promptly implement a plan to complete such remediation as soon as practicable, which plan shall be presented to the JSC for review and approval. If any deficiencies or areas of remediation are identified in the course of such audit, then the cost and expense of such audit shall be borne by Licensee. If Licensor and Licensee disagree on the magnitude of the Clinical Trial Issue relative to its potential impact on the global program, Licensee shall, at Licensor's expense, audit (or re-audit) a Clinical Trial site(s), vendor(s), or contract research organization to determine the extent of the issue and to facilitate Licensor's participation in the risk assessment and remediation plans.

4.4.2 Deficient Sublicensees/Subcontractors or Sites and Replacement. With respect to any Clinical Trial conducted by or on behalf of Licensee under this Agreement, if Licensee identifies, including any non-compliance identified in an audit conducted pursuant to Section 4.4.1 (Conduct of Audits), any non-compliance by such Clinical Trial site with the AZ License, this Agreement, the applicable Japanese Clinical Development Plan, ICH guidelines, cGLP, cGMP, cGCP, or Applicable Law (each, a "**Deficient Site**") that may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from Licensee's conduct of any such Clinical Trial (as applicable) at such Deficient Site, and if Licensee is unable to successfully remediate the situation in a timely manner and reasonably eliminate the condition causing the Clinical Trial site to be a Deficient Site, then Licensee shall promptly remove such Deficient Site from the applicable Clinical Trial and replace such Deficient Site with a new Clinical Trial site (a "**Replacement Site**") within Japan at Licensee's sole cost and expense (unless not permitted by Applicable Law, including cGLP, cGMP, and cGCP, as applicable, or for ethical reasons). Any such Replacement Site shall be compliant in all respects with Applicable Law (including cGLP, cGMP, and cGCP, as applicable). In addition, if Licensee identifies, including any non-compliance identified in an audit conducted pursuant to Section 4.4.1 (Conduct of Audits), that any Sublicensee or Subcontractor is not performing its activities in accordance with the terms of the AZ License, this Agreement, the applicable Japanese Clinical Development Plan, ICH guidelines, cGLP, cGMP, or cGCP, as applicable, and Applicable Law, or that any deficiencies identified as a result of any such audit related to any such Sublicensee's performance may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from Licensee's conduct of any such Clinical Trial (as applicable) (each, a "**Deficient Sublicensee/Subcontractor**"), then, Licensee shall take action to prohibit such Deficient Sublicensee/ Subcontractor from performing further activities under the applicable Japanese Clinical Development Plan and replace such Deficient Sublicensee/Subcontractor with a new Sublicensee engaged in accordance with Section 2.5 (Sublicensing and Subcontractors) to perform the applicable Development Activities at Licensee's sole cost and expense unless such deficiencies can be promptly remedied to Licensor's reasonable satisfaction in a timely manner.

4.4.3 Licensee Audit Reports. Licensee shall promptly notify Licensor of all upcoming audits, including, subject to the requirements of Section 5.7 (Regulatory Audits), those conducted by health authorities, ethics boards, or institutional review boards (which, for the avoidance of doubt, shall be treated as Governmental Authorities for the purposes of compliance with Section 5.7 (Regulatory Audits)) as well as those conducted by Licensee or its Affiliates or Sublicensees

against any Sublicensee, Subcontractor, or Clinical Trial site, and Licensee shall prepare, or cause to be prepared, a brief report summarizing such Critical Findings and provide such report to Licensor within [***] days. Licensor may provide any such reports to the counterparty to the AZ License if and to the extent required by the terms of the AZ License.

4.5 Development Records. Licensee will, and will cause its Affiliates, Sublicensees, and Subcontractors to, maintain reasonably complete, current, and accurate records of all Development Activities conducted by or on behalf of Licensee, and its Affiliates, Sublicensees, and Subcontractors, respectively, pursuant to this Agreement and all data and other information resulting from such activities consistent with its usual practices, in accordance with Applicable Law (including cGLP, cGMP, and cGCP, as applicable) of Japan. Licensee will maintain all such records for a period of [***]. Such records will fully and properly reflect all work done and results achieved in the performance of the Development Activities for the Licensed Products in good scientific manner appropriate for regulatory and patent purposes and must be kept on a Licensed Product-by-Licensed Product basis and may record only activities performed under this Agreement and not include or be comingled with records of activities not conducted under this Agreement. Licensee will document all non-clinical and preclinical studies and Clinical Trials in formal written study reports in accordance with cGLP, cGMP, and cGCP, as applicable, and in compliance with Applicable Law. Upon Licensor's reasonable request, not more frequently than [***] each Calendar Quarter during which Licensee or its Affiliates, Sublicensees, or Subcontractors are performing or having performed Development Activities for any Licensed Product, such other Party will, and will cause its Affiliates, Sublicensees, and Subcontractors to, allow the requesting Party to access, review, and copy such records (including access to relevant databases).

4.6 Development Reports. No later than [***] days after the end of each Calendar Quarter during which Licensee is performing, or having performed, Development Activities, Licensee will provide Licensor a written report (a) summarizing the Development Activities conducted by or on behalf of Licensee, its Affiliates and Sublicensees during the period since the preceding report (or, in case of the first such report, the Effective Date), including a summary of the data, timelines, and results (including a comparison of results versus goals, as such goals are set forth in each then-current Japanese Clinical Development Plan) of such Development Activities (each, a "**Development Report**") and (b) in the first Development Report following the end of each Calendar Year, including a reasonably detailed description of future Development Activities it expects to initiate during the subsequent Calendar Year. Without limiting the foregoing, each such Development Report by Licensee will contain sufficient detail to enable Licensor to assess Licensee's compliance with its diligence obligations set forth in Article 9 (Diligence) and progress towards obtaining Regulatory Approval for the Licensed Products, including under each then-current Japanese Clinical Development Plan, and each such report by Licensee will also include any other information as may be required by the AZ License or Japanese Clinical Development Plan. Licensee will promptly respond to Licensor's reasonable requests from time to time for additional information regarding significant Development Activities for any Licensed Product performed by or on behalf of Licensee or its Affiliates, Sublicensees, or Subcontractors. The Parties will discuss the status, progress, and results of all Development Activities at each JSC meeting.

4.7 Licensee Data Disclosure and Use. In addition to its regulatory cooperation obligations set forth in Section 5.1 (Licensee's Responsibilities) and adverse event and safety data

reporting obligations set forth in Section 5.6 (Pharmacovigilance and Adverse Events Reporting), at each meeting of the JSC, Licensee will provide the JSC with copies of all finalized data and results and, upon reasonable request of Licensor, all supporting documentation (*e.g.*, protocols, Investigator's Brochures, case report forms, and analysis plans,) Controlled by Licensee that are generated by or on behalf of Licensee or its Affiliates, Sublicensees, or Subcontractors, if applicable, in the conduct of Development Activities in Japan under a Japanese Clinical Development Plan (collectively, "**Development Data**"). Notwithstanding the generality of the foregoing, Licensee will disclose all Development Data made, collected, or otherwise generated under or in connection with the conduct of any Clinical Trial for a Licensed Product under a Japanese Clinical Development Plan (collectively, "**Clinical Data**") to Licensor no later than [***] Business Days after the tables, figures, and listings for such Clinical Trial first become available. If Licensor intends to disclose such Development Data or Clinical Data to a Third Party, Licensor will notify Licensee of such intention and the intended purpose of using such disclosure of such data no later than the earlier of (a) [***] Business Days (or such shorter time period as required by Applicable Law) prior to such disclosure or (b) reasonably prior to issuing a press release related to such Clinical Data or Development Data; *provided* that, if in Licensor's good faith belief, such data is required to be promptly disclosed to Regulatory Authorities or otherwise pursuant to Applicable Law, including the rules of the U.S. Securities and Exchange Commission, prior notice will not be required prior to such disclosure but Licensor will provide notice promptly after such disclosure. Licensor and its Affiliates and its and their designees will have the exclusive right to use and reference such Development Data provided by Licensee, for the purpose of Developing the Licensed Products, and obtaining, supporting, or maintaining Regulatory Approval or any Reimbursement Approval, as applicable, of any Licensed Product for any use outside Japan or, subject to this Agreement, outside the Field in Japan, without additional consideration.

4.8 Development of New Formulations, Concentrations, or Indications. Except as set forth in this Section 4.8 (Development of New Formulations, Concentrations, or Indications), Licensee will not have the right to develop the Licensed Products for any additional formulations, concentrations, or indications other than (a) those set forth in Schedule 1.12 (ARQ-151) and Schedule 1.13 (ARQ-154), (b) concentrations for the applicable Licensed Product which Licensor or its Affiliates obtains Regulatory Approval for outside Japan and subject to the provisions of Section 2.8 (Negotiation for Product Improvements), or (c) in the Indications, as applicable (the "**Approved Formulations, Concentrations, and Indications**"). Licensor and Licensee mutually agree and understand that Crodafos CES, a composition of Schedule 1.12 (ARQ-151) and Schedule 1.13 (ARQ-154) is considered a new pharmaceutical ingredient in Japan. Licensor shall provide Licensee with necessary Commercially Reasonable Efforts, including, but not limited to, assisting the supplier of Crodafos CES to obtain a DMF concerning the above-mentioned new ingredient for the purpose of obtaining required approvals in the Territory. If Licensee is interested in Developing a new formulation or new concentration for any of the Licensed Products or Developing any of the Licensed Products for a new indication that is not, at the time, an Indication (a "**Proposed New Formulation, Concentration, or Indication**"), then upon notice from Licensee, if the Parties agree on Licensee conducting such Development for such Proposed New Formulation, Concentration, or Indication, then Licensee will submit to the JSC an amendment to the Japanese Clinical Development Plan reflecting such Proposed New Formulation, Concentration, or Indication, and the JSC will discuss and determine whether to approve such amendment. If the JSC approves such amendment to the Japanese Clinical Development Plan for the Proposed New Formulation, Concentration, or Indication, then such Proposed New

Formulation, Concentration or Indication shall become an Approved Formulation, Concentration or Indication and (i) Schedule 1.12 (ARQ-151) or Schedule 1.13 (ARQ-154), as applicable, will be amended to include the formulation or concentration included in such Proposed New Formulation, Concentration, or Indication as an Approved Formulation, Concentration, and Indication, or (ii) such indication will be deemed an Indication hereunder, as applicable.

4.9 Licensor Data and Documentation. Licensor will use Commercially Reasonable Efforts under the standards applicable within the territory of Japan to provide, to a Regulatory Authority in the territory of Japan, any data or other documentation in the form maintained by Licensor for its own internal purposes that (a) Licensor Controls, (b) is in existence as of the Effective Date, or, with respect to documents and data for (i) Licensed Product Improvements, the date Licensee is granted a license to such Licensed Product Improvements pursuant to Section 2.8 (Negotiation for Product Improvements), or (ii) Proposed New Formulations, Concentrations, or Indications, the date such Proposed New Formulations, Concentrations, or Indication becomes an Approved Formulations, Concentrations, and Indications, (c) is necessary or otherwise required by such Regulatory Authority for Licensee's Development, Manufacture, Commercialization or Exploitation of the Licensed Products in the Field in the territory of Japan, and (d) can only be provided by Licensor or its designate, in each case upon Licensee's request for such data or documentation to be provided to the applicable Regulatory Authority. Licensee will bear all the reasonable out-of-pocket cost incurred by Licensor in providing any requested data or documentation pursuant to this Section 4.9 (Licensor Data and Documentation).

ARTICLE 5
REGULATORY

5.1 Licensee's Responsibilities. Licensee will be responsible for preparing and submitting all Regulatory Submissions, including each MAA, for Licensed Products in the territory of Japan on the timeline set forth in the applicable Japanese Clinical Development Plan. Licensee or its designee will be the Marketing Authorization Holder in the territory of Japan for each Licensed Product. In addition, Licensee will be responsible for conducting all regulatory activities and interactions with Regulatory Authorities in the territory of Japan in connection with the Development Activities for any Licensed Product in accordance with this Section 5.1 (Licensee's Responsibilities).

5.1.1 Review and Approval of Regulatory Submissions. At each JSC meeting, Licensee will present (a) key planned upcoming regulatory activities and (b) summaries of all meetings with Regulatory Authorities related to a Licensed Product in the territory of Japan. Upon Licensor's request, Licensee will provide, within [***] Business Days of such request, copies of meeting minutes for any such meeting with Regulatory Authorities in the territory of Japan described in this Section 5.1.1(b) (Review and Approval of Regulatory Submissions). Licensee will provide to Licensor for review drafts of all Regulatory Submissions for which Licensee is responsible under this Agreement, including proposed responses to communications from Regulatory Authorities in the territory of Japan, reasonably in advance of any applicable submission deadline (and in no event less than [***] Business Days prior to such submission deadline). Licensor will reasonably consider any comments Licensee may have regarding such Regulatory Submissions. Licensee will ensure that its relevant Affiliates and Sublicensees, conduct

all regulatory activities in compliance with this Section 5.1.1 (Review and Approval of Regulatory Submissions).

5.1.2 Cooperation. Each Party shall, at its own cost and expense, reasonably cooperate with the other Party in connection with its regulatory activities with respect to the Licensed Products inside Japan (in the case of Licensee) and outside Japan (in the case of Licensor), including by providing access to its qualified personnel on a reasonable basis to consult with the other Party with respect to such regulatory activities.

5.1.3 Regulatory Reports. At each meeting of the JSC, Licensee will keep Licensor informed of regulatory developments related to the Licensed Products in the territory of Japan and will promptly notify Licensor in writing of any decision by any Regulatory Authority in the territory of Japan regarding any Licensed Product.

5.2 Licensor's Responsibilities. Licensor will, and will cause its Affiliates to, use Commercially Reasonable Efforts to cause any other Third Parties (*e.g.* Licensor's CMO(s)) to, provide reasonable assistance and support to Licensee or its designated party for Licensee or its designated party to apply for, hold, and maintain MA for the Licensed Products in the territory of Japan, including by providing access to its qualified personnel on a reasonable basis to consult with Licensee with respect to such regulatory activities. Upon Licensee's written request for Licensor's assistance, Licensor shall provide [***] hours of such assistance for each of ARQ-151 and ARQ-154 separately and independently without charge, and Licensee would pay for all further assistance in excess of such [***] hours for each of ARQ-151 and ARQ-154 separately and independently at the FTE Rate, and Licensee would pay for all out-of-pocket costs incurred by Licensor in providing such assistance, in each case within [***] days of receipt of an invoice from Licensor for such FTE expenses or out of pocket costs.

5.3 Costs and Expenses. Except as set forth in Section 5.2 (Licensor's Responsibilities), each Party will conduct the regulatory activities for which it is responsible under this Agreement at its own cost and expense.

5.4 Communications with Regulatory Authorities Outside Japan. Unless otherwise agreed by the Parties, Licensee will not, and will ensure that its Affiliates and its Sublicensees do not, communicate with any Regulatory Authority having jurisdiction outside of Japan with respect to any Licensed Product, unless and solely to the extent so ordered by such Regulatory Authority, in which case, Licensee will immediately notify Licensor of such order and provide Licensor with a copy of such order. To the extent that Licensee is so ordered to communicate with any such Regulatory Authority having jurisdiction outside of Japan, the provisions of Section 5.1.1 (Review and Approval of Regulatory Submissions) will apply to all such communications, *mutatis mutandis*.

5.5 Right of Reference.

5.5.1 Licensor Right of Reference. Licensee will grant, and hereby does grant, to Licensor and its Affiliates and licensees a right of reference to all MAs and Regulatory Submissions pertaining to the Licensed Products in the territory of Japan submitted by or on behalf of Licensee or its Affiliates. Licensor may use such right of reference to seek, obtain, support, and

maintain Regulatory Approval and any Reimbursement Approvals for the Licensed Products outside the Field or the territory of Japan. Licensor will bear its own costs and expenses associated with exercising the right of reference pursuant to this Section 5.5.1 (Licensor Right of Reference). Licensee will take such actions as may be reasonably requested by Licensor to give effect to the intent of this Section 5.5.1 (Licensor Right of Reference) and to give Licensor the benefit of such Regulatory Approvals and Regulatory Submissions as provided herein. Such actions may include providing to Licensor copies of correspondence and communications received from the applicable Regulatory Authorities that are related to Licensee's Regulatory Submissions pertaining to the Licensed Products in the territory of Japan.

5.5.2 Licensee Right of Reference. Subject to Section 4.9 (Licensor Data and Documentation) Licensor will grant, and hereby does grant, to Licensee and its Affiliates and Sublicensees a right of reference to all Regulatory Approvals and Regulatory Submissions pertaining to the Licensed Products submitted by or on behalf of Licensor or its Affiliates in existence as of the Effective Date. Licensee may use such right of reference solely to conduct Development Activities in accordance with the terms of the applicable Japanese Clinical Development Plan, to perform Medical Affairs in accordance with the Japanese Medical Affairs Plan, to submit Regulatory Submissions and Regulatory Approvals for the Licensed Products, and to Commercialize Licensed Products, in each case solely in the territory of Japan in the Field. Licensor will bear its own costs and expenses associated with providing Licensee with the right of reference pursuant to this Section 5.5.2 (Licensee Right of Reference). Licensor will take such actions as may be reasonably requested by Licensee to give effect to the intent of this Section 5.5.2 (Licensee Right of Reference) and to give Licensee the benefit of Licensor's Regulatory Approvals and Regulatory Submissions as provided herein. Such actions may include providing to Licensee copies of correspondence and communications received from the applicable Regulatory Authorities that are related to Licensor's Regulatory Submissions pertaining to the Licensed Products in the territory of Japan.

5.6 Pharmacovigilance and Adverse Events Reporting.

5.6.1 Safety Data Exchange Agreement. Within [***] days of the Effective Date, the Parties will negotiate and enter into one or more written agreements on Licensor's standard form setting forth safety and pharmacovigilance procedures for the Parties with respect to the Licensed Products (each a "**Safety Data Exchange Agreement**"). Each Safety Data Exchange Agreement will describe the obligations of both Parties with respect to the coordination, collection, investigation, reporting, and exchange of information between the Parties concerning any adverse event experienced by a subject, and the seriousness thereof, whether or not determined to be attributable to any Licensed Product, including any such information received by either Party from a Third Party (subject to receipt of any required consents from such Third Party) and will be sufficient to permit each Party and its Affiliates, licensees, or Sublicensees (as applicable) to comply with all Applicable Law (including cGLP, cGMP, and cGCP, as applicable) and its legal obligations with respect thereto, including each Party's obligations as the owner or holder of Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals for such Licensed Product either inside or outside Japan, as applicable. Each Safety Data Exchange Agreement will also detail each Party's responsibilities with respect to recalls and withdrawals of the Licensed Products within Japan. If required by changes in Applicable Law (including cGLP, cGMP, and cGCP, as applicable), the Parties will make appropriate updates to each Safety Data Exchange

Agreement. Each Party will comply with its respective obligations under each Safety Data Exchange Agreement and cause its Affiliates, licensees, and Sublicensees to comply with such obligations. Notwithstanding any provision to the contrary in this Agreement or any Safety Data Exchange Agreement, each Party and its Affiliates, licensees, and sublicensees will have the right to disclose information related to the safety of one or more Licensed Products to the extent that such disclosure is required for (a) such Party to comply with its obligations under Applicable Law (including cGLP, cGMP, and cGCP, as applicable) or the safety requirements of the applicable Regulatory Authorities or (b) in the case of disclosure by Licensor, to the extent reasonably necessary for Licensor to perform its obligations under the AZ License. The Parties will cooperate with each other to address any safety-related inquiries or requests for safety assessment by any Regulatory Authority, including providing any necessary data or information in a timely manner. To the extent that there is a conflict between the terms of this Agreement and the terms of any Safety Data Exchange Agreement, the terms of the applicable Safety Data Exchange Agreement will govern with respect to the subject matter set forth therein.

5.6.2 Safety Databases. As between the Parties, Licensor or its designee will maintain a global safety database for Clinical Trials for the Licensed Products, including those Clinical Trials conducted under a Japanese Clinical Development Plan. Licensor will be responsible for: (a) reporting to the applicable Regulatory Authorities in the territory of Japan all quality complaints, adverse events, and safety data related to such Licensed Product for all Clinical Trials conducted under a Japanese Clinical Development Plan; and (b) responding to safety issues and to all requests of Regulatory Authorities related to such Licensed Product and any Japanese Clinical Development Plan. Licensee will be responsible for reporting and responding to all quality complaints, adverse events, and safety data related to such Licensed Product for all Clinical Trials conducted under a Japanese Clinical Development Plan. Licensee and its Affiliates and Sublicensees, at the sole cost and expense of Licensee, will (i) host and maintain a local safety database capable of transmitting reports to Licensor using ICH E2B Guidance and (ii) provide to Licensor, promptly after receipt thereof, all safety reports regarding the Licensed Products in the territory of Japan, and Licensee acknowledges and agrees that Licensor will have the right to include in the global safety database such safety reports and other information provided by Licensee or its Affiliates or Sublicensees related to the safety of the Licensed Products. Upon Licensee's request, Licensor will (or will cause its designee to) query results from the global safety database for each Licensed Product.

5.7 Regulatory Audits. In addition to its rights to conduct audits pursuant to Section 4.4 (Clinical Trial Audit Rights), upon reasonable notification, Licensor or its representatives will be entitled to conduct audits of safety and regulatory systems, procedures, or practices of Licensee or its Affiliates or Sublicensees (including Clinical Trial sites) relating to any Licensed Product. With respect to any inspection of Licensee or its Affiliates or Sublicensees (including Clinical Trial sites) by any Governmental Authority relating to any Licensed Product, Licensee will notify Licensor of such inspection (a) no later than [***] Business days after Licensee receives notice of such inspection (or in any event with as much advanced notice as is possible prior to such inspection if Licensee receives notice thereof less than [***] Business days in advance of the applicable inspection) or (b) within [***] Business days after the completion of any such inspection of which Licensee did not receive prior notice. Licensee will promptly provide Licensor with all available information related to any such inspection, and Licensor may provide any such reports to the counterparty to the AZ License if required by the terms of the AZ License.

Licensee will also permit Governmental Authorities outside the territory of Japan to conduct inspections of Licensee or its Affiliates or Sublicensees (including Clinical Trial sites) relating to any Licensed Product and will ensure that all such Affiliates or Sublicensees permit such inspections. Licensor or its designee will have the right, but not the obligation (unless required by Applicable Law (including cGLP, cGMP, and cGCP, as applicable) or any Governmental Authority), to be present at and participate in any such inspection at its sole cost and expense. Following any such regulatory inspection related to one or more Licensed Products, Licensee will provide Licensor with (i) an unredacted copy of any findings, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to a Licensed Product) within [***] Business days of Licensee receiving the same, and (ii) a written summary of any findings, notice, or report of a Governmental Authority related to such inspection (to the extent related to a Licensed Product) no later than [***] Business Days after receiving the same.

5.8 Notice of Regulatory Action. If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of Licensee relating to any Licensed Product, then Licensee will notify Licensor of such contact, inspection, notice, or action within [***] Business days after receipt of such notice (or, if action is taken without notice, within [***] Business days of Licensee becoming aware of such action). Licensor will have the right to review and determine whether to approve such responses.

ARTICLE 6
MANUFACTURING, SUPPLY AND TECHNOLOGY TRANSFER

6.1 Clinical Supply. Within [***] days following the Effective Date of this Agreement (subject to extension by mutual agreement of the Parties), the Parties will initiate negotiations in good faith of one or more clinical supply agreement(s) and associated quality agreement(s) that will govern the terms of supply of Licensed Products to Licensee for the Development Activities under this Agreement, which clinical supply agreement(s) will (a) be consistent with the applicable terms of this Agreement, the AZ License, and any agreement between Licensor and the applicable CMO(s) related to the Manufacturing and supply of Licensed Products, (b) will be for Licensed Product in the same fill volume of finished drug product that Licensor is Manufacturing (or having Manufactured) for use outside Japan as of the Effective Date, (c) have a supply price of Licensor's fully-burdened Manufacturing cost, *plus* a [***]% markup, and (d) will otherwise be on commercially reasonable terms.

6.2 Commercial Supply. Licensee will be solely responsible for the manufacture and supply of Licensed Products for commercial purposes in the territory of Japan. Licensor will use Commercially Reasonable Efforts to assist Licensee in contracting with the existing CMO(s) of Licensor for the purpose of manufacturing Roflumilast (bulk drug substance) and Licensed Products for commercial use. Licensee shall manufacture and distribute the Licensed Products in the Territory in accordance with one of the following methods: (a) Licensee may enter into an agreement, at its own cost and expense, with one or more of Licensor's CMO(s), including CMO(s) of Licensor's commercial products, and Licensee may distribute the Licensed Products manufactured by such CMO(s) contracted with Licensee; or (b) Licensee or its designee (the "**Licensee Manufacturer**") may manufacture and distribute the Licensed Products itself. Licensor and Licensee mutually acknowledge and understand that a Licensed Product must be sold to the public within [***] days from National Health Insurance ("**NHI**") price listing upon Regulatory

Approval of such Licensed Product in Japan. On a Licensed Product-by-Licensed Product basis, Licensee will notify Licensor of the date of its anticipated First Commercial Sale in the territory of Japan at least [***] prior to the date of its anticipated First Commercial Sale in the territory of Japan. Reasonably in advance of the anticipated First Commercial Sale of the first Licensed Product in Japan, Licensor will commence transferring to Licensee Manufacturer and will use Commercially Reasonable Efforts to transfer (i) any Licensor Technology that is necessary or useful to enable the Manufacture of such Licensed Product, and not previously transferred to Licensee under this Agreement, by providing copies or samples of relevant documentation, materials, and other embodiments of applicable Know-How, and by making available its qualified technical personnel on a reasonable basis to consult with the Licensee Manufacturer with respect to such Know-How, and (ii) materials used by Licensor or its Affiliates or Subcontractors necessary in the Manufacture of such Licensed Product as reasonably requested by the Licensee Manufacturer. The first [***] hours of such assistance for ARQ-151 and ARQ-154 separately and independently provided by Licensor and its Affiliate, in the aggregated amount of [***] hours in connection with such transfer would be without charge. Licensee would pay for all out-of-pocket costs and FTE expenses in excess of such [***] hours for each of ARQ-151 and ARQ-154 incurred by Licensor in providing such transfer, in each case, within [***] days of receipt of an invoice from Licensor for such or out of pocket costs or FTE expenses. Licensee will be solely responsible for all of its and the Licensee Manufacturer's costs and expenses in connection with such transfer. Additionally, if Licensee or Licensee Manufacturer Manufactures or has Manufactured the Licensed Product in a manner that is Covered by a Valid Claim of any AstraZeneca Patents (as defined in the AZ License), then Licensee will provide to Licensor any information required under the AZ License as a result of such Manufacture and will reimburse Licensor for any additional amounts due to AstraZeneca under the AZ License as a result of such Manufacture.

ARTICLE 7
MEDICAL AFFAIRS

7.1 Japanese Medical Affairs Plans. All Medical Affairs activities conducted by or on behalf of Licensee with respect to any Licensed Product under this Agreement will be conducted pursuant to a written Medical Affairs plan approved by the JSC (each such plan with respect to a Licensed Product, as such plan may be updated from time to time in accordance with this Section 7.1 (Japanese Medical Affairs Plans), a "**Japanese Medical Affairs Plan**"). No later than [***] days prior to the anticipated date of performance of the first Medical Affairs activities for each Licensed Product in the territory of Japan, and in no event later than [***] prior to the anticipated commercial launch of such Licensed Product in the territory of Japan, the JSC will develop, review, discuss, and determine whether to approve an initial Japanese Medical Affairs Plan for such Licensed Product in the territory of Japan. Each Japanese Medical Affairs Plan and all updates thereto will include (a) a high-level summary of the major Medical Affairs activities to be undertaken for the applicable Licensed Product in the territory of Japan, and (b) the estimated timelines for performing such activities. Following the approval of a Japanese Medical Affairs Plan in accordance with the terms of this Agreement, from time to time during the Term, either Party may propose updates to such Japanese Medical Affairs Plan and submit such proposed updated Japanese Medical Affairs Plan to the JSC to review, discuss, and determine whether to approve. Once approved in accordance with the terms of this Agreement, each update to a Japanese Medical Affairs Plan will become effective and supersede the then-current Japanese Medical Affairs Plan for such Licensed Product.

7.2 Medical Affairs Reports. For each Calendar Quarter in which any Medical Affairs are conducted by or on behalf of Licensee or its Affiliates or Sublicensees for any Licensed Product in the territory of Japan, no later than the end of such Calendar Quarter, Licensee will provide Licensor a reasonably detailed written report summarizing the Medical Affairs activities conducted by or on behalf of Licensee under this Agreement with respect to each Licensed Product in the territory of Japan during the period since the preceding report (or, in case of the first such report, the first Regulatory Approval for a Licensed Product in the territory of Japan) (each, a "**Medical Affairs Report**"). Each such report by Licensee will also include any other information as may be required by the AZ License or Japanese Medical Affairs Plan.

7.3 Coordination of Medical Affairs Activities. The Parties recognize that each Party may benefit from the coordination of certain Medical Affairs activities for the Licensed Products within and outside Japan. Accordingly, a Party may present certain aspects of its Medical Affairs activities to the JSC for discussion and, if the Parties elect, the Parties will coordinate such activities where appropriate.

ARTICLE 8
COMMERCIALIZATION

8.1 Commercialization. Licensee will have the sole and exclusive right to Commercialize (and will solely and exclusively control, at its discretion, the Commercialization of), itself or with or through its Affiliates, Sublicensees or other Third Parties, the applicable Licensed Products in the Field in the territory of Japan. All such Commercialization will be at Licensee's sole cost and expense, including: (a) developing and executing a commercial launch and pre-launch plan; (b) negotiating with applicable Governmental Authorities regarding the pricing and reimbursement status of the Licensed Products, including matters relating to the Central Social Insurance Medical Council; (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; and (f) conforming its practices and procedures to Applicable Law relating to the marketing, detailing, and promotion of the Licensed Products.

8.2 Commercialization Reports. For each Calendar Quarter following the first Regulatory Approval for a Licensed Product in the territory of Japan, no later than [***] days after the end of the Calendar Quarter, Licensee will provide Licensor a written report (a) summarizing the Commercialization activities conducted by or on behalf of Licensee under this Agreement with respect to each Licensed Product in the territory of Japan during the period since the preceding report (or, in case of the first such report, the first Regulatory Approval for a Licensed Product in the territory of Japan) (each, a "**Commercialization Report**"), and (b) in the first Commercialization Report following the end of each Calendar Year, including a reasonably detailed description of future Commercialization activities it expects to initiate during the subsequent Calendar Year. Without limiting the foregoing, each such Commercialization Report by Licensee will contain sufficient detail to enable Licensor to assess Licensee's compliance with the obligations set forth in the AZ License.

8.3 Licensor Commercialization Insights. At each JSC meeting, Licensor may, in its sole discretion, bring to the JSC's attention certain materials used by or on behalf of Licensor, or

certain insights gained by Licensor, in each case related to the Commercialization of Licensed Products outside Japan. Any such materials or insight presented to the JSC will be deemed Licensor Know-How and subject to the term of this Agreement.

ARTICLE 9
DILIGENCE

Licensee, by itself or through its Affiliates and Sublicensees, will use Commercially Reasonable Efforts (a) to Develop and obtain and maintain MA for each Licensed Product [***], and (b) to Commercialize each Licensed Product in the territory of Japan in which Licensee obtains Regulatory Approval for such Licensed Product.

ARTICLE 10
FINANCIAL TERMS

10.1 Upfront Payment. In partial consideration of the licenses, rights, and privileges granted by Licensor to Licensee under this Agreement and subject to the terms and conditions of this Agreement, Licensee will pay to Licensor, no later than [***] Business Days following the Effective Date, a one-time payment of $25,000,000.

10.2 Milestones.

10.2.1 Regulatory Milestones. Subject to the terms and conditions of this Agreement, Licensee will pay the applicable amount set forth in Table 10.2.1 (Regulatory Milestones) associated with each milestone event described below (each event described in Table 10.2.1 (Regulatory Milestones), a "**Regulatory Milestone Event**," and each respective payment, a "**Regulatory Milestone Payment**"), in accordance with Section 10.2.3(a) (Regulatory Milestone Payments):

Table 10.2.1 – Regulatory Milestones

Regulatory Milestone Event	Regulatory Milestone Payment
PMDA approval of the MA for the first Indication of ARQ-151	$[***]
PMDA approval of the MA for the second Indication of ARQ-151	$[***]
PMDA approval of the MA for the first Indication of ARQ-154	$[***]
PMDA approval of the MA for the second Indication of ARQ-154	$[***]

Each Regulatory Milestone Payment will be payable one time only as set forth in the table above, upon first achievement of the applicable Regulatory Milestone Event.

10.2.2 Sales Milestones.

(a) **Sales Milestone Payments**. Licensee will notify Licensor of the first achievement of a given milestone event set forth in Table 10.2.2 (Sales Milestones) (each event described in Table 10.2.2 (Sales Milestones), a "**Sales Milestone Event**") in accordance with Section 10.2.3(b) (Sales Milestone Payments), and Licensee will thereafter pay the applicable one-time sales-based amounts set forth in Table 10.2.2 (Sales Milestones) associated with the applicable Sales Milestone Event for Annual Net Sales of all Licensed Products (each, a "**Sales Milestone Payment**") in accordance with Section 10.2.3(b) (Sales Milestone Payments):

Table 10.2.2 – Sales Milestones	
Sales Milestone Event	**Sales Milestone Payment**
First Calendar Year in which aggregate Annual Net Sales of all Licensed Products in Japan exceed $[***]	$[***]
First Calendar Year in which aggregate Annual Net Sales of all Licensed Products in Japan exceed $[***]	$[***]
First Calendar Year in which aggregate Annual Net Sales of all Licensed Products in Japan exceed $[***]	$[***]
First Calendar Year in which aggregate Annual Net Sales of all Licensed Products in Japan exceed $[***]	$[***]
First Calendar Year in which aggregate Annual Net Sales of all Licensed Products in Japan exceed $[***]	$[***]
First Calendar Year in which aggregate Annual Net Sales of all Licensed Products in Japan exceed $[***]	$[***]

(b) **Achievement of Sales Milestones**. Each Sales Milestone Event will be payable one time only as set forth in the table above, upon achievement of the applicable Sales Milestone Event for all Licensed Products. For clarity, no Sales Milestone Payment will be due hereunder for any subsequent or repeated achievement of such same Sales Milestone Event. For the avoidance of doubt, if the aggregate Annual Net Sales for all Licensed Products exceeds one of the sales milestone thresholds set forth above during through the applicable Calendar Year, the corresponding Sales Milestone Payment shall accrue and become payable at the end of the Calendar Quarter in which such milestone is achieved, and not the end of the applicable Calendar Year.

10.2.3 Invoicing and Payment of Milestone Payments.

(a) **Regulatory Milestone Payments**. In the event that Licensee, its Affiliates or its Sublicensees under this Agreement achieves a Regulatory Milestone Event, it will notify Licensor thereof within [***] days of such achievement. Following Licensor's receipt of notice from Licensee that Licensee has achieved a Regulatory Milestone Event, Licensor will invoice Licensee for the applicable Regulatory Milestone Payment, and Licensee will pay to Licensor such Regulatory Milestone Payment within [***] days after receipt of such an invoice in immediately available funds by wire transfer, in accordance with wire instructions to be provided by Licensor to Licensee together with such invoice.

(b) **Sales Milestone Payments**. In the event that Annual Net Sales of all Licensed Products first achieve a Sales Milestone Event during a particular Calendar Quarter in a Calendar Year, Licensee will notify Licensor thereof in the next due Royalty Report for such Calendar Quarter as described in Section 10.5 (Royalty Payments and Reporting). Following Licensor's receipt of such Royalty Report, Licensor will invoice Licensee for the applicable Sales Milestone Payment and Licensee will pay to Licensor such Sales Milestone Payment within [***] days after receipt of such an invoice in immediately available funds by wire transfer, in accordance with wire instructions to be provided by Licensor to Licensee together with such invoice.

10.3 Royalties.

10.3.1 Royalty Rates. Licensee will pay Licensor royalties on Annual Net Sales of all Licensed Products during the applicable Royalty Term as set forth in the table below in this Section 10.3.1 (Royalty Rates), as may be adjusted in accordance herewith ("**Royalties**").

Annual Net Sales for all Licensed Products	**Royalty Rate**
Portion of Annual Net Sales of all Licensed Products up to and including $[***]	[***]%
Portion of Annual Net Sales of all Licensed Products above $[***] up to and including $[***]	[***]%
Portion of Annual Net Sales of all Licensed Products above $[***]	[***]%

10.3.2 Royalty Term. Licensee's Royalty obligations to Licensor under Section 10.3.1 (Royalty Rates) will apply, on a Licensed Product-by-Licensed Product basis, only during the applicable Royalty Term for such Licensed Product. Following the expiration of the applicable Royalty Term for a given Licensed Product: (a) no further Royalties will be payable with respect to sales of such Licensed Product; and (b) the license granted to Licensee under this Agreement with respect to such Licensed Product will become fully paid-up, perpetual, irrevocable, and royalty-free in accordance with Section 15.3.1 (Expiration of the Royalty Term). For clarity, the Net Sales for a Licensed Product for which the Royalty Term has expired will not be included in the Annual Net Sales for purposes of calculating the Royalties (and Royalty tiers).

10.3.3 Royalty Reductions.

(a) **Absence of Valid Claims**. On a Licensed Product-by-Licensed Product basis, during the Royalty Term for such Licensed Product, if the Exploitation of such Licensed Product in Japan is not Covered by a Valid Claim of any Patent Right included in the Licensor Patent Rights , then the then-applicable Royalty rate payable with respect to Annual Net Sales of such Licensed Product pursuant to this Section 10.3 (Royalties) will be reduced by [***]%.

(b) **Generic Competition**. On a Licensed Product-by-Licensed Product basis, during the Royalty Term for such Licensed Product, if in a Calendar Quarter following the first Calendar Quarter in which the First Commercial Sale of a Generic Product occurs in Japan (such first Calendar Quarter, the "**Launch Quarter**") the Annual Net Sales of such

Licensed Product in Japan decline by [***]% or more relative to the average Net Sales of such Licensed Product in Japan occurring during the four consecutive Calendar Quarters immediately preceding the Launch Quarter, then, for such Calendar Quarter, the then-applicable Royalty rate payable with respect to Annual Net Sales of such Licensed Product pursuant to this Section 10.3 (Royalties) will be reduced by [***]%.

(c) **Expiration of AZ Royalty Term**. On a Licensed Product-by-Licensed Product basis, during the Royalty Term for such Licensed Product [***].

10.4 Aggregate Limitation on Deduction. Notwithstanding the foregoing, in no event will the deductions set forth in Section 10.3.3 (Royalty Reductions) and reduce the royalties payable to Licensor with respect to a particular Calendar Quarter to less than [***]% of the royalties that would otherwise be due pursuant to Section 10.3.1 (Royalty Rates).

10.5 Royalty Payments and Reporting. Licensee will calculate, on a Licensed Product-by-Licensed Product basis, all amounts payable to Licensor pursuant to Section 10.3 (Royalties) at the end of each Calendar Quarter. Commencing as of the First Commercial Sale for a Licensed Product, Licensee will, with respect to each Calendar Quarter (or portion thereof), provide a written report showing: (a) the amount of gross sales and aggregate Net Sales (and such deductions to arrive at Net Sales attributable to each Licensed Product in Japan) of such Licensed Product that are royalty-bearing and the Royalties due thereon for such Calendar Quarter, (b) the withholding Taxes, if any, required by law to be deducted in respect of such Royalties, and (c) the exchange rates used in determining the Royalty amount expressed in any currency other than Dollars (each, a "**Royalty Report**"), within [***] days after the end of such Calendar Quarter. Licensee will provide such Royalty Reports for so long as any Royalty Term remains in effect for a given Licensed Product. Each Royalty Report will be the Confidential Information of Licensee subject to Article 11 (Confidentiality; Publication). Following Licensor's receipt of each Royalty Report, Licensor will invoice Licensee for the Royalty amounts due for such Calendar Quarter and Licensee will pay to Licensor such amounts, less any applicable withholding Tax that is required by Applicable Law in accordance with Section 10.11 (Taxes), within [***] days after receipt of such an invoice in immediately available funds by wire transfer, in accordance with wire instructions to be provided by Licensor to Licensee together with such invoice.

10.6 Accounting Standards. If Licensee changes its general accounting principles from the then-current Accounting Standard (*e.g.*, from GAAP to IFRS) at any time during the Term, then at least [***] days prior to adopting such change in principles, Licensee will provide written notice to Licensor of such change. Licensee may not change its general accounting principles to any accounting standard other than GAAP or IFRS without the prior written approval of Licensor.

10.7 Currency; Exchange Rate. All payments to be made by Licensee to Licensor or Licensor to Licensee under this Agreement will be made in Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by Licensor or Licensee, as applicable. Conversion of amounts recorded in local currencies and other amounts reimbursable, payable, or reportable by a Party hereunder will be converted to Dollars. The rate of exchange to be used in computing the amount of currency equivalent in Dollars owed under this Agreement will be equal to the Telegraphic Transfer Selling (TTS) rate between each currency of origin and Dollars as reported by MUFG Bank, Ltd.., or an equivalent resource as agreed by the Parties, for

Royalty payments, the [***] Business Day in Tokyo of the Calendar Quarter ending immediately prior to the date on which the applicable Royalty payment pursuant to Section 10.3 (Royalties) is due.

10.8 Blocked Payments. If by reason of Applicable Law in any country or jurisdiction, it becomes impossible or illegal for a Party to transfer, or have transferred on its behalf, payments owed the other Party hereunder, then such Party will promptly notify the other Party of the conditions preventing such transfer and use reasonable efforts to deposit such payments in U.S. Dollars. If, after using reasonable efforts, such Party is not able to deposit such payments in U.S. Dollars, then such payments will be deposited in local currency in the relevant country or jurisdiction to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party within a period of [***] days, in a recognized banking institution selected by the transferring Party, as the case may be, and identified in a written notice given to the other Party.

10.9 Late Payments. Any undisputed payments or portions thereof due hereunder that are not paid on or before the date such payments are due under this Agreement will bear interest from the due date until the date of payment at a per-annum rate equal to the lesser of (a) [***]% above the prime rate as published by *The Wall Street Journal*, Eastern Edition, or any successor thereto or (b) the maximum rate permitted by Applicable Law.

10.10 Financial Records and Audits. Licensee and its Affiliates will use, and will require its Sublicensees and Subcontractors to use, reasonable efforts to maintain complete and accurate records in sufficient detail to permit Licensor to confirm the accuracy of the amounts paid, reimbursed, credited, offset, or shared (or required to be paid, reimbursed, credited, offset, or shared) by Licensee pursuant to this Agreement (the "**Amounts**"). Upon reasonable prior notice, such records will be open during regular business hours for a period of [***] years (or such longer period as may be required under Applicable Law) from the creation of individual records for examination by an independent certified public accountant (the "**Auditor**") selected by Licensor and reasonably acceptable to Licensee or its applicable Affiliate for the sole purpose of verifying for Licensor the accuracy of (a) the financial statements, reports, or notices (the "**Financial Documents**") furnished by Licensee or such Affiliate pursuant to this Agreement or (b) the Amounts. Such Auditor will be subject to written obligations of confidentiality and non-use applicable to Licensee's Confidential Information that are at least as stringent as those set forth in this Agreement. Such audit will not be performed more frequently than [***] per Calendar Year during the Term or [***] during the [***] year period after the expiration or termination of this Agreement. Any such audit will not disclose Licensee's or its Affiliates' or Sublicensees' or Subcontractors' Confidential Information to Licensor, except to the extent such disclosure is necessary for verifying the accuracy of the Financial Documents or the Amounts. The Auditor will report whether or not there was a discrepancy uncovered by the audit, and if such a discrepancy was uncovered, the amount and direction of such discrepancy. Any amounts shown to be owed but unpaid, or overpaid and in need of reimbursement, will be paid or refunded (as the case may be) within [***] days after the Auditor's report, plus interest (as set forth in Section 10.9 (Late Payments)) from the original due date (unless challenged in good faith by Licensee, in which case (i) any undisputed portion will be paid in accordance with the foregoing timetable, (ii) any Dispute with respect to such challenge will be resolved in accordance with Article 16 (Dispute Resolution), (iii) any remaining disputed portion will be paid within [***] days after resolution of the Dispute,

and (iv) interest will not accrue with respect to the disputed portion during the period of time the Dispute is being resolved). Licensor will bear the full cost and expense of such audit unless such audit reveals an overpayment to, or an underpayment by, Licensee or its Affiliates that resulted from a discrepancy in a Financial Document that Licensee or its Affiliates provided to Licensor during the applicable audit period, which underpayment or overpayment was more than the greater of (A) $[***] or (B) [***]% of the amount set forth in such Financial Document, in which case Licensee or its applicable Affiliate will bear the full cost and expense of such audit. Licensor, at the request of Licensee, will make available to Licensee the results of any audit performed by Licensor on Licensee's Sublicensees hereunder. Licensee consents and agrees that Licensor may disclose the results of any such audit to the extent necessary to perform its obligations under the AZ License.

10.11 Taxes.

10.11.1 Taxes on Income. Except as otherwise set forth in this Section 10.11 (Taxes), each Party will be solely responsible for the payment of any and all Taxes levied on account of all payments it receives under this Agreement or imposed on its share of income arising directly or indirectly from the collaborative efforts of the Parties under this Agreement.

10.11.2 Withholding Tax. Any and all payments made pursuant to this Agreement will be paid without deduction or withholding for any Taxes, except as required by Applicable Law. To the extent a Party is required by Applicable Law to deduct or withhold Taxes on any payment to the other Party (the "**Withheld Amount**"), such Party will remit such Withheld Amount to the proper Governmental Authority in a timely manner and promptly transmit to the other Party an official Tax certificate or other evidence of any withholding sufficient to enable the other Party to claim available credits for such Withheld Amount. The withholding Party will have the right to deduct such Withheld Amount from payment due to the other Party. For the avoidance of doubt, to the extent such Withheld Amount is so withheld and remitted in accordance with this Section 10.11.2 (Withholding Tax), such Withheld Amount will be treated for all purposes of this Agreement as having been paid to the other Party.

10.11.3 Tax Cooperation. The Parties agree to cooperate with one another in accordance with Applicable Law and use reasonable best efforts to mitigate or reduce Tax withholding or similar obligations in respect of payments made by each Party to the other Party under this Agreement. Such cooperation will include the withholding Party, within a reasonable amount of time prior to making any payment that is subject to withholding, (a) notifying the other Party in writing that (i) such payment is subject to withholding, (ii) the amount that will be withheld or rate of withholding, and (iii) a reasonable description of the provision of Applicable Law that requires such withholding and (b) providing the other Party a reasonable opportunity to provide any forms, certificates, applications or other documents or evidence that would exempt or reduce the amount required to be withheld. In addition, the withholding Party, at the other Party's reasonable written request, will request an extension, to the extent available, from the applicable Governmental Authority for a late submission of any forms, certificates, applications or other documents or evidence that would exempt or reduce the amount required to be withheld. Without limiting the generality of the foregoing, each Party will provide the other with any forms, certificates, applications or other documents or evidence that may be reasonably necessary to reduce withholding based on an applicable treaty or otherwise, including a properly completed Internal

Revenue Service ("**IRS**") Form W-9 or appropriate IRS Form W-8 or similar forms, certificates, applications or other documents or evidence required by the applicable Governmental Authority of the jurisdiction from which payment is made, as applicable, before a payment is made. If any form, certificate, application or other document or evidence a Party previously delivered expires or becomes obsolete or inaccurate in any respect, such Party will provide the other Party with an updated version of such form, certificate, application or other document or evidence or promptly notify the other Party in writing of its legal inability to do so. Each Party will provide the other Party with reasonable assistance to enable the recovery or refund, as permitted by Applicable Law, of withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery or refund to be for the benefit of the Party bearing such withholding Tax.

10.11.4 Indirect Taxes. All payments under this Agreement exclude any Indirect Taxes. If any Indirect Taxes are chargeable in respect of any payments, the paying Party shall pay such Indirect Taxes at the applicable rate in respect of such payments following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by the receiving Party in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes. If the Indirect Taxes originally paid or otherwise borne by the paying Party are in whole or in part determined to be refundable to the receiving Party (including by reason of not having been properly chargeable in the first instance), all reasonably necessary steps requested by the paying Party will be taken by the receiving Party to receive a refund of such Indirect Taxes from the applicable Governmental Authority and any amount of such Indirect Taxes repaid or refunded by such Governmental Authority to the receiving Party (net of any amounts incurred with respect to the receipt of such amounts) will be transferred to the paying Party within [***] days of receipt. "**Indirect Taxes**" means any value added, sales, purchase, turnover, or similar tax as may be applicable in any relevant jurisdiction.

10.11.5 No Partnership. Nothing contained in this Agreement shall be deemed or construed by the Parties or any of their Affiliates, or any third person to treat the relationship between the Parties contemplated by this Agreement as a partnership, joint venture or other business entity under U.S. Treasury Regulations Section 301.7701-1(a)(2) (or any corresponding provision under state, local or non-U.S. tax law) (an "**Entity**"). Without the prior written consent of the Parties (such consent not to be unreasonably withheld, delayed or conditioned), no Party (or successor or assignee) shall, for Tax purposes, report the relationships established by this Agreement as an Entity, unless required by a Governmental Authority upon final resolution of an audit or other examination or proceeding.

10.12 Other Agreements of Licensor. For the avoidance of doubt, Licensor will be solely responsible for all payment(s) owed or otherwise arising from any agreement between Licensor and any Third Party except for those payments under the AZ License set forth in Section 6.2 (Commercial Supply).

ARTICLE 11
CONFIDENTIALITY; PUBLICATION

11.1 Duty of Confidence. Subject to the other provisions of this Article 11 (Confidentiality; Publication), and except to the extent expressly authorized by this Agreement:

11.1.1 a Party (the "**Receiving Party**") that receives Confidential Information of the other Party (the "**Disclosing Party**") pursuant to this Agreement will maintain such Confidential Information in confidence and otherwise safeguard such Confidential Information; *provided*, that any Confidential Information that is marked AZ Confidential Information is expressly subject to, and will be handled in compliance with, Article 6 of the AZ License in addition to the requirements set forth in this Article 11 (Confidentiality; Publication);

11.1.2 the Receiving Party will treat all Confidential Information provided by the Disclosing Party at a minimum, with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care;

11.1.3 the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement;

11.1.4 the Receiving Party must not disclose any Confidential Information provided by the Disclosing Party without first obtaining the prior written consent of the Disclosing Party, except that a Receiving Party may disclose Confidential Information of the Disclosing Party to: (a) such Receiving Party's Affiliates, licensees, sublicensees, and Subcontractors and (b) employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, collaborators, and advisors of the Receiving Party and its Affiliates, licensees, sublicensees, and Subcontractors, in each case ((a) and (b)), to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided* that such Persons are bound by legally enforceable obligations of confidentiality, non-use, and non-disclosure with respect to the Disclosing Party's Confidential Information or professional ethical obligations no less stringent than the confidentiality and non-use obligations set forth in this Agreement; *provided* that the term of any such obligation may be customary for the nature of the party to whom such disclosure is made. Each Party will remain responsible for any failure by its Affiliates, licensees, sublicensees, and Subcontractors, and their respective employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors, in each case, to treat such Confidential Information as required under this Section 11.1 (Duty of Confidence) (as if such Persons were Parties directly bound to the requirements of this Section 11.1 (Duty of Confidence)); and

11.1.5 each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information, *provided* that any such notification will not be deemed an admission of liability or responsibility for any such misuse or unauthorized disclosure.

The confidentiality, non-use, and non-disclosure obligations set forth in this Section 11.1 (Duty of Confidence) will be in full force and effect from the Effective Date until [***] years after expiration or termination of this Agreement, *provided* that, with respect to any Know-How that is a trade secret and is identified as such by the Disclosing Party at the time of disclosure, the obligations of this Section 11.1 (Duty of Confidence) will continue for so long as such Know-How remains a trade secret.

11.2 Confidential Information. The Licensor Know-How will be the Confidential Information of Licensor (and Licensor will be deemed to be the Disclosing Party and Licensee the

Receiving Party with respect thereto). The Licensee Collaboration Know-How will be the Confidential Information of Licensee (and Licensee will be deemed to be the Disclosing Party and Licensor the Receiving Party with respect thereto). The existence and terms of this Agreement will be the Confidential Information of both Parties (and both Parties will be deemed to be the Disclosing Party and the Receiving Party with respect thereto).

11.3 Exemptions. Information of a Disclosing Party will not be subject to the confidentiality, non-use, and non-disclosure obligations set forth in Section 11.1 (Duty of Confidence) to the extent that the Receiving Party can demonstrate through competent evidence that such information:

(a) was already known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party or any of its Affiliates, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

(b) was generally available to the public or part of the public domain before its receipt from the Disclosing Party other than through any act or omission of the Receiving Party or any of its Affiliates or disclosees in breach of this Agreement or the Confidentiality Disclosure Agreement;

(c) became generally available to the public or otherwise part of the public domain after its receipt from the Disclosing Party other than through any act or omission of the Receiving Party or any of its Affiliates or disclosees in breach of this Agreement or the Confidentiality Disclosure Agreement;

(d) is subsequently disclosed to the Receiving Party or any of its Affiliates without an obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting legal or contractual obligation of confidentiality to the Disclosing Party with respect thereto; or

(e) is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party. The Parties acknowledge that Confidential Information has been provided by each Party or their Affiliates to the other Party prior to the Effective Date of this Agreement pursuant to the Confidentiality Disclosure Agreement. The Parties agree that, as of the Effective Date, all such Confidential Information will be protected by the terms and conditions of this Agreement, which will replace those of the Confidentiality Disclosure Agreement.

11.4 Authorized Disclosures.

11.4.1 Permitted Circumstances. Notwithstanding the obligations set forth in Section 11.1 (Duty of Confidence), a Party may disclose the other Party's Confidential Information (including the specifically relevant terms of this Agreement) to the extent such disclosure is reasonably necessary in the following situations:

(a) in connection with Regulatory Submissions and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of a Licensed Product;

(b) with prior notice to the other Party as permitted by Applicable Law, disclosure of (i) the specifically relevant material terms of Agreement or (ii) the status and results of Exploitation of one or more Licensed Products, including the Development Reports and the contained therein, in each case ((i) and (ii)), to actual or *bona fide* potential investors, investment bankers, acquirers, merger partners, and other potential or actual *bona fide* financial partners, licensees, sublicensees, or collaborators; *provided* that, in each such case, such Persons are bound by obligations of confidentiality and non-use or professional ethical obligations at least as stringent as those set forth in this Agreement prior to any such disclosure, except that, where the disclosee is an investor, investment banker, or financial partner, such disclosee will only need to be bound by commercially reasonable obligations of confidentiality and non-use;

(c) responding to a valid order of a court of competent jurisdiction or other competent authority; *provided* that the Receiving Party will, to the extent reasonably practicable under the circumstances, first have given to the Disclosing Party notice and reasonable opportunity to quash the order or to obtain a protective order requiring that the Confidential Information be held in confidence or used only for the purpose for which the order was issued or such disclosure was required by Applicable Law or such rules; and *provided*, *further* that if such order is not quashed or a protective order is not obtained, the Confidential Information disclosed will be limited to the information that is legally required to be disclosed;

(d) making such disclosures as, in the opinion of the Receiving Party's legal counsel, are required by Applicable Law, including the rules of the U.S. Securities and Exchange Commission, any foreign equivalent, or any stock exchange on which the securities of the Disclosing Party (or its parent entity) are listed (or to which an application for listing has been submitted);

(e) in the case of Licensor, disclosure to the extent reasonably necessary to perform its obligations under or confirm its compliance with the AZ License; or

(f) disclosure as otherwise expressly permitted pursuant to the terms of this Agreement.

11.4.2 Confidential Treatment.

(a) Notwithstanding any provision to the contrary set forth in this Agreement, in each case of a disclosure to be made pursuant to Section 11.4.1 (Permitted Circumstances), where some or all of the terms of this Agreement are to be disclosed, Licensee will, to the extent reasonably possible, provide to Licensor a redacted version of this Agreement to be used in connection with any such disclosure, and Licensee will not disclose or provide any other redacted

version hereof or thereof, unless such version has been approved in writing by Licensor. Licensee will promptly deliver to Licensor any written correspondence received by it or its representatives from any Governmental Authority with respect to such redacted version(s) and promptly advise Licensor of any other material communications between it and its representatives with such Governmental Authority with respect to such redacted version(s). If such Governmental Authority requests any changes to the redactions set forth in the redacted version(s), then Licensee will use reasonable efforts consistent with Applicable Law to support the redactions in the redacted version(s) as originally provided and not agree to any changes in the redacted version(s) without, to the extent practical, first discussing such changes with Licensor and taking Licensor's comments into consideration when deciding whether to agree to such changes. Licensee will use reasonable efforts consistent with Applicable Law to obtain confidential treatment of the terms redacted from this Agreement, as reflected in the redacted version(s) provided by Licensor, for at least [***] years and, if necessary and legally justifiable, request an appropriate extension of such confidential treatment period.

(b) Subject to the foregoing, but notwithstanding any other provision to the contrary set forth in this Agreement, if a Party is required or permitted to make a disclosure of the other Party's Confidential Information pursuant to Section 11.4.1, (a), (c), or (d) (Permitted Circumstances), then it will, to the extent not prohibited by Applicable Law or judicial or administrative process, except where impracticable, give reasonable advance notice to the other Party of such proposed disclosure and use reasonable efforts to secure confidential treatment of such information and will only disclose that portion of Confidential Information that is legally required to be disclosed as advised by its legal counsel. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

(c) Notwithstanding the foregoing or any other provision to the contrary set forth in this Agreement, Licensee acknowledges and agrees that Licensor may provide a copy of this Agreement to the counterparty of the AZ License and in accordance with the terms thereof.

11.5 Publications.

11.5.1 By Licensee. Licensee will not publicly present or publish any Clinical Trial data, non-clinical or preclinical data, or any associated results or conclusions generated by or on behalf of Licensee pursuant to this Agreement (each such proposed presentation or publication, a "**Publication**") without Licensor's prior written consent, not to be unreasonably withheld, conditioned, or delayed, and subject to the additional limitations set forth in this Section 11.5 (Publications) and Section 11.6 (Publication and Listing of Clinical Trials). If Licensee desires to publicly present or publish a Publication in accordance with the foregoing sentence, then Licensee will provide Licensor (including the Alliance Manager and all Licensor members of the JSC) with a copy of such proposed Publication to review, discuss, and determine whether to approve at least [***] days prior to the earlier of its presentation or intended submission for publication (such applicable period, the "**Review Period**"). Licensee will not submit or present any Publication until (a) Licensor has approved such Publication or provided written comments thereon, in each case, during such Review Period, or (b) the applicable Review Period has elapsed without approval or written comments from Licensor, in which case Licensee may proceed and the Publication will be considered approved in its entirety. If Licensee receives written comments from Licensor on any Publication during the applicable Review Period, then it will incorporate such comments [***].

Notwithstanding any provision to the contrary set forth in this Agreement, Licensee will (i) delete any Confidential Information of Licensor that Licensor identifies for deletion in Licensor's written comments, (ii) delete any Clinical Trial data, results, conclusions, or other related information for a Licensed Product, the publication of which Licensor determines, in its sole discretion, could conflict with Licensor's global publication strategy with respect to the applicable Licensed Product or with the AZ License, and (iii) delay such Publication for a period of up to an additional [***] days after the end of the applicable Review Period to enable Licensor to draft and file one or more patent applications with respect to any subject matter to be made public in such Publication. Licensee will provide Licensor a copy of the Publication at the time of the submission or presentation thereof. Licensee agrees to acknowledge the contributions of Licensor and the employees of Licensor, in each case, in all Publications as scientifically appropriate. Licensee will require its Affiliates and Sublicensees to comply with the obligations of this Section 11.5 (Publications) as if they were Licensee, and Licensee will be liable for any non-compliance of such Persons.

11.5.2 By Licensor. Licensor will provide Licensee (including the Alliance Manager and all Licensee members of the JSC) with a copy of any proposed Publication that discloses Clinical Data generated by Licensee under this Agreement for review and comment. If Licensor receives written comments from Licensee on any such Publication during the applicable Review Period, then Licensor will consider such comments in good faith.

11.6 Publication and Listing of Clinical Trials. With respect to the listing of Clinical Trials or the publication of Clinical Trial results for the Licensed Products and to the extent applicable to a Party's activities conducted under this Agreement, (a) each Party will comply with Applicable Law and applicable industry codes, including the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) all results of such Clinical Trials that are necessary for obtaining a Regulatory Approval for a Licensed Product will be listed in accordance with the registration and publication guidelines of the International Committee of Medical Journal Editors, to the extent required by Applicable Law or applicable industry codes. The Parties agree that any such listings or publications made pursuant to this Section 11.6 (Publication and Listing of Clinical Trials) will be considered a Publication for purposes of this Agreement and will be subject to Section 11.5 (Publications).

11.7 Publicity; Use of Names.

11.7.1 Press Release. The Parties will jointly issue a press release announcing this Agreement, as set forth on Schedule 11.7.1 (Joint Press Release), on such date and time as may be agreed by the Parties. Other than the press release set forth on Schedule 11.7.1 (Joint Press Release) and the public disclosures permitted by this Section 11.7 (Publicity; Use of Names) or Section 11.4 (Authorized Disclosures), the Parties agree that the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information other than that already in the public domain will first be reviewed and approved by both Parties.

11.7.2 Disclosures by Licensor. Notwithstanding any provision to the contrary set forth in this Agreement, Licensor or its designees may publicly disclose (in written, oral, or other form),

present, or publish (a) any information relating to any Clinical Trial of a Licensed Product, including the commencement, completion, material data from (including Development Data and Clinical Data disclosed by Licensee pursuant to and in accordance with Section 4.7 (Licensee Data Disclosure and Use)), or key results of such Clinical Trial and (b) the receipt of Regulatory Approval or Reimbursement Approval for any Licensed Product.

11.7.3 Use of Names. Other than the press release set forth on Schedule 11.7.1 (Joint Press Release) and the use of names in public disclosures permitted by Section 11.4 (Authorized Disclosures) and Section 11.7.2 (Disclosures by Licensor), the Parties agree that each Party's use of other Party's name and logo in presentations, its website, collateral materials, and corporate overviews to describe the collaboration relationship, as well as in taglines of press releases issued pursuant to this Section 11.7 (Publicity; Use of Names) will first be reviewed and approved by the other Party (with such approval not to be unreasonably withheld or delayed). Except as permitted under this Section 11.7 (Publicity; Use of Names) or Section 11.4 (Authorized Disclosures) or with the prior express written permission of the other Party, neither Party will use the name, trademark, trade name, or logo of the other Party or its Affiliates or their respective employees in any publicity, promotion, news release, or disclosure relating to this Agreement or the subject matter hereof.

11.7.4 Repeated Disclosures. The Parties agree that after (a) the issuance of a disclosure or press release made in accordance with Section 11.7.1 (Press Release) or Section 11.4 (Authorized Disclosures), (b) the use of the other Party's name or logo by a Party in presentations, its website, collateral materials, or corporate overviews to describe the collaboration relationship in accordance with Section 11.7.3 (Use of Names), or (c) use of the other Party's name or logo by a Party in any taglines of press releases issued pursuant to Section 11.7.1 (Press Release) or Section 11.4 (Authorized Disclosures), in each case ((a)-(c)), the Disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such press release, other public announcement, or other materials remains true, correct, and the most current information with respect to the subject matters set forth therein. Similarly, after a Publication has been made available to the public, each Party may post such Publication or a link to it on its corporate website (or any website managed by such Party in connection with a Clinical Trial for a Licensed Product, as appropriate) without the prior written consent of the other Party, so long as the information in such Publication remains true, correct, and the most current information with respect to the subject matters set forth therein. Notwithstanding any provision to the contrary set forth in this Agreement, each Party will use the other Party's corporate name in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of such other Party will not be impaired, and consistent with best practices used by such other Party for its other collaborators.

ARTICLE 12
REPRESENTATIONS, WARRANTIES, AND COVENANTS

12.1 Representations and Warranties of Each Party. Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

12.1.1 It is a corporation or limited company duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and it has the full right, power, and authority to enter into this Agreement and to perform its obligations hereunder, including the legal right to carry on its business as it is now being conducted and as contemplated in this Agreement, and to grant the licenses granted by it hereunder in accordance with the terms of this Agreement.

12.1.2 It has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.

12.1.3 It and its Affiliates have not been Debarred/Excluded and no proceeding that could result in it or its Affiliates being Debarred/Excluded is pending, and neither it nor any of its Affiliates has used, in any capacity in the performance of obligations relating to the Licensed Products, any employee, Subcontractor, consultant, agent, representative, or other Person who has been Debarred/Excluded or is the subject of any proceedings that could result in such Person being Debarred/Excluded.

12.1.4 All consents, approvals, waivers, and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained.

12.1.5 This Agreement has been duly executed and delivered by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument, or understanding, oral or written, to which it or an Affiliate is a party or by which it or an Affiliate may be bound, nor violate any Applicable Law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it.

12.1.6 It and its Affiliates, and their respective directors, officers, employees, agents, or other persons or entities acting on its behalf (all of the foregoing, collectively, "**Representatives**") have conducted their respective activities under this Agreement in compliance with applicable Anti-Corruption Laws.

12.2 Representations and Warranties of Licensor. Licensor hereby represents and warrants to Licensee as of the Effective Date as follows:

12.2.1 The execution and delivery of this Agreement by Licensor does not, and the consummation of the transactions contemplated by this Agreement shall not, conflict with, or result in any material violation of or default under (with or without notice, lapse of time, or both), or give rise to a right of termination, cancellation, or acceleration of any obligation or loss of any benefit under, or require any consent, approval, or waiver from any Person pursuant to any provision of the organizational or governing documents of Licensor, as amended to date.

12.2.2 It has the right under the Licensor Technology to grant to Licensee the licenses set forth in this Agreement, and it has not granted any license or other right under the Licensor Technology that is inconsistent with the licenses granted to Licensee hereunder.

12.2.3 Schedule 1.104 (Licensor Patent Rights) lists all Licensor Patent Rights existing as of the Effective Date that are necessary (or, with respect to patent applications, would be necessary

if such patent applications were to issue as patents) to Exploit the Licensed Products in Japan in the Field.

12.2.4 There is no pending or, to Licensor's Knowledge, threatened litigation, nor has Licensor received any written notice from any Third Party, asserting or alleging that the Exploitation of any Licensed Product prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party.

12.2.5 There are no pending or, to Licensor's Knowledge, threatened, adverse actions, suits, or proceedings against Licensor or any of its Affiliates involving the Licensor Technology.

12.2.6 Except as disclosed in Licensor's public filings with the U.S. Securities and Exchange Commission, there are no legal claims, judgments, or settlements against or owed by Licensor or any of its Affiliates, or pending or, to Licensor's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust law, anti-competition law, Anti-Money Laundering Law, or Anti-Corruption Law violations.

12.2.7 Other than the AZ License, as of the Effective Date there are no agreements between Licensor and any Third Party pursuant to which Licensor Controls any Licensor Technology licensed to Licensee under this Agreement.

12.2.8 Neither Licensor nor the counterparty to the AZ License has in writing alleged or threatened that the other party has breached the AZ License (which has not been cured) or, to Licensor's Knowledge, threatened in writing to terminate the AZ License.

12.3 Representations and Warranties of Licensee. Licensee represents and warrants to Licensor as of the Effective Date as follows:

12.3.1 The execution and delivery of this Agreement by Licensee does not, and the consummation of the transactions contemplated by this Agreement will not, conflict with, or result in any material violation of or default under (with or without notice, lapse of time, or both), or give rise to a right of termination, cancellation, or acceleration of any obligation or loss of any benefit under, or require any consent, approval, or waiver from any Person pursuant to any provision of the organizational or governing documents of Licensee, as amended to date.

12.3.2 Neither the execution, delivery, and performance by Licensee of this Agreement, nor the consummation by Licensee of the transactions contemplated hereby, will require Licensee to obtain any consent or authorization of, give any notice to, or make any filing or registration with, any Governmental Authority or other Person, except, in each case, for any filings required by applicable antitrust law or applicable securities law (including the requirements of Securities Act of 1933 (as amended), the Securities Act of 1934 (as amended), the Financial Industry Regulatory Authority, Inc., Nasdaq, Inc., and applicable state securities law).

12.3.3 There are no legal claims, judgments, or settlements against or owed by Licensee or any of its Affiliates, or pending or, to Licensee's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust law, anti-competition law, Anti-Money Laundering Law, or Anti-Corruption Law violations.

12.3.4 Licensee has, or can readily obtain, sufficient technical, clinical, and regulatory expertise to perform all of its obligations pursuant to this Agreement, including its obligations relating to Development, performance of Medical Affairs, and Commercialization, in each case, of the Licensed Products as contemplated under this Agreement.

12.3.5 There is no agreement, instrument, or understanding, oral or written, to which Licensee or any of its Affiliates is a party or by which Licensee or any of its Affiliates may be bound that would preclude Licensee or any such Affiliate from Developing or promoting or otherwise Commercializing an approved Licensed Product in Japan.

12.3.6 To its Knowledge, neither Licensee nor any of its Affiliates, predecessors, or its or their directors, officers, employees, distributors, consultants, agents, representatives, sales intermediaries, or other Third Parties acting on behalf of Licensee or any of its Affiliates:

(a) has taken any action in violation of any applicable Anti-Corruption Laws or Anti-Money Laundering Laws;

(b) has conducted or initiated any internal investigation with respect to any alleged act or omission arising under or relating to any potential noncompliance with any Anti-Corruption Law, Anti-Money Laundering Law, or Global Trade Law and Regulation, or been the subject of current, pending, or threatened investigation, formal or informal inquiry, enforcement proceedings, or received any notice, request, or citation for alleged violations of such laws;

(c) has engaged in any direct or indirect dealings or transactions in or with a Restricted Party or Restricted Country, or engaged in any direct or indirect dealings with Sudan, individuals ordinarily resident in Sudan, or entities incorporated under the laws of Sudan prior to October 12, 2017; or

(d) has offered, paid, given, promised to pay or give, or authorized the payment or gift of, received, or solicited anything of value, directly or indirectly, to any Public Official, for the purposes of:

(i) influencing any act or decision of any Public Official in his or her official capacity;

(ii) inducing any Public Official to do or omit to do any act in violation of his or her lawful duty;

(iii) securing any improper or undue advantage; or

(iv) inducing any Public Official to use his or her influence with a government, Governmental Entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

12.3.7 Licensee and each subsidiary of Licensee has maintained complete and accurate books and records, including records of payments to any agents, consultants, representatives, Third Parties, and Public Officials in accordance with applicable Accounting Standards.

12.3.8 None of the officers, directors, ultimate beneficial owners with an equity stake in excess of [***]%, or employees of Licensee or of any of its Affiliates or agents acting on behalf of Licensee or any of its Affiliates, in each case, that are employed or reside outside the United States, is a Public Official or Restricted Party.

12.3.9 Licensee and its Affiliates have entered into a written agreement or employment policy with each of its employees performing activities under this Agreement that (a) compels prompt disclosure to Licensee (or its Affiliate, Sublicensee, or Subcontractor, as applicable) of all Licensee Collaboration Technology discovered, developed, invented, or filed by such employee during any performance under this Agreement; (b) automatically and presently assigns to Licensee (or its Affiliate, Sublicensee, or Subcontractor, as applicable) all rights, title, and interests in and to all Licensee Collaboration Technology, and requires each employee, existing or otherwise, to execute all documents and take such other actions as may be necessary to effectuate such assignment; (c) includes an invention and patent reward and remuneration policy providing for the payment by Licensee (or its Affiliate, Sublicensee, or Subcontractor, as applicable) of any reward or remuneration required under Applicable Law in such country or jurisdiction in consideration for the development of inventions by such employees that is legally sufficient under Applicable Law in Japan; (d) includes a waiver of pre-emption rights under any Applicable Law in such country or jurisdiction; and (e) includes obligations of confidentiality and non-use no less restrictive than those set forth in Article 11 (Confidentiality; Publication).

12.4 Covenants of Licensee. Licensee covenants to Licensor that:

12.4.1 In the course of performing its obligations or exercising its rights under this Agreement, it will comply with all terms of the AZ License.

12.4.2 Licensee will conduct all Development Activities for the Licensed Products solely in accordance with, and will not conduct any Development Activities other than as set forth in, the applicable Japanese Clinical Development Plan. Licensee will not knowingly take any action in the territory of Japan that would have or be reasonably likely to have a Material Adverse Impact on the Exploitation of the Licensed Products, whether inside or outside the territory of Japan.

12.4.3 Licensee will cause Clinical Trial sites engaged by Licensee or its Affiliates under a Japanese Clinical Development Plan to conduct all Clinical Trials in compliance with Applicable Law, including cGCP and the GCP guidelines and that are approved by the applicable Regulatory Authority in Japan in which such Clinical Trial site is located. Licensee will, and will cause its Affiliates and its and their respective licensees, to employ Persons with appropriate knowledge, expertise, and experience to conduct and to oversee the conduct of Clinical Trials with respect to the Licensed Products.

12.4.4 Licensee will maintain its corporate compliance program as existing as of the Effective Date or a variant thereof. Licensee has provided to Licensor the Business Compliance Policies of Licensee in effect as of the Effective Date prior to the Effective Date, and Licensee will be responsible for complying with such policies in connection with its activities under this Agreement, including being responsible for its compliance trainings and training certifications, monitoring, and enforcement. Licensee will establish and maintain during the Term a corporate compliance program, including at least one full-time employee whose sole area of responsibility

is compliance and who primarily reports to someone not in any commercial function and is responsible for ensuring that all employees of Licensee and any of its Affiliates comply with Applicable Law (including cGLP, cGMP, and cGCP, as applicable), national and international pharmaceutical industry codes of practice and guidelines, and Licensee's business conduct rules and regulations, which, subject to the foregoing, will be consistent with Licensor's Business Compliance Policies. Each compliance program will, at a minimum, provide for: (a) a compliance committee or other appropriate body with responsibility for operation of the compliance program, (b) a periodic risk assessment that guides development of policies, training, and monitoring activities, (c) appropriate corporate compliance policies, (d) regular compliance training and communication to applicable employees as selected on a risk-based approach, (e) auditing or monitoring or other risk-evaluation processes for applicable activities, and (f) mechanisms, compliant with all Applicable Laws (including cGLP, cGMP, and cGCP, as applicable), to receive complaints or questions and investigate and remediate potential noncompliance, including a disciplinary component to handle compliance violations. Licensee will abide by the International Federation of Pharmaceutical Manufacturers Code of Conduct and Interactions with, Healthcare Professionals where applicable, and applicable local country codes and guidelines with respect to the promotion of the Licensed Product in Japan.

12.4.5 Licensee and its Affiliates will comply with, and will cause its Sublicensees and Subcontractors to comply with, all Applicable Laws pertaining to Personal Information, including, the Japanese Act on Protection of Personal Information and, to the extent applicable, the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act, the Health Information Technology for Economic and Clinical Health Act (the "**Privacy Laws**") to which they are subject in connection with their activities related to this Agreement. To the extent that Licensee or its Affiliates, Sublicensees, or Subcontractors access or come into possession of Personal Information in connection with their activities related to this Agreement, Licensee and its Affiliates will (and will cause its Sublicensees and Subcontractors) to comply with applicable Privacy Laws to which they may be subject as a result thereof. Any processing by Licensee or its Affiliates, Sublicensees, or Subcontractors of Personal Information obtained in connection with this Agreement will be done solely for the purpose of performing Licensee's obligations under this Agreement or under a Japanese Clinical Development Plan or Japanese Medical Affairs Plan, and will be done in accordance with all applicable Privacy Laws. Licensee and its Affiliates will take, and ensure that its Sublicensees and Subcontractors take, commercially reasonable and appropriate technical and organizational measures reflective of current good industry practice and technological development to protect the privacy and security of Personal Information in its possession and to prevent (a) unauthorized access to or disclosure, use, or destruction of Personal Information, (b) accidental or unlawful destruction, loss, or alteration (including corruption) of or damage to Personal Information, and (c) all other unauthorized or unlawful forms of processing of Personal Information ("**Data Breach**"). Licensee and its Affiliates will further maintain, and ensure that its Sublicensees and Subcontractors maintain, a commercially reasonable program for protecting against Data Breaches of Personal Information in its possession pursuant to activities under this Agreement or under a Japanese Clinical Development Plan or Japanese Medical Affairs Plan. Without limiting the generality of the foregoing, with respect to all activities performed by or on behalf of Licensee under this Agreement or under a Japanese Clinical Development Plan or Japanese Medical Affairs Plan, Licensee and its Affiliates will use reasonable efforts to, and to ensure that its Sublicensees and Subcontractors, implement multi-factor authentication and encryption and put in place access

controls for Personal Information (including by ensuring that Personal Information is accessible on a need-to-know basis for the purpose of fulfilling Licensee's obligations or exercising its rights under this Agreement or a Japanese Clinical Development Plan or Japanese Medical Affairs Plan). Prior to transferring any data, results, or supporting documentation containing any Personal Information to Licensor hereunder, the Parties will agree upon the manner and format of such transfer. In the event of a Data Breach, Licensee will (i) promptly, and in any event so as to allow Licensor to comply with its obligations under Applicable Law, notify Licensor by phone and email after becoming aware of such Data Breach and (ii) comply with the relevant requirements and procedures of the applicable Privacy Laws in resolving such Data Breach. Licensor will have the right, upon reasonable advance notice and at a time agreed by the Parties, to audit Licensee's and its Affiliates' compliance with the requirements of this Section 12.4.5 (Covenants of Licensee). To the extent permitted under Licensee's or its Affiliates' agreements with its or their Sublicensees or Subcontractors, Licensor will have the right to audit the data privacy and information security measures implemented by any Sublicensees or Subcontractors performing activities under this Agreement or under a Japanese Clinical Development Plan or Japanese Medical Affairs Plan. If such audit is not permitted under Licensee's or its Affiliates' agreements with its or their Sublicensees or Subcontractors, then Licensee will use reasonable efforts to obtain the right to conduct such an audit of the data privacy and information security measures of such Sublicensees or Subcontractors.

12.4.6 In the course of performing its obligations or exercising its rights under this Agreement, Licensee and its Affiliates will comply with all Applicable Law, including, as applicable, cGMP, cGCP, and cGLP standards, and will not employ or engage, and if so employed and engaged, will thereafter terminate, any Person who has been Debarred/Excluded, or is the subject of any proceedings that could result in such Person being Debarred/Excluded. Licensee will promptly notify Licensor of any Debarment/Exclusion or Debarment/Exclusion proceeding that could have an impact on the use of the results of any Clinical Trials for Licensed Products.

12.4.7 Notwithstanding any provision to the contrary in this Agreement, Licensee agrees as follows:

(a) It, its Affiliates, and its and their Representatives will not, in the performance of this Agreement, perform any actions that are prohibited by any Anti-Corruption Laws, Anti-Money Laundering Laws, or Global Trade Laws and Regulations.

(b) It, its Affiliates, and its and their Representatives will 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 physician or health care practitioner, Public Official, government employee, political party, candidate for political office, hospital, medical insurance company or similar provider organization, customer, any Person acting in an official capacity for or on behalf of any Governmental Entity, or to any other Third Party with the purpose of influencing decisions related to either Party or its business (including in order to induce or encourage approval, referrals, purchase, or reimbursement) in a manner that would violate applicable Anti-Corruption Laws.

(c) It, its Affiliates, and its and their Representatives will not, directly or indirectly, solicit, receive, or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.

(d) It, its Affiliates, and its and their Representatives will comply with the Anti-Corruption Laws and will not take any action that will, or would reasonably be expected to, cause Licensor or its Affiliates or licensors to be in violation of any such laws.

(e) It, its Affiliates, and its and their Representatives will maintain policies and procedures designed to promote and achieve compliance with Anti-Corruption Laws, Anti-Money Laundering Laws, and applicable Global Trade Laws and Regulations.

(f) It will, no later than [***] days following the end of each Calendar Year, verify in writing that to its Knowledge, there have been no violations of Anti-Corruption Laws by it or its Affiliates or Sublicensees, or Persons employed by or Subcontractors used by it or its Affiliates or Sublicensees in the performance of this Agreement, or will provide details of any exception to the foregoing.

(g) It will maintain records and keep books (financial and otherwise), accounts, and supporting documentation, which in reasonable detail accurately and fairly reflect the transactions and dispositions of this Agreement, related to the subject matter of this Section 12.4.7 (Compliance with Anti-Corruption Laws) in order to document or verify compliance with the provisions of this Section 12.4.7 (Compliance with Anti-Corruption Laws).

(h) It will promptly provide Licensor with written notice of the following events: (i) upon becoming aware of any breach or violation by Licensee, its Affiliates, and its or their Representatives of any covenant or undertaking set out in this Section 12.4.7 (Compliance with Anti-Corruption Laws); or (ii) upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a material Anti-Corruption Law violation in connection with the subject matter of this Agreement, or upon receipt of information from its Affiliates, agents, representatives, consultants, and Sublicensees, Subcontractors hired in connection with the subject matter of this Agreement that any of them is the target of a formal investigation by a Governmental Authority for a material Anti-Corruption Law violation.

12.5 Covenants of Licensor. Licensor covenants to Licensee that:

12.5.1 Licensor shall not, and shall not cause its Affiliates to, without Licensee's prior written consent: (a) amend, restate, delete, substitute, or waive any terms or conditions of the AZ License; or (b) exercise any right to terminate (including its unilateral right to terminate the AZ License pursuant to Section 9.2.4 of the AZ License) or consent to any termination, in whole or in part, of the AZ License, in each case, ((a)-(b)) in a manner that would have a material adverse impact on the rights granted to Licensee under this Agreement.

12.5.2 Upon execution of any amendment of the AZ License after the Effective Date, Licensor shall promptly provide Licensee with a copy of such amendment or other agreement, which may be redacted to the extent not relevant to this Agreement.

12.5.3 In the event that the AZ License is terminated, Licensor shall use reasonable efforts to assist Licensee to enter into a license agreement directly with the counterparty to the AZ License pursuant to Section 9.4.1(a) of the AZ License.

12.5.4 In the course of performing its obligations or exercising its rights under this Agreement, Licensor and its Affiliates shall comply with all Applicable Laws, including, as applicable, cGMP, cGCP, and cGLP standards, and shall not employ or engage, and if so employed and engaged, shall thereafter terminate, any Person who has been Debarred/Excluded, or is the subject of any proceedings that could result in such Person being Debarred/Excluded. Licensee shall promptly notify Licensor of any Debarment/Exclusion or Debarment/Exclusion proceeding that could have an impact on the use of the results of any Clinical Trials for Licensed Products.

12.5.5 Licensor and its Affiliates shall comply with, all Applicable Laws pertaining to Personal Information, including, to the extent applicable, Privacy Laws to which they are subject in connection with their activities related to this Agreement. To the extent that Licensor or its Affiliates access or come into possession of Personal Information in connection with their activities related to this Agreement, Licensor and its Affiliates shall comply with applicable Privacy Laws to which they may be subject as a result thereof. Any processing by Licensor or its Affiliates of Personal Information obtained in connection with this Agreement shall be done solely for the purpose of performing Licensor's obligations under this Agreement, and shall be done in accordance with all applicable Privacy Laws. Licensor and its Affiliates shall take, and ensure that its Sublicensees and Subcontractors take, commercially reasonable and appropriate technical and organizational measures reflective of current good industry practice and technological development to protect the privacy and security of Personal Information in its possession and to prevent a Data Breach. Licensor and its Affiliates shall further maintain a commercially reasonable program for protecting against Data Breaches of Personal Information in its possession pursuant to activities under this Agreement or under a Japanese Clinical Development Plan. Licensor and its Affiliates shall use reasonable efforts to implement multi-factor authentication and encryption and put in place access controls for Personal Information (including by ensuring that Personal Information is accessible on a need-to-know basis for the purpose of fulfilling Licensor's obligations or exercising its rights under this Agreement or a Japanese Clinical Development Plan). Prior to transferring any data, results, or supporting documentation containing any Personal Information to Licensee hereunder, the Parties shall agree upon the manner and format of such transfer. In the event of a Data Breach, Licensor shall (i) promptly, and in any event so as to allow Licensee to comply with its obligations under Applicable Law, notify Licensee by phone and email after becoming aware of such Data Breach and (ii) comply with the relevant requirements and procedures of the applicable Privacy Laws in resolving such Data Breach.

12.6 Export Controls. Licensee acknowledges and agrees that the subject matter of this Agreement, including the Licensed Products, is subject to certain restrictions concerning the export of products, technology, or any other information or data, from the United States, or the reexport from other countries, that may be imposed on the Parties from time to time pursuant to Applicable Law. Licensee agrees that it will not, and will cause its Affiliates, Subcontractors, Sublicensees, and its and their Representatives to not, export, reexport, directly or indirectly, (nor knowingly facilitate any export or reexport) any products, technology, or any other information or data licensed or otherwise provided to Licensee under this Agreement, or any products using such technology, or any other information or data to a location or in a manner that at the time of export

or reexport requires an export license or other governmental approval or authorization from (a) any Governmental Authority in the United States, or (b) any Governmental Authority within Japan, without first obtaining the written consent to do so from the appropriate Governmental Authority in accordance with Applicable Law. For the avoidance of doubt, none of Licensee's distributors, manufacturers, or other agents outside the United States may reexport any products, technology, or any other information or data related to this Agreement unless appropriate authorizations from the United States government has been obtained, including any foreign-produced items that are the direct product of United States technology and software as detailed in the Export Administration Regulations.

12.7 No Conflict. Neither Party nor any of their Affiliates will enter into any agreement that would prevent it from granting the rights granted or intended to be granted to the other Party under this Agreement or from performing its obligations under this Agreement.

12.8 Compliance.

12.8.1 Notice. Each Party will promptly notify the other Party of any Compliance Breach or Compliance Finding.

12.8.2 Compliance Audits. Licensor will have the right, during normal business hours (or at such other times as the Parties may mutually agree), upon reasonable prior notice to Licensee from time to time during the Term, to inspect and audit any books, records, and accounts or other information of Licensee and its Affiliates, Sublicensees, and Subcontractors relating to Licensee's activities under this Agreement or under any Japanese Clinical Development Plan or Japanese Medical Affairs Plan, as may be necessary to enable Licensor to monitor and confirm compliance by Licensee and such Affiliates, Sublicensees, and Subcontractors with Applicable Law and other compliance obligations under this Agreement within the scope of Section 4.4 (Clinical Trial Audit Rights), Section 5.7 (Regulatory Audits), or Section 10.10 (Financial Records and Audits) of this Agreement. Licensee and its Affiliates will, and will cause its Sublicensees and Subcontractors to, provide Licensor with reasonable access to their respective facilities and personnel in connection with the foregoing, and the method Licensor uses to perform any such audit or inspection will be at the sole discretion of Licensor. For the avoidance of doubt, nothing in this Section 12.8.2 (Compliance Audits) will limit the rights or obligations of the Parties or their Affiliates, Sublicensees, or Subcontractors with respect to the conduct of audits under the terms of Section 4.4 (Clinical Trial Audit Rights), Section 5.7 (Regulatory Audits), or Section 10.10 (Financial Records and Audits) of this Agreement.

12.8.3 Remediation. Without limiting the indemnification, termination, dispute resolution, and other rights of Licensor hereunder, including Licensor's termination rights set forth in Section 15.2.3 (Termination for Material Breach) and Section 15.2.5 (Termination for Anti-Corruption Violation):

(a) If Licensor has a good faith belief that there has been or is reasonably likely to be a breach by Licensee or its Affiliates, Sublicensees, or Subcontractors of the compliance provisions of this Agreement and desires to have a discussion regarding same, then upon Licensor's request, the Parties will convene a meeting of appropriate representatives from each Party within [***] Business Days after such request, which may at the request of Licensor be

required to include either or both of each Party's general counsel or chief compliance officer. At such meeting, the Parties' representatives will agree in writing upon a plan to rectify the situation and Licensee and its Affiliates will (and will cause its Sublicensees and Subcontractors to) take such action as required under the plan.

(b) In the case of any Compliance Breach or Compliance Finding, the Parties will promptly, but in any event within [***] Business Days, meet to discuss, and Licensee will commence remediation of such Compliance Breach or Compliance Finding. If Licensee does not cure such Compliance Breach or Compliance Finding within [***] days after the conclusion of such meeting, then Licensor may deliver to Licensee a notice specifying the applicable Compliance Breach or Compliance Finding and the activities the subject of such Compliance Breach or Compliance Finding that Licensor desires that Licensee suspend ("**Suspension Notice**"), and Licensee will suspend its conduct of any such activities. Upon delivery of a Suspension Notice, the Parties will work to develop a mutually acceptable remediation plan to address the applicable Compliance Breach or Compliance Finding. If the Parties have not agreed on a remediation plan within [***] days after delivery of the Suspension Notice (such agreement not to be unreasonably withheld or delayed), or if at any time Licensee is not using its best efforts to implement the remediation plan adopted by the Parties, then Licensor may deliver to Licensee a notice that it is permanently suspending the activities referenced in the Suspension Notice. In such case, Licensor and Licensee will reasonably cooperate to transition to Licensor Licensee's activities referenced in the Suspension Notice with respect to the applicable Licensed Products so as to minimize disruption to such activities. In all cases, Licensee will withdraw its personnel or employees involved in such activities in a professional manner.

12.9 NO OTHER REPRESENTATIONS OR WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 12 (REPRESENTATIONS, WARRANTIES, AND COVENANTS) (A) NO REPRESENTATION, CONDITION, OR WARRANTY WHATSOEVER, WHETHER EXPRESS OR IMPLIED, IS MADE OR GIVEN BY OR ON BEHALF OF LICENSOR OR LICENSEE; AND (B) ALL OTHER REPRESENTATIONS, CONDITIONS, AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, NON-MISAPPROPRIATION, OR NON-INFRINGEMENT. ANY INFORMATION PROVIDED BY LICENSOR OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS, OR FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

ARTICLE 13
INDEMNIFICATION

13.1 By Licensee. Licensee will defend, indemnify, and hold harmless Licensor and its Affiliates, and their respective directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Licensor Indemnitee(s)**") from and against all Losses incurred by such Licensor Indemnitees in connection with any Third Party Claims to the extent arising from or based on (a) the negligence or willful misconduct of any Licensee Indemnitee or

Licensee's Sublicensees or Subcontractors in connection with this Agreement, (b) Licensee's breach of any of its representations, warranties, covenants, or obligations set forth in or entered into pursuant to this Agreement, (c) the Exploitation of any Licensed Product by Licensee, its Affiliates or Sublicensees in Japan, or (d) any claim or demand from any employee or contractor of Licensee or its Affiliate who is an inventor of any Licensee Collaboration Technology with respect to the ownership thereof, in each case of clauses (a) through (d) above, except to the extent such Third Party Claims arise out of a Licensor Indemnitee's negligence or willful misconduct, breach of this Agreement, or failure to abide by Applicable Law (including cGLP, cGMP, and cGCP, as applicable).

13.2 By Licensor. Licensor will defend, indemnify, and hold harmless Licensee, its Affiliates, and their respective directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Licensee Indemnitee(s)**") from and against all Losses incurred by such Licensee Indemnitees in connection with any Third Party Claims to the extent arising from or based on (a) the negligence or willful misconduct of Licensor or any of its Affiliates, licensees, sublicensees (not including Licensee or its Affiliates, Sublicensees, or its Subcontractors), or Subcontractors, (b) Licensor's breach of any of its representations, warranties, covenants, or obligations set forth in or entered into pursuant to this Agreement, or (c) the failure of Licensor or any of its Affiliates, licensees, sublicensees (not including Licensee or its Affiliates, Sublicensees, or Subcontractors), or Subcontractors to abide by Applicable Law (including cGLP, cGMP, and cGCP, as applicable) in connection with this Agreement, in each case of clauses (a) through (c) above, except to the extent such Third Party Claims arise out of any of a Licensee Indemnitee's negligence or willful misconduct, breach of this Agreement, or to the extent otherwise indemnifiable by Licensee under Section 13.1 (By Licensee).

13.3 Indemnification Procedure. If either Party is seeking indemnification under Section 13.1 (By Licensee) or Section 13.2 (By Licensor) (the "**Indemnified Party**"), then it will inform the other Party (the "**Indemnifying Party**") of the Third Party Claim giving rise to such indemnification obligations promptly after receiving written notice of the Third Party Claim (it being understood and agreed, *however*, that the failure or delay by an Indemnified Party to give such notice of a Third Party Claim will not affect the Indemnifying Party's indemnification obligations hereunder except to the extent the Indemnifying Party will have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party will have the right, at its option, to assume the defense of any such Third Party Claim for which it is obligated to indemnify the Indemnified Party by giving written notice to the Indemnified Party within [***] days after receipt of the notice of the Third Party Claim. The assumption of defense of a Third Party Claim will not be construed as an acknowledgement that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Third Party Claim, nor will it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. The Indemnified Party will cooperate with the Indemnifying Party and the Indemnifying Party's agents and representatives (including insurers) as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any Third Party Claim that has been assumed by the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, then (a) the Indemnified Party may defend against such Third Party Claim (and the Indemnified Party need not consult with the Indemnifying Party in connection therewith) and

(b) the Indemnified Party reserves any rights it may have under this Article 13 (Indemnification) to obtain indemnification from the Indemnifying Party with respect to such Third Party Claim. Neither Party will have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent will not be unreasonably withheld, conditioned, or delayed. The Indemnifying Party will not admit liability, responsibility, or fault of the Indemnified Party without the Indemnified Party's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed. The Indemnifying Party will not settle any Third Party Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, conditioned, or delayed, unless the settlement involves only the payment of money for which the Indemnifying Party is responsible and places no obligations other than such payment obligation on the Indemnified Party or its indemnitees. If the Parties cannot agree as to the application of Section 13.1 (By Licensee) or Section 13.2 (By Licensor) as to any Third Party Claim, pending resolution of the Dispute pursuant to Article 16 (Dispute Resolution), then the Parties may conduct separate defenses of such Third Party Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 13.1 (By Licensee) or Section 13.2 (By Licensor), as applicable, upon resolution of the underlying Third Party Claim; *provided* that the Parties will engage in good faith discussions regarding such Dispute before conducting separate defenses.

13.4 Insurance. Licensee will procure and maintain in full force and effect during the Term of this Agreement insurance required by Applicable Law where Licensee performs any activities under this Agreement. Without limiting the foregoing, Licensee will maintain in full force and effect during the Term insurance policies with the following insurance coverages, with limits of liability not less than those specified below:

(a) Any combination of commercial general liability and umbrella coverages with minimum limits of $[***] each occurrence and $[***] general aggregate, including coverage for premises liability, personal and advertising injury, contractual liability, and broad form property damage.

(b) Products and completed operations liability with minimum limits of $[***] each occurrence and $[***] general aggregate.

(c) Clinical Trial liability with minimum limits of $[***] each occurrence and $[***] general aggregate.

(d) Workers' compensation insurance in compliance with Applicable Law of the state or other jurisdiction in which activities are performed under this Agreement and employer's liability insurance in amounts not less than $[***] bodily injury by accident-each accident, $[***] bodily injury by disease-policy limit and $[***] bodily injury by disease-each employee. Where permitted by Applicable Law, such policies will contain a waiver of the insurer's subrogation rights against Licensor.

All insurance programs required to be maintained hereunder will be from insurers having an A.M. Best rating of A.M. Best A-VII or better, or its equivalent. To the extent requested by Licensor, Licensee will provide the other with an original certificate of insurance evidencing that (i) all such insurance coverages are in effect and (ii) none of the required policies of insurance will be

terminated or canceled by insurers except upon at least [***] days' written notice to Licensor. Nothing contained in this Section 13.4 (Insurance) is intended, or will be construed, to limit Licensee's indemnity obligations.

ARTICLE 14
INTELLECTUAL PROPERTY

14.1 Inventions.

14.1.1 Ownership of Background Intellectual Property. As between the Parties, each Party will solely own (or retain ownership of) all rights, title, and interests in and to all intellectual property to which such Party has rights and that was owned by such Party prior to the Effective Date or that arose outside of activities conducted under this Agreement.

14.1.2 Ownership of Arising Intellectual Property. Ownership of Know-How, and all intellectual property rights therein, that is conceived, reduced to practice, discovered, developed, or made by or on behalf of either Party or any Third Parties acting on their behalf (or any of their Affiliates, licensees, or Sublicensees) in the course of performing activities under this Agreement ("**Program IP**") will be as follows:

(a) Licensor will solely own (or retain ownership of) (i) all Program IP that is conceived, reduced to practice, discovered, developed, or made solely by or on behalf of Licensor or Licensee or jointly by Licensor or Licensee or any Third Parties acting on their behalf (or any of their Affiliates or licensees or Sublicensees), and all intellectual property rights therein, related to a Licensed Product (the "**Licensor Product-Related Program IP**") and (ii) all other Program IP that is conceived, reduced to practice, discovered, developed, or made solely by or on behalf of Licensor (or any of its Affiliates), and all intellectual property rights therein (collectively, "**Licensor Program IP**").

(b) Licensee will [***], and all intellectual property rights therein ("**Licensee Program IP**").

(c) (i) Licensor will [***], on the one hand, and Licensee [***], on the other hand, and all intellectual property rights therein ("**Joint IP**") outside Japan, and [***] inside Japan.

14.2 Assignments of Intellectual Property Rights.

14.2.1 Inventor Assignment Obligation. Licensee and its Affiliates will, and will cause its Sublicensees, and Subcontractors performing activities or exercising rights under this Agreement to, enter into with each of their respective employees legally binding and sufficient agreements or employment policies providing for the payment by Licensee (or its Affiliate, Sublicensee, or Subcontractor, as applicable) of any reward or remuneration required under Applicable Law in Japan in consideration for the development and assignment of inventions by such employees. Without limiting the generality of the foregoing, Licensee and its Affiliates will, and will cause its Sublicensees and Subcontractors to, enter into a written agreement or employment policy with each of its employees performing activities under this Agreement [***].

14.2.2 Assignment of Licensor Product-Related Program IP. Licensee (on behalf of itself and its Affiliates) will and does hereby assign to Licensor its right, title, and interest in and to the Licensor Product-Related Program IP. Licensee will not file any Patent Rights claiming the Licensor Product-Related Program IP.

14.2.3 Assignment of Joint IP. Licensee (on behalf of itself and its Affiliates) will and does hereby assign to Licensor, its right, title, and interest in and to all Joint IP outside Japan. [***], *provided* that Licensor shall have final decision-making authority as to whether to jointly file such Patent Rights, *provided, further,* [***].

14.2.4 Inventors. Inventorship will be determined in accordance with U.S. patent law.

14.2.5 Disclosure. Licensee will promptly disclose to Licensor all inventions within the Licensee Collaboration Know-How that it conceives, discovers, develops, generates, invents, or otherwise makes, whether solely or jointly with others (in any event, prior to the filing of any patent application with respect to such inventions), including all invention disclosures or other similar documents submitted to Licensee by its or its Affiliates' employees, agents, Sublicensees, Subcontractors, or independent contractors relating thereto. Licensee will also promptly respond to reasonable requests from Licensor for additional information relating thereto.

14.2.6 Reward and Remuneration Payments to Licensee Employees. As between the Parties, Licensee will be solely responsible for the payment of, and Licensee will pay, any rewards and remuneration for inventions and technical achievements required by Applicable Law to be paid to its employees for the development or invention of any Licensee Collaboration Technology, regardless of the form of such payment (including, for example, as a royalty).

14.3 CREATE Act. Notwithstanding any provision to the contrary set forth in this Agreement, Licensee may not invoke the Cooperative Research and Technology Enhancement Act, 35 U.S.C. § 102(c) (the "**CREATE Act**") when exercising its rights under this Agreement without the prior written approval of Licensor. If Licensee intends to invoke the CREATE Act, then it will notify Licensor and if agreed by the Parties, Licensor will cooperate and coordinate its activities with Licensee with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act.

14.4 Patent Prosecution.

14.4.1 Licensor-Prosecuted Patent Rights.

(a) **Right to Prosecute**. As between the Parties, Licensor or its Affiliate will have the sole right to control the Patent Prosecution of the Licensor Patent Rights and Patent Rights claiming Joint IP (the "**Licensor Prosecuted Patent Rights**") worldwide. Such Patent Prosecution will be at Licensor's sole expense, *except* any maintenance fees imposed by the Japan Patent Office shall be solely borne by Licensee.

(b) **Review and Consult**. Licensor will use Commercially Reasonable Efforts to consult with Licensee and keep Licensee informed regarding the Patent Prosecution of the Licensor Patent Rights in Japan and will provide Licensee with all substantive correspondence

received from any patent authority in Japan in connection therewith. In addition, Licensor will provide Licensee with drafts of all proposed substantive filings in Japan and correspondence to any patent authority in Japan in connection with the Patent Prosecution of the Licensor Patent Rights in Japan for Licensee's review and comment at least [***] days prior to the submission of such proposed filings and correspondence, which comments (if any) Licensee must provide no later than [***] Business Days after receipt of the applicable filing or correspondence. Further, Licensor will notify Licensee of any decision to cease Patent Prosecution of any Licensor Patent Rights in Japan. Licensor will consider in good faith Licensee's reasonable comments on Patent Prosecution of the Licensor Patent Rights in Japan, but Licensor will have final decision-making authority regarding Patent Prosecution of such Patent Rights under this Section 14.4.1(b) (Review and Consult).

14.4.2 Licensee Collaboration Patent Rights.

(a) **Right to Prosecute**. As between the Parties, Licensee will have the first right to control the Patent Prosecution of all Licensee Collaboration Patent Rights throughout the world at its sole expense.

(b) **Review and Consult**. Licensee will use Commercially Reasonable Efforts to consult with Licensor and keep Licensor informed regarding the Patent Prosecution of the Licensee Collaboration Patent Rights and will provide Licensor with all substantive correspondence received from any patent authority in connection therewith. In addition, Licensee will provide Licensor with drafts of all proposed substantive filings and correspondence to any patent authority in connection with the Patent Prosecution of the Licensee Collaboration Patent Rights for Licensor's review and comment at least [***] days prior to the submission of such proposed filings and correspondence, which comments (if any) Licensor must provide no later than [***] Business Days after receipt of the applicable filing or correspondence. Further, Licensee will notify Licensor of any decision to cease Patent Prosecution of any Licensee Collaboration Patent Rights. Licensee will consider in good faith Licensor's reasonable comments on Patent Prosecution and will incorporate such comments where appropriate.

14.5 Patent Enforcement.

14.5.1 Notice. Each Party will notify the other Party (a) within [***] Business Days after becoming aware of any application for approval of a Generic Product with respect to a Licensed Product in Japan and (b) within [***] days after becoming aware of any other suspected, threatened, or actual infringement by a Third Party product in Japan of any of the Licensor Prosecuted Patent Rights in Japan or any related declaratory judgment or equivalent action alleging the invalidity, unenforceability, or non-infringement of such Patent Rights (collectively "**Licensor Patent Right Infringement**"). For clarity, Licensor Patent Right Infringement excludes any adversarial Patent Prosecution proceedings.

14.5.2 Enforcement Rights.

(a) **Licensee First Right**. Licensee will have the first right, at Licensee's cost and expense, to bring and control any legal action to enforce the Licensor Prosecuted Patent Rights against Competitive Infringement in Japan as it reasonably determines appropriate, and Licensee

will consider the interests of Licensor in such enforcement of the Licensor Prosecuted Patent Rights against such Competitive Infringement. Licensee will keep Licensor regularly informed of the status and progress of any such legal action, and will reasonably consider Licensor's comments on such efforts.

(b) **Licensor Step-In Right**. If Licensee or its designee fails to file an action to abate such Competitive Infringement in Japan within [***] months after a written request from Licensor to do so or fails to abate such Competitive Infringement in Japan, or if the Licensee discontinues the prosecution of any such action after filing without abating such infringement, then, in either case, as between the Parties, Licensor will have the right to enforce the applicable Patent Rights against such Competitive Infringement as Licensor reasonably determines appropriate at its sole cost and expense; *provided* that Licensor will reasonably consider Licensee's rationale for not doing so or continuing to do so (including a substantive concern regarding counter-claims by the infringing Third Party). Licensor will keep the Licensee regularly informed of the status and progress of such efforts, and will reasonably consider Licensee's comments on such efforts.

14.5.3 Cooperation. At the request of the Party bringing an action in accordance with this Section 14.5 (Patent Enforcement), the other Party will provide reasonable assistance reasonably requested by the enforcing Party in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if reasonably requested by the enforcing Party, at the enforcing Party's expense.

14.5.4 Recoveries. Any recoveries resulting from an enforcement action relating to a Competitive Infringement in Japan will be first applied against payment of each Party's costs and expenses in connection therewith, which costs and expenses may include any payments owed by a Party pursuant to the AZ License. Any such recoveries in excess of such costs and expenses will (a) if Licensee is the enforcing Party, be treated as "Net Sales" hereunder, or (b) if Licensor is the enforcing Party, retained by Licensor.

14.6 Infringement of Third Party Rights.

14.6.1 Notice. If any Licensed Product used or sold by Licensee or its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in Japan that are owned or controlled by such Third Party, then Licensee will promptly notify Licensor within [***] Business Days after receipt of such claim or assertion and will include in such notice a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Thereafter, the Parties will promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties will assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

14.6.2 Defense. As between the Parties, Licensee will be solely responsible for the defense of any such infringement claims brought against Licensee at Licensee's sole expense; *provided* that Licensee will not agree to any settlement, consent to judgment, or other voluntary final

disposition in connection with such defense action without Licensor's prior written consent if such settlement, consent to judgment, or other voluntary final disposition would (a) result in the admission of any liability or fault on behalf of Licensor or any of its Affiliates, (b) result in or impose any payment obligations upon Licensor or any of its Affiliates, or (c) subject Licensor or any of its Affiliates to an injunction or otherwise limit Licensor's or any of its Affiliates' ability to take any actions or refrain from taking any action with respect to any Licensed Product or the Third Party's Patent Rights or other rights. Licensee will keep Licensor reasonably informed on the status of such defense action, and Licensor or its Affiliate will have the right, but not the obligation, to participate and be separately represented in such defense action at its sole option and at its own expense.

14.7 Patent Listings. With respect to patent listings in any patent listing system established by any applicable Regulatory Authority in Japan or under Applicable Law, for Licensor Patent Rights, the Parties will discuss and agree which Licensor Patent Rights to list in such patent listing in Japan (the "**Listing Patent Rights**") (i) prior to the submission of the first and any subsequent MAA for such Licensed Product in Japan to such applicable Regulatory Authority, (ii) within [***] days, but in any event reasonably in advance of the deadline for listing under Applicable Laws, after the receipt of the first and any subsequent Regulatory Approval in Japan for such Licensed Product from such Regulatory Authority, including any additional indication for such Licensed Product, and (iii) within [***] days, but in any event reasonably in advance of the deadline for listing under Applicable Laws, after the issuance in Japan of a patent included in the Listing Patent Rights; *provided* that, except as otherwise permitted under Applicable Laws, Licensee will not list, and will not be obligated to list, as of the date of listing, (A) any unissued patent, (B) any Patent Right that does not Cover the Licensed Product, (C) any patent that is of a type or that contains patent claims that are of a type not permitted to be listed under Applicable Law, or (D) any patent that such Party knows or has a reasonable basis to know is reasonably likely to be declared invalid by a competent Governmental Authority in such jurisdiction. In furtherance of the foregoing clause (D), if either Party has such knowledge or reasonable basis, then such Party will promptly notify and inform the Party of all facts and circumstances it is aware of underlying such knowledge or reasonable basis. If the Parties are unable to agree on which Patent Rights to list by the time required as provided under clause (i) to (iv) above, subject to the above proviso, then, as between the Parties, Licensee will have the final decision-making right over such listing. Licensee will promptly, and in any event at least [***] days prior to the applicable deadline for listing under Applicable Laws, list the Listing Patent Rights in the applicable patent listing system in Japan. Licensee will provide copies of all documentation to be filed in connection with any such listing of Listing Patent Rights to Licensor prior to filing thereof and will consider Licensor's comments with respect to such documentation. Licensor will cooperate with Licensee to the extent reasonably requested by Licensee to effectuate the intent of this Section 14.7 (Patent Listings), including providing all documentation, certifications, and consents necessary to effectuate the foregoing and setting up an account to list patents on the applicable patent listing system, and granting Licensee access to and a right to use such account as reasonably necessary to effectuate the intent of this Section 14.7 (Patent Listings). Licensee will not list any patent in any patent listing system in Japan for the Licensed Product, except in accordance with this Section 14.7 (Patent Listings).

14.8 Patent Term Extensions. With respect to any system for extending the term of Patent Rights in Japan or supplementary protection certificates and any other extensions that are

now or become available in the future under Applicable Laws in Japan, in each case, due to the time needed to obtain Regulatory Approval of a pharmaceutical product established by any applicable Regulatory Authority or other Governmental Authority in Japan (a "**Patent Term Extension**"), or adjusting the term of Patent Rights in Japan due to the time needed to prosecute and obtain a grant of a Patent Right under Applicable Laws in Japan (a "**Patent Term Adjustment**"), as between the Parties, Licensor will have the right, but not the obligation, and will be solely responsible for making all decisions regarding Patent Term Extensions or Patent Term Adjustments that are applicable to Licensor Patent Rights and that become available for a patent included in the Licensor Patent Rights, *provided* that Licensor will consult with Licensee with respect to such decisions and consider the reasonable comments and concerns raised by Licensee. Licensor will, upon Licensee's support, make the appropriate filings and applications in Japan in order to effectuate Licensor's decisions regarding Patent Term Extensions or Patent Term Adjustments in Japan in accordance with the foregoing sentence. Each Party will cooperate with the other Party to the extent reasonably required by the other Party to effectuate the intent of this Section 14.8 (Patent Term Extensions), including providing to the other Party all documentation, certifications, and consents necessary to make and prosecute such application and obtain such Patent Term Extension or Patent Term Adjustment.

14.9 Patent Marking. Licensee will mark all Licensed Products with patent numbers or indicia to the extent permitted by Applicable Law and otherwise in accordance with the applicable patent marking laws and in a reasonable manner consistent with industry custom and practice, and will require all of its Affiliates and Sublicensees to do the same. To the extent permitted by Applicable Law, Licensee will indicate on the product packaging and advertisement and promotional materials that such Licensed Product is in-licensed from Licensor in language acceptable to Licensor.

14.10 Product Trademarks.

14.10.1 Global Brand Elements. Licensee acknowledges that Licensor or its Affiliate may decide to develop and adopt certain distinctive colors, logos, images, symbols, trade dress, and trademarks to be used in connection with the Commercialization of each Licensed Product on a global basis (such branding elements, collectively, the "**Global Brand Elements**").

14.10.2 Product Marks in Japan. [***]. Licensee and its Affiliates, Sublicensees, and Subcontractors will not use any trademark, trade dress, or logo except for the Product Marks in connection with the Commercialization of the Licensed Products in Japan, and will not use the Global Brand Elements in a way that might materially prejudice or diminish their distinctiveness or validity or the goodwill of Licensor therein.

14.10.3 Ownership. [***] Licensor will be the sole and exclusive owner of all Global Brand Elements, in each case including all trademark registrations and applications therefor and all goodwill associated therewith; *provided*, that [***].

ARTICLE 15
TERM AND TERMINATION

15.1 Term. This Agreement will be effective as of the Effective Date and, if not terminated earlier pursuant to the terms of this Agreement, will expire, on a Licensed Product-by-Licensed Product basis, on the expiration of the Royalty Term for such Licensed Product and will finally expire in its entirety upon the expiration of the last Royalty Term for the last Licensed Product in Japan. (the "**Term**"). Upon expiry of the Term on a Licensed Product-by-Licensed Product basis, all rights and licenses granted by Licensor to Licensee under this Agreement with respect to a Licensed Product in Japan will remain in effect in accordance with their terms and will become irrevocable, unrestricted, perpetual, and fully paid-up.

15.2 Termination.

15.2.1 Termination by Mutual Agreement. The Parties may terminate this Agreement, in whole or in part, by mutual written agreement.

15.2.2 Licensee's Termination for Convenience. Licensee may terminate this Agreement at will, in its sole discretion, in its entirety, but not in part, upon delivery of [***] days' prior written notice to Licensor.

15.2.3 Termination for Material Breach. If either Party believes that the other Party is in material breach of any of its obligations under this Agreement, then the non-breaching Party may deliver notice of such breach to the other Party stating the cause and proposed remedy ("**Breach Notification**"). For any breach arising from a failure to make a payment set forth in this Agreement, the allegedly breaching Party will have [***] days from the receipt of the applicable Breach Notification to dispute or cure such breach. For all breaches other than a failure to make a payment as set forth in this Agreement, the allegedly breaching Party will have [***] days from the date of the Breach Notification to dispute or cure such breach. If the Party receiving notice of breach fails to cure, or fails to dispute, such breach within the applicable period set forth above, then the Party originally delivering the Breach Notification may terminate this Agreement in its entirety effective on written notice of termination to the other Party. Any Dispute regarding (a) the existence or materiality of a breach specified in a notice provided by a Party in accordance with this Section 15.2.3 (Termination for Material Breach) or (b) whether a material breach has been cured within the applicable cure period described in this Section 15.2.3 (Termination for Material Breach) will be subject to Article 16 (Dispute Resolution).

15.2.4 Termination for Patent Challenge. Except to the extent unenforceable under Applicable Law, Licensor may terminate this Agreement, in its entirety, by providing written notice of termination to Licensee if Licensee or its Affiliates or Sublicensees (individually or in association with any Person) contests or assists a Third Party in contesting the scope, validity, or enforceability of any Licensor Prosecuted Patent Right or any foreign counterpart thereof anywhere in the world in any court, tribunal, arbitration proceeding, or other proceeding, including the U.S. Patent and Trademark Office and the U.S. International Trade Commission (a "**Patent Challenge**"). In the event of such a Patent Challenge, Licensor will provide prompt written notice of such Patent Challenge to Licensee, and Licensor may immediately terminate this Agreement in its entirety by providing written notice of such termination to Licensee. Licensee will immediately

terminate the sublicense agreement with any Sublicensee that commences a Patent Challenge. As used herein, a Patent Challenge includes: (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patent Right; (b) filing or joining in a petition under 35 U.S.C. § 311 to institute *inter partes* review of any such Patent Right; (c) filing or joining in a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patent Right or any portion thereof; (d) filing or commencing any opposition, nullity, or similar proceedings challenging the validity of any such Patent Right in any country or jurisdiction; or (e) any foreign equivalent of clauses (a), (b), (c), or (d).

15.2.5 Termination for Anti-Corruption Violation. If there is [***] against Licensee or its Representatives, Affiliates, Sublicensees, or Subcontractors regarding a violation of Anti-Corruption Laws, Anti-Money Laundering Laws, or Global Trade Laws and Regulations, then Licensor may terminate this Agreement in its entirety by providing written notice to Licensee.

15.2.6 Cessation of Development and Commercialization in Japan. If Licensee and its Affiliates and Sublicensees do not conduct any material Development or Commercialization activities with respect to a Licensed Product in Japan for a continuous period of longer than [***] months, and such suspension of activity is not: (a) contemplated in a Japanese Clinical Development Plan or otherwise by written agreement of the Parties or (b) a force majeure event pursuant to Section 17.4 (Force Majeure), or (c) due to Licensor's failure to supply such Licensed Product in accordance with the terms of a supply agreement between the Parties, then Licensor may, at its election, terminate this Agreement in its entirety.

15.2.7 Termination for Insolvency.

(a) **Reject Events**. If either Party (i) makes a general assignment for the benefit of, or an arrangement or composition generally with, its creditors, (ii) appoints or suffers appointment of an examiner or of a receiver or trustee over all or substantially all of its assets to which this Agreement relates, (iii) passes a resolution for its winding up, (iv) files a petition under any bankruptcy or insolvency act or law, or (v) has any such petition filed against it which is not dismissed, discharged, bonded, or stayed within [***] days after the filing thereof, and in each case, seeks to reject this Agreement, then the other Party may treat this Agreement as terminated by such rejection, effective immediately upon written notice to such Party.

(b) **Section 365(n) Rights**. For purposes of Section 365(n) of the U.S. Bankruptcy Code (the "**Code**") and any similar laws in any other country, all rights and licenses granted under or pursuant to any Section of this Agreement are rights to "intellectual property" (as defined in Section 101(35A) of the Code). The Parties agree that the licensee of such rights under this Agreement will retain and may fully exercise all of its protections, rights, and elections under the Code and any similar laws in any other country. Each Party hereby acknowledges that copies of research data, laboratory samples, product samples and inventory, formulas, laboratory notes and notebooks, pre-clinical research data and results, tangible Know-How, and rights of reference, in each case that relate to such intellectual property, constitute "embodiments" of such intellectual property pursuant to Section 365(n) of the Code, and that the licensee will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to it upon its written request therefor and election under Bankruptcy Code

Section 365(n)(1)(B) to retain the licenses granted by Licensee to Licensor hereunder in the event of Licensee's rejection of this Agreement, or by Licensor to Licensee hereunder in the event of Licensor's rejection of this Agreement, unless Licensor elects to continue to perform all of its obligations under this Agreement. The provisions of this Section 15.2.7(b) (Section 365(n) Rights) are without prejudice to any rights the non-subject Party may have arising under the Code, laws of other jurisdictions governing insolvency and bankruptcy or other Applicable Law. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, including for purposes of the Code and any similar laws in any other country: (i) the right of access to any intellectual property (including all embodiments thereof) of Licensor, or any Third Party with whom Licensor contracts to perform an obligation of such licensor under this Agreement which is necessary for the Development or Commercialization of a Licensed Product; (ii) the right to contract directly with any such Third Party described in (i) to complete the contracted work, and (iii) the right to cure any breach of or default under any such agreement with a Third Party and set off the costs thereof against amounts payable to such licensor under this Agreement.

15.2.8 Full Force and Effect During Notice Period. This Agreement will remain in full force and effect until the expiration of the applicable termination notice period and each Party will continue to perform all of its obligations under this Agreement with respect to the Licensed Products, including pursuant to each then-in-effect Japanese Clinical Development Plan during such termination notice period. Licensee will continue to pay all Royalties which accrue with respect to the applicable Licensed Products during the termination notice period in accordance with the terms of this Agreement.

15.3 Effects of Expiration or Termination.

15.3.1 Expiration of the Royalty Term. Upon the expiration of the Royalty Term with respect to a Licensed Product in Japan, the license granted by Licensor pursuant to Section 2.1 (License Grant to Licensee) for such Licensed Product will become fully paid-up, irrevocable, perpetual and royalty-free in Japan.

15.3.2 Termination of this Agreement. Upon the termination (but not expiration) of this Agreement:

(a) **Licenses**. All licenses and all other rights, including the right of reference described in Section 5.5.2 (Licensee Right of Reference), granted by Licensor to Licensee under the Licensor Technology will terminate. All licenses and other rights, including the license grant in Section 2.3 (License Grant to Licensor) and the right of reference in Section 5.5.1 (Licensor Right of Reference), granted by Licensee to Licensor will survive.

(b) **Regulatory Submissions and Regulatory Approvals**. To the extent requested by Licensor, Licensee will and hereby does, and will cause its Affiliates and Sublicensees to, (a) no later than [***] days after the effective date of termination of this Agreement (or such longer period as may be required under Applicable Law), assign and transfer to Licensor or its designee all of Licensee's rights, title, and interests in and to all Regulatory Submissions and Regulatory Approvals then owned or Controlled by Licensee or any of its Affiliates or Sublicensees, and (b) to the extent assignment pursuant to clause (a) is delayed or is not permitted by the applicable Regulatory Authority, permit and does hereby grant to Licensor

the right to reference and rely upon any Regulatory Submissions and Regulatory Approvals filed by Licensee or any of its Affiliates or Sublicensees. Licensee will take all steps necessary to transfer ownership of all such Regulatory Submissions and Regulatory Approvals to Licensor, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Licensor) notifying such Regulatory Authority of the transfer of such ownership of each Regulatory Submission and Regulatory Approval to Licensor. In addition, upon Licensor's written request, Licensee will provide to Licensor copies of all substantive related documentation, including non-clinical, preclinical, and Clinical Data that are held by or reasonably available to Licensee or its Affiliates or Sublicensees. Where the effective date of termination of this Agreement is after Regulatory Approval for any Licensed Product in Japan, Licensee will no longer serve as the legal agent for such Licensed Product in Japan as of the effective date of such termination; *provided* that, if required by Applicable Law, then, at Licensor's election, Licensee will continue to serve as the legal agent for such Licensed Product in Japan for so long as required by Applicable Law. The Parties will discuss and establish appropriate arrangements with respect to safety data exchange, *provided* that Licensor will assume all safety and pharmacovigilance activities with respect to all Licensed Products no later than [***] days after the effective date of termination of this Agreement.

(c) **Assignment and Disclosure**.

(i) To the extent requested by Licensor following the date that a Party provides notice of termination of this Agreement, Licensee will promptly (and in any event within [***] days after the effective date of termination):

(A) provide to Licensor for its review unredacted copies of all clinical trial agreements, distribution agreements (to the extent assignable and not cancelled), and confidentiality and other agreements, in each case, that are necessary or reasonably useful for the Exploitation of each Licensed Product in Japan and, following such review, upon Licensor's request, assign and transfer to Licensor or its designee all of Licensee's rights, title, and interests in and to any such agreements. If any such agreement is not assignable, then Licensee will cooperate with Licensor in all reasonable respects to secure the consent of the applicable Third Party to such assignment or to cause such Third Party to enter into a separate agreement with Licensor or its designee on terms substantially similar to those granted to Licensee;

(B) disclose to Licensor or its designee, and hereby assign and transfer to Licensor or its designee all of Licensee's rights, title, and interests in and to, all data, information, documents, records, and materials related to the Licensed Products that are Controlled by Licensee or that Licensee is able to obtain using reasonable efforts, and that embody the foregoing; and

(C) assign and transfer to Licensor or its designee all of Licensee's rights, title, and interests in and to any promotional materials, training materials, medical education materials, packaging and labeling, and all other literature or other information related the Licensed Products and copyrights and any registrations for the foregoing.

(d) **Costs and Expenses**. Licensee will bear the costs and expenses associated with the assignments set forth in this Section 15.3.2(c) (Assignment and Disclosure) unless this

Agreement is terminated by Licensee pursuant to Section 15.2.3 (Termination for Material Breach) due to material breach of this Agreement by Licensor, in which case, Licensor will bear the costs and expenses associated with the assignments set forth in this Section 15.3.2(c) (Assignment and Disclosure) . To the extent that any agreement or other asset described in this Section 15.3.2(c) (Assignment and Disclosure) is not assignable by Licensee, then such agreement or other asset will not be assigned, and upon the request of Licensor, Licensee will take such steps as may be necessary to allow Licensor or its designee to obtain and to enjoy the benefits of such agreement or other asset, without additional payment therefor, in the form of a license or other right to the extent Licensee has the right and ability to do so. For clarity, Licensor will have the right to request that Licensee take any or all of the foregoing actions in whole or in part, or with respect to all or any portion of the assets set forth in this Section 15.3.2(c) (Assignment and Disclosure).

15.3.3 Regulatory Transfer Support. In furtherance of the assignment of Regulatory Submissions and Regulatory Approvals and other data pursuant to Section 15.3.2(b) (Regulatory Submissions and Regulatory Approvals) and Section 15.3.2(c) (Assignment and Disclosure), upon Licensor's request, Licensee will appoint Licensor or its designee as Licensee's or its Affiliate's agent for all Licensed Product-related matters involving Regulatory Authorities until all Regulatory Approvals, Regulatory Submissions, and other governmental or regulatory filings that are not then in Licensor's or its Affiliate's name have been assigned to Licensor or its designee. In the event of failure to obtain such assignment, Licensee hereby consents and grants to Licensor the right to access and reference (without any further action required on the part of Licensee, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to the Licensed Products.

15.3.4 Know-How Transfer Support. In furtherance of the assignment of Know-How pursuant to Section 15.3.2(c) (Assignment and Disclosure), Licensee will, for a period of [***] months from the effective date of termination of this Agreement, provide such reasonable consultation or other reasonable assistance as Licensor may reasonably request to assist Licensor in becoming familiar with such Know-How in order for Licensor to undertake further Exploitation of each Licensed Product. Such assistance with be at Licensee's sole cost and expense. After the expiration of such [***] month period, and for a period of up to [***] months from the effective date of termination of this Agreement, Licensor may request continued reasonable assistance from Licensee at Licensor's sole cost and expense, and Licensee shall use Commercially Reasonable Efforts to provide such reasonable assistance upon Licensor's request and to the extent agreed to by Licensee.

15.3.5 Inventory. At Licensor's election and request, Licensee will either (a) transfer to Licensor or its designee or (b) destroy, in each case ((a) and (b)), some or all inventory of each Licensed Product (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or control of Licensee or its Affiliates or Sublicensees. In the event that Licensor elects to proceed under clause (a), then Licensor will pay Licensee a price equal to the price paid by Licensee to Licensor for such transferred Licensed Product.

15.3.6 Wind Down and Transition. Licensee will be responsible, at its own cost and expense, for the wind-down of Licensee's and its Affiliates' and its Sublicensees' Exploitation of

each Licensed Product in Japan. Licensee will, and will cause its Affiliates and Sublicensees to, at its sole expense, reasonably cooperate with Licensor as Licensor may reasonably request to facilitate orderly transition of the Exploitation of each Licensed Product to Licensor or its designee, including (a) assigning or amending as appropriate, upon request of Licensor, any agreements or arrangements with Third Party vendors (including distributors) to Exploit each Licensed Product or, to the extent any such Third Party agreement or arrangement is not assignable to Licensor, reasonably cooperating with Licensor to arrange to continue to provide such services on a non-exclusive basis for a reasonable time after termination of this Agreement with respect to such Licensed Product and (b) to the extent that Licensee or its Affiliate is performing any activities described in the foregoing clause (a), reasonably cooperating with Licensor as Licensor may reasonably request to transfer such activities to Licensor or its designee and continuing to perform such activities on a non-exclusive basis on Licensor's behalf for a reasonable time after termination of this Agreement with respect to such Licensed Product until such transfer is completed.

15.3.7 Ongoing Clinical Trials.

(a) **Transfer to Licensor**. If, as of the effective date of termination of this Agreement with respect to a Licensed Product, Licensee or its Affiliate or Sublicensee is conducting any Clinical Trial for such Licensed Product, then, at Licensor's request and election, on a Clinical Trial-by-Clinical Trial basis, Licensee will fully cooperate, and will ensure that its Affiliates and Sublicensees fully cooperate, with Licensor to transfer the conduct of such Clinical Trial to Licensor or its designees. If Licensor so elects, then Licensee will continue to conduct such Clinical Trial, at Licensor's cost, to enable such transfer to be completed without interruption of any such Clinical Trial (including the assignment of all related Regulatory Submissions and investigator and other agreements related to such Clinical Trials). Licensee will provide such knowledge transfer and other training to Licensor or its designated Affiliate or Third Party as reasonably necessary for and requested by Licensor or such designated Affiliate or Third Party to continue such Clinical Trial for the applicable Licensed Product.

(b) **Wind-Down**. If Licensor does not elect to assume control of any such Clinical Trials for a Licensed Product, then Licensee will, in accordance with accepted pharmaceutical industry norms and ethical practices, wind-down the conduct of any such Clinical Trial in an orderly manner. Licensee will be responsible for any costs and expenses associated with such wind-down.

15.3.8 Further Assistance. Licensee will provide any other assistance or take any other actions, in each case, reasonably requested by Licensor as necessary to transfer to Licensor the Exploitation of any Licensed Product or as otherwise required to comply with the terms of the AZ License, and will execute all documents as may be reasonably requested by Licensor in order to give effect to this Section 15.3 (Effects of Expiration or Termination).

15.3.9 Return of Confidential Information. Following the termination of this Agreement, at the Disclosing Party's election and request, the Receiving Party will return or destroy, at the Receiving Party's expense, all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party that are in the Receiving Party's or its Affiliates' or Sublicensees' possession or control and provide written certification of such return or destruction (except to the extent (a) any information is the Confidential Information of both

Parties, or (b) the Receiving Party has the continuing right to use the Confidential Information under this Agreement, including to exercise any rights and licenses which expressly survive expiration or termination of this Agreement) within [***] days after the expiration or termination of this Agreement; *provided* that the Receiving Party may retain one copy of such Confidential Information solely for archival purposes and compliance with Applicable Law. Notwithstanding any provision to the contrary set forth in this Agreement, the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

15.4 Survival. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the following provisions of this Agreement will survive the expiration or termination of this Agreement: Article 1 (Definitions) (solely to the extent such definitions are used in other surviving provisions); Section 2.3 (License Grant to Licensor), Section 2.4 (No Implied Licenses; Retained Rights); Section 2.5.5 (Responsibility for Sublicensees and Subcontractors); Section 4.5 (Development Records) (solely for the time period set forth therein); Sections 10.6 (Accounting Standards), 10.7 (Currency; Exchange Rate), 10.8 (Blocked Payments), 10.9 (Late Payments), 10.10 (Financial Records and Audits), and 10.11 (Taxes) (in each case, solely to the extent that any payment accrued prior to the effective date of expiration or termination of this Agreement and with respect to Section 10.10 (Financial Records and Audits) solely for the time period set forth therein); Section 11.1 (Duty of Confidence) (solely for the time period set forth therein); Section 11.2 (Confidential Information); Section 11.3 (Exemptions); Section 11.4 (Authorized Disclosures); Section 11.7 (Publicity; Use of Names); Section 12.9 (No Other Representations or Warranties); Section 13.1 (By Licensee); Section 13.2 (By Licensor); Section 13.3 (Indemnification Procedure); Section 14.1 (Inventions); 14.2 (Assignments of Intellectual Property); Section 14.10.3 (Ownership); Section 15.3 (Effects of Expiration or Termination) this Section 15.4 (Survival); Section 15.5 (Cumulative Remedies; Termination Not Sole Remedy); Article 16 (Dispute Resolution); and Article 17 (Miscellaneous).

15.5 Cumulative Remedies; Termination Not Sole Remedy. No remedies referred to in this Agreement are intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law. Without limiting the generality of the foregoing, termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding any provision to the contrary set forth in this Agreement, all other remedies will remain available except as expressly set forth herein.

ARTICLE 16
DISPUTE RESOLUTION

16.1 Exclusive Dispute Resolution Mechanism. The Parties recognize that a dispute may arise relating to this Agreement (a "**Dispute**"). Except as otherwise expressly set forth in this Agreement, including in Section 3.5 (Resolution of JSC Disputes), any Dispute, including Disputes that may involve the Affiliates of any Party, will be resolved in accordance with this Article 16 (Dispute Resolution). The Parties agree that the procedures set forth in this Article 16 (Dispute Resolution) will be the exclusive mechanism for resolving any Dispute.

16.2 Negotiation; Escalation. Except as otherwise set forth in this Agreement, in the event of an unresolved Dispute, the Parties will refer the Dispute to the Executive Officers for discussion and resolution. If the Executive Officers are unable to resolve such Dispute within [***] days of the Dispute being referred to them by either Party in writing, then either Party will be free to initiate the arbitration proceeding outlined in Section 16.3 (Arbitration) to resolve the matter by providing the other Party written notice (a "**Notice of Dispute**").

16.3 Arbitration. Any unresolved Disputes between the Parties relating to, arising out of or in any way connected with this Agreement or any term or condition hereof, or the performance by either Party of its obligations hereunder, whether before or after termination of this Agreement, will be resolved by final and binding arbitration administered by the Judicial Arbitration and Mediation Services ("**JAMS**") (or any successor entity thereto) and in accordance with the Comprehensive Arbitration Rules and Procedures then in effect and the Streamlined Rules and Procedures contained therein, as modified in this paragraph (the "**Rules**"), except to the extent such Rules are inconsistent with this Section 16.3 (Arbitration) in which case, this Section 16.3 (Arbitration) will control (including with regard to any limitations of liability or forms of relief). Pursuant to this Section:

16.3.1 Upon receipt of a Notice of Dispute by a Party, the applicable Dispute will be resolved by final and binding arbitration before a single arbitrator mutually agreed by the Parties; *provided*, *however*, that if the Parties cannot agree within [***] days of the date such Notice of Dispute is received, then the arbitrator will be chosen in accordance with JAMS Rule 15 (the "**Arbitrator**"). The Arbitrator (a) will not be from academia, (b) will be a qualified attorney in private practice or a retired judge with experience in complex commercial disputes, (c) will be professionally fluent in English, (d) will have not less than [***] years of experience in the biotechnology or pharmaceutical industry and subject matter expertise with respect to the matter subject to arbitration, and (e) will have educational training and industry experience sufficient to demonstrate a reasonable level of scientific, financial, medical, and industry knowledge relevant to the particular Dispute.

16.3.2 The Arbitrator will, within [***] days after the conclusion of the hearing, issue a written award and statement of decision describing the material facts and the grounds for the conclusions on which the award is based, including the calculation of any damages awarded. The Arbitrator will be authorized to award compensatory damages, but will not be authorized to reform, modify, or materially change this Agreement. The proceedings and decisions of the Arbitrator will be confidential, final, and binding on the Parties, and judgment upon the award of the Arbitrator may be entered in any court having jurisdiction thereof. For clarity, neither Party will have any right to appeal the decisions of the Arbitrator.

16.3.3 Each Party will bear its own costs and expenses (including legal fees and expenses) relating to the arbitration proceeding, except that the fees of the Arbitrator and other related costs of the arbitration will be shared equally by the Parties, unless the Arbitrator determines that a Party has incurred unreasonable expenses due to vexatious or bad faith positions taken by the other Party, in which event the Arbitrator may make an award of all or any portion of such expenses (including legal fees and expenses) so incurred.

16.3.4 The Arbitrator will be required to render the decision in writing. The Arbitrator will comply with, and the award will be limited by, any express provisions of this Agreement relating to damages or the limitation thereof. The Arbitrator will not have the power to award punitive damages under this Agreement regardless of whether any such damages are contained in a proposal, and such award is expressly prohibited.

16.3.5 Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Agreement: (a) the Parties will continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding; (b) in the event the arbitration proceeding concerns a potential material breach under Section 15.2.3 (Termination for Material Breach), the cure period will be stayed until the conclusion of the proceedings under this Section 16.3 (Arbitration); and (c) in the event that the subject of the Dispute relates to the exercise by a Party of a termination right hereunder, including in the case of a material breach of this Agreement, the effectiveness of such termination will be stayed until the conclusion of the proceedings under this Section 16.3 (Arbitration). All arbitration proceedings and decisions of the Arbitrator under this Section 16.3 (Arbitration) will be deemed Confidential Information of both Parties under Article 11 (Confidentiality; Publication).

16.3.6 The arbitration proceedings will take place in Los Angeles, California, in the English language.

16.3.7 In the event of a Dispute regarding any payments owing under this Agreement, all undisputed amounts will be paid promptly when due and the balance, if any, promptly after resolution of the Dispute.

16.4 Patent and Trademark Disputes. Notwithstanding Section 16.3 (Arbitration), any Dispute regarding the scope, construction, validity, enforceability, or infringement of any Patent Rights, trademark rights, or trade dress rights applicable to the Licensed Products will be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the Applicable Laws of the United States or Japan in which such Patent Rights, trademark rights, or trade dress rights were granted or arose.

16.5 Equitable Relief. Notwithstanding anything to the contrary set forth in this Agreement, either Party may at any time seek to obtain preliminary injunctive relief or other applicable provisional relief from a court of competent jurisdiction in the United States or Japan with respect to an issue arising under this Agreement if the rights of such Party would be prejudiced absent such relief. A request by a Party to a court of competent jurisdiction for interim measures necessary to preserve the Party's rights, including attachments or injunctions, will not be deemed incompatible with, or a waiver of, the agreement to arbitrate under Section 16.3 (Arbitration), or the availability of interim measures of protection under JAMS rules.

16.6 Waiver of Right to Jury Trial. THE PARTIES HEREBY WAIVE, AND COVENANT THAT THEY WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT, OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY ACTION ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION WITH THIS AGREEMENT, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN

CONTRACT, TORT, OR OTHERWISE. THE PARTIES AGREE THAT EITHER OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY, AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT, AND THE PARTIES WILL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

16.7 Confidentiality. Any and all activities conducted under this Article 16 (Dispute Resolution), including any and all non-public proceedings and decisions hereunder, will be the Confidential Information of each of the Parties, and will be subject to the terms of Article 11 (Confidentiality; Publication) to the extent permitted in accordance with Applicable Law.

ARTICLE 17
MISCELLANEOUS

17.1 Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or otherwise transferred, by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, (a) Licensor may assign or otherwise transfer, without consent of Licensee, its rights to receive payments under this Agreement to one or more Persons (including as part of a monetization transaction), and (b) each Party may assign or otherwise transfer, without consent of the other Party, (i) this Agreement in whole or in part to any Affiliate, only so long as such Affiliate remains an Affiliate of the assigning Party, (ii) this Agreement in its entirety to a Third Party in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a merger, acquisition, sale of stock, sale of assets, reorganization, or other transaction or series of related transactions, or (iii) this Agreement in part on a Licensed Product-by-Licensed Product basis to a Third Party in connection with the sale of all or substantially all of the assets to which such Licensed Product and this Agreement relate, whether in a merger, acquisition, sale of stock, sale of assets, reorganization, or other transaction or series of related transactions. Any attempted assignment or transfer of this Agreement not in accordance with this Section 17.1 (Assignment) will be null, void, and of no legal effect. Any permitted successor or assignee of rights or obligations hereunder will, in a writing to the other Party, expressly assume performance of such assigned or transferred rights and obligations (and in any event, any Party assigning or otherwise transferring this Agreement to an Affiliate will remain bound by the terms and conditions hereof). The terms of this Agreement will be binding upon, and will inure to the benefit of, the Parties and their respected successors and permitted assigns.

17.2 Limitation of Liability. NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR LOSS OF PROFIT (EVEN IF DEEMED DIRECT DAMAGES) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT OR IN CONNECTION WITH THIS AGREEMENT, IN EACH CASE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 17.2 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 13.1 (BY LICENSEE) OR SECTION 13.2 (BY LICENSOR), (B)

DAMAGES AVAILABLE TO EITHER PARTY FOR THE OTHER PARTY'S BREACH OF ARTICLE 11 (CONFIDENTIALITY; PUBLICATION) AND DAMAGES AVAILABLE TO LICENSOR FOR LICENSEE'S BREACH OF SECTION 12.4.5 (COVENANTS OF LICENSEE), (C) DAMAGES AVAILABLE TO EITHER PARTY FOR THE OTHER PARTY'S BREACH OF THE LICENSES GRANTED TO OR BY SUCH PARTY PURSUANT TO ARTICLE 2 (LICENSES; EXCLUSIVITY; RIGHT OF FIRST NEGOTIATION), (D) DAMAGES AVAILABLE TO EITHER PARTY FOR THE OTHER PARTY'S FRAUD, GROSS NEGLIGENCE, OR WILLFUL MISCONDUCT, OR (E) DAMAGES AVAILABLE TO EITHER PARTY FOR BREACH OF THE OTHER PARTY'S OBLIGATIONS HEREUNDER RELATING TO SECTION 2.7 (EXCLUSIVITY COVENANTS), OR MISAPPROPRIATION OR INFRINGEMENT OF INTELLECTUAL PROPERTY OWNED OR CONTROLLED BY LICENSOR.

17.3 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal, or unenforceable in any respect by an arbitrator or by any court of competent jurisdiction from which no appeal can be or is taken, then the provision will be considered severed from this Agreement and will not serve to invalidate the validity, legality, and enforceability of the remaining provisions contained herein. The Parties will in such an instance made a good faith effort to replace the invalid, illegal, or unenforceable provisions with valid, legal, and enforceable provisions that, insofar as practical, implement the objectives contemplated by the Parties when entering into this Agreement.

17.4 Force Majeure. Each Party will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented or delayed by force majeure and the nonperforming Party promptly provides notice of the prevention or delay to the other Party. Such excuse will continue only so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. When the force majeure no longer exists, the affected Party must promptly resume performance. For purposes of this Agreement, "force majeure" will include conditions beyond the reasonable control of the non-performing Party, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, global health conditions (including any epidemic, pandemic, or disease outbreak), failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm, or like catastrophe, failure of plant or machinery (*provided* that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced Person engaged in the same type of undertaking under the same or similar circumstances), and act (or failure to act) of a government of any country or of any Governmental Authority (other than as a result of the non-performing Party's failure to comply with Applicable Law, including cGLP, cGMP, and cGCP, as applicable), or any other force majeure events, including any material worsening of such conditions threatened or existing as of the date of this Agreement. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder because of a force majeure affecting such Party. The affected Party will notify the other Party in writing of any force majeure circumstances that may affect its performance under this Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under the Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such force majeure circumstances and resume normal performance of its obligations hereunder as soon as

reasonably practicable under the circumstances. Throughout the duration of the force majeure event, the affected Party will update such notice to the other Party on a bi-weekly basis, or more frequently if requested by the other Party, to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Agreement will be able to resume. In any event, if a Party's failure to perform its obligations under this Agreement as a result of a force majeure event continues for longer than [***] days, then the other Party may terminate this Agreement by providing written notice to the Party affected by the force majeure event and the effects of termination set forth in Section 15.3 (Effects of Expiration or Termination) will apply.

17.5 Notices. All notices or other communication that are required or permitted hereunder will be in writing (whether or not specifically stated), will refer specifically to this Agreement, will be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 17.5 (Notices), and will be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable international expedited delivery service (with receipt confirmed) or (b) [***] Business Days after mailing, if mailed by first class certified or registered mail with FedEx or DHL, postage prepaid, return receipt requested. This Section 17.5 (Notices) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under this Agreement (for which e-mail and other methods of communication will suffice).

If to Licensor:

Arcutis Biotherapeutics, Inc.
3027 Townsgate Road, Suite 300
Westlake Village, CA 91361 USA
Attn: Chief Business Officer

with a copy to (which will not constitute notice):

Arcutis Biotherapeutics, Inc.
3027 Townsgate Road, Suite 300
Westlake Village, CA 91361 USA
Attn: Legal Department

If to Licensee:

Sato Pharmaceutical Co. Ltd.
AHC Building 1-5-27
Moto-Akasaka, Minato-ku, Tokyo 107-0051 Japan
Attn: Head of Business Development Department

with a copy to (which copy will not constitute notice):

Sato Pharmaceutical Co. Ltd.

AHC Building 1-5-27
Moto-Akasaka, Minato-ku, Tokyo 107-0051 Japan
Attn: Head of Financial Department

17.6 Governing Law. This Agreement, and all claims or causes of action (whether in contract, tort, statute, or otherwise) that may be based upon, arise out of, or relate to this Agreement, or the negotiation, execution, or performance of this Agreement, or the breach thereof (including any claim or cause of action based upon, arising out of, or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), will be governed by, and enforced in accordance with, the internal laws of the State of New York, including its statutes of limitations, without giving effect to any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The provisions of the United Nations Convention on Contracts for the International Sale of Goods are expressly excluded.

17.7 Entire Agreement; Amendments. This Agreement (including the Schedules hereto) contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes all prior agreements and understandings between the Parties existing as of the Effective Date with respect to the subject matter hereof, including the Confidentiality Disclosure Agreement. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof are hereby superseded by the terms of this Agreement. The Schedules to this Agreement are incorporated herein by reference and will 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 Party. The foregoing will not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party's or its Affiliate's obligations pursuant to the Confidentiality Disclosure Agreement.

17.8 Headings. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

17.9 Independent Contractors. Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein will be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

17.10 No Third Party Beneficiary Rights. Except as expressly set forth in this Agreement with respect to Licensor Indemnitees and Licensee Indemnitees, this Agreement is not intended to and will not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

17.11 Performance by Affiliates. Notwithstanding any provision to the contrary set forth in this Agreement, each Party will have the right to perform any or all of its obligations and

exercise any or all of its rights under this Agreement through any Affiliate. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

17.12 Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

17.13 Waiver of Rule of Construction. This Agreement has been prepared jointly and each Party has had the opportunity to consult with counsel in connection with the review, drafting, and negotiation of such agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

17.14 Further Actions. Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.

17.15 Construction. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes," and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will 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 will 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 will be construed to include the Person's successors and assigns, (f) the words "herein," "hereof," and "hereunder" and words of similar import, will each be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Sections, Schedules, or Exhibits will be construed to refer to Articles, Sections, Schedules, or Exhibits of this Agreement, and references to this Agreement will be construed to include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will 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," "approve," or the like will 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 Section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule, or regulation thereof, and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or." Except as otherwise expressly set forth in this Agreement, when applied to Licensor, the phrases "at its own cost and expense," "at its sole cost and expense," "at its cost and expense," and similar phrases used in this

Agreement do not preclude the possibility that Licensor may share such costs or expenses with a Third Party.

17.16 Language; Translations. All communications and notices to be made or given by one Party to the other Party pursuant to this Agreement, and any Dispute proceeding related to or arising hereunder, will be in the English language. If any data, information, documentation, or other materials not already required but requested to be delivered by Licensee to Licensor under this Agreement are not already in English, then, together with the original form, Licensee will provide to Licensor a full certified English translation of such data, information, documentation, or other materials at Licensor's cost and expense. Each Party will transmit all records or other documents to the other Party electronically under this Agreement over secure systems that include adequate encryption safeguards to prevent unauthorized access and maintain data security.

17.17 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[The remainder of the page has been intentionally left blank. The signature page follows.]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this License Agreement to be executed by their respective duly authorized representatives as of the Effective Date.

Arcutis Biotherapeutics, Inc.

By: /s/ Frank Watanabe

Name: Frank Watanabe

Title: President and CEO

Sato Pharmaceutical Co., Ltd.

By: /s/ Seiichi Sato

Name: Seiichi Sato

Title: President & CEO

[***]

FIRST AMENDMENT TO THE LICENSE AGREEMENT

THIS FIRST AMENDMENT TO THE LICENSE AGREEMENT (this "Amendment") is made as of [●], 2024 (the "Amendment Effective Date"), by and between Arcutis Biotherapeutics, Inc. ("Arcutis") and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd ("Huadong"). Capitalized terms used herein but not defined herein shall have the same meaning as set forth in the License Agreement (as defined below). Each of Arcutis and Huadong may be referred to herein as a "Party" or together as the "Parties."

WHEREAS, Arcutis and Huadong are parties to that certain License Agreement, dated as of August 10, 2023 (the 'License Agreement"); and

WHEREAS, the Parties wish to amend the License Agreement as set forth herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties do hereby amend the License Agreement as follows:

1. Section 6.1.1 (Importation Model) of the License Agreement is hereby amended by adding the following to the end of Section 6.1.1 (Importation Model):

The Parties acknowledge that securing sufficient commercial supply of Licensed Products is important for Licensee's successful commercial launch of Licensed Product, and as such the Parties agree to collaborate in good faith, and Licensor shall provide such reasonable assistance, for Licensee to negotiate with Licensor's CMOs to secure capacity for Licensee's commercial requirements of Licensed Product. For the avoidance of doubt, such assistance shall not require Licensor to bear any out-of-pocket costs in order to secure such supply.

2. Table 10.2.1 (Regulatory Milestones) of the License Agreement is hereby deleted and replaced in its entirety as follows:

Table 10.2.1 – Regulatory Milestones	
Development and Regulatory Milestone Event	**Development Regulatory Milestone Payment**
1: For ARQ-151 (0.3% concentration), the earlier of: (a) issuance of a Certificate of Pharmaceutical Product ("CPP") by FDA for [***] by [***] or no later than 4 weeks prior to Huadong IND submission, (b) Changes Being Effected in 30 Days ("CBE-30") in effect by [***] for [***], or (c) Prior Approval Supplement ("PAS") approval by [***] for [***].	$[***]
2: For ARQ-154 (0.3% concentration), the earlier of: (a) issuance of a CPP by FDA for [***]no later than 4 weeks prior to Huadong IND submission, (b) CBE-30 in effect by [***] for [***] or Licensor designated CMO, or (c) PAS approval by [***]for [***]or Licensor designated CMO.	$[***]
3: Dosing of 1st patient in the first Clinical Trial in China	$[***]
4: Filing of the first NDA for a Licensed Product in China	$[***]
5: First Regulatory Approval of a Licensed Product in China for psoriasis	$[***]
6: First Regulatory Approval of a Licensed Product in China for atopic dermatitis	$[***]
7: First Regulatory Approval of a Licensed Product in China for seborrheic dermatitis	$[***]

3. Section 10.2.1 (Regulatory Milestones) of the License Agreement is hereby amended by adding the following to the end of Section 10.2.1 (Regulatory Milestones):

For each of ARQ-151 and ARQ-154, Licensee will provide notice to Licensor of (a) Licensee's planned IND submission date for such Product at least [***] in advance of such submission, and (b) the date that an IND has been submitted for such Product promptly after such submission, except in each case ((a) and (b)) if Development and Regulatory Milestone Events 1 (in the case of ARQ-151) or 2 (in the case of ARQ-154), have already been achieved as of such date, in which case no such notice shall be required.

In the event a Development and Regulatory Milestone Event is achieved by or on behalf of Licensor, Licensor will provide notice of such achievement to Licensee, and will invoice Licensee and Licensee will pay such invoice as set forth in Section 10.2.3(a) (Development and Regulatory Milestone Payments).

4. **Confidentiality**. The terms of this Amendment shall be deemed to be the Confidential Information of both Parties and shall be subject to the same confidentiality terms under the License Agreement as apply to the terms of the License Agreement.

5. **Effect of Amendment**. This Amendment shall not constitute a waiver, amendment or modification of any other provision of the License Agreement or any other provision not expressly referred to herein. Except as amended hereby, each of the License Agreement shall remain in full force and effect as originally written. Upon the effectiveness of this Amendment, on and after the date hereof,

each reference in the License Agreement to “this Agreement,” “hereunder,” “hereof,” “herein” or words of like import, and each reference in the other documents entered into in connection with such agreement, shall mean and be a reference to such agreement, as amended hereby.

6. **Governing Law**. This Amendment will be governed by, and enforced in accordance with, the internal laws of the State of New York, including its statutes of limitations, without giving effect to any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Amendment to the substantive law of another jurisdiction.

7. **Amendments; Waiver; Assignment**. No amendment, modification or waiver of the terms of this Amendment will be binding on either Party unless reduced to writing and signed by authorized representatives of both Parties, or in the case of a waiver, by the Party waiving compliance. This Amendment may not be assigned except in connection with an assignment of the License Agreement.

8. **Counterparts**. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

(*Remainder of this page left blank intentionally; signature page follows*)

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Effective Date.

Arcutis Biotherapeutics, Inc.

By: /s/Frank Watanabe

Name: Frank Watanabe

Title: President & CEO

Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd

By: /s/ LV, Liang

Name: LV, Liang

Title: Chairman & CEO

[Signature Page to First Amendment to the License Agreement]

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Todd Franklin Watanabe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arcutis Biotherapeutics, 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 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 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.

Date: May 14, 2024

By: /s/ Todd Franklin Watanabe

Todd Franklin Watanabe
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Topper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arcutis Biotherapeutics, 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 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 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.

Date: May 14, 2024

By: /s/ David Topper

David Topper
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Arcutis Biotherapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Todd Franklin Watanabe, Chief Executive Officer of the Company, and David Topper, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2024

By: /s/ Todd Franklin Watanabe

Todd Franklin Watanabe
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 14, 2024

By: /s/ David Topper

David Topper
Chief Financial Officer
(Principal Accounting and Financial Officer)