UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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 October 31, 2023 was 94,382,074 .

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 September 30, 2023. 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

Item 1. Financial Statements

ARCUTIS BIOTHERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and par value)

	September 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 107,471	$ 53,641
Restricted cash	925	1,234
Marketable securities	119,642	355,948
Trade receivables, net	19,417	8,458
Inventories	13,913	7,514
Prepaid expenses and other current assets	20,180	10,611
Total current assets	281,548	437,406
Property, plant, and equipment, net	1,735	1,881
Intangible assets, net	6,625	7,188
Operating lease right-of-use asset	2,455	2,721
Other assets	596	78
Total assets	$ 292,959	$ 449,274
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,179	$ 8,827
Accrued liabilities	27,995	28,323
Operating lease liability	715	657
Total current liabilities	41,889	37,807
Operating lease liability, noncurrent	3,570	4,117
Long-term debt, net	200,783	197,769
Total liabilities	246,242	239,693
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $ 0.0001 par value; 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; no shares issued and outstanding at September 30, 2023 and December 31, 2022;	—	—
Common stock, $ 0.0001 par value; 300,000,000 shares authorized at September 30, 2023 and December 31, 2022; 61,861,736 and 61,052,250 shares issued at September 30, 2023 and December 31, 2022, respectively; 61,858,044 and 61,037,403 shares outstanding at September 30, 2023 and December 31, 2022, respectively	6	6
Additional paid-in capital	962,515	930,425
Accumulated other comprehensive loss	(184)	(1,086)
Accumulated deficit	(915,620)	(719,764)
Total stockholders' equity	46,717	209,581
Total liabilities and stockholders' equity	$ 292,959	$ 449,274

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Product revenue, net	$ 8,109	$ 725	$ 15,660	$ 725
Other revenue	30,000	—	30,420	—
Total revenues	38,109	725	46,080	725
Operating expenses:				
Cost of sales	1,182	269	2,741	269
Research and development	26,236	69,731	86,800	148,558
Selling, general, and administrative	47,595	35,473	136,471	85,101
Total operating expenses	75,013	105,473	226,012	233,928
Loss from operations	(36,904)	(104,748)	(179,932)	(233,203)
Other income (expense):				
Other income, net	2,721	1,938	9,114	2,501
Interest expense	(7,559)	(4,899)	(21,950)	(8,737)
Loss before income taxes	(41,742)	(107,709)	(192,768)	(239,439)
Provision for income taxes	3,023	—	3,088	—
Net loss	$ (44,765)	$ (107,709)	$ (195,856)	$ (239,439)
Other comprehensive income (loss):				
Unrealized income (loss) on marketable securities	165	(344)	1,017	(1,341)
Foreign currency translation adjustment	(57)	—	(115)	—
Total other comprehensive income (loss)	$ 108	$ (344)	$ 902	$ (1,341)
Comprehensive loss	$ (44,657)	$ (108,053)	$ (194,954)	$ (240,780)
Per share information:				
Net loss per share, basic and diluted	$ (0.73)	$ (1.89)	$ (3.19)	$ (4.52)
Weighted-average shares used in computing net loss per share, basic and diluted	61,727,278	57,091,743	61,462,025	53,028,962

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, 2021	50,255,614	$ 5	$ 706,233	$ (255)	$ (408,306)	$ 297,677
Issuance of shares of common stock under ATM, net of issuance costs of $ 634	882,353	—	14,366	—	—	14,366
Issuance of common stock upon the exercise of stock options	102,935	—	260	—	—	260
Issuance of common stock upon the vesting of restricted stock units	79,421	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	40,025	—	25	—	—	25
Stock-based compensation expense	—	—	6,533	—	—	6,533
Unrealized loss on marketable securities	—	—	—	(765)	—	(765)
Net loss	—	—	—	—	(64,324)	(64,324)
Balance—March 31, 2022	51,360,348	$ 5	$ 727,417	$ (1,020)	$ (472,630)	$ 253,772
Issuance of common stock upon the exercise of stock options	57,113	—	156	—	—	156
Issuance of common stock upon the vesting of restricted stock units	6,625	—	—	—	—	—
Vesting of founder shares subject to repurchase	—	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	27,830	—	20	—	—	20
Shares issued pursuant to the employee stock purchase plan	74,237	—	976	—	—	976
Stock-based compensation expense	—	—	8,096	—	—	8,096
Unrealized loss on marketable securities	—	—	—	(232)	—	(232)
Net loss	—	—	—	—	(67,406)	(67,406)
Balance—June 30, 2022	51,526,153	$ 5	$ 736,665	$ (1,252)	$ (540,036)	$ 195,382
Issuance of shares of common stock, net of discount and issuance costs of $ 10,844	8,625,000	1	161,656	—	—	161,657
Issuance of shares of common stock related to acquisition of Ducentis Biotherapeutics LTD	610,258	—	12,468	—	—	12,468
Issuance of common stock upon the exercise of stock options	130,817	—	494	—	—	494
Issuance of common stock upon the vesting of restricted stock units	12,695	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	3,718	—	37	—	—	37
Stock-based compensation expense	—	—	8,789	—	—	8,789
Unrealized loss on marketable securities	—	—	—	(344)	—	(344)
Net loss	—	—	—	—	(107,709)	(107,709)
Balance—September 30, 2022	60,908,641	$ 6	$ 920,109	$ (1,596)	$ (647,745)	$ 270,774

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, 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	—	100	—	—	100
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	—	—	—	—	—
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
Issuance of common stock upon the exercise of stock options	35,700	—	74	—	—	74
Issuance of common stock upon the vesting of restricted stock units	77,221	—	—	—	—	—
Vesting of founder shares subject to repurchase	—	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	3,719	—	—	—	—	—
Shares issued pursuant to the employee stock purchase plan	155,446	—	993	—	—	993
Stock-based compensation expense	—	—	10,578	—	—	10,578
Unrealized gain on marketable securities	—	—	—	128	—	128
Foreign currency translation adjustment	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	(70,991)	(70,991)
Balance—June 30, 2023	61,630,018	$ 6	$ 951,649	$ (292)	$ (870,855)	$ 80,508
Issuance of common stock upon the exercise of stock options	172,320	—	867	—	—	867
Issuance of common stock upon the vesting of restricted stock units	51,988	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	3,718	—	—	—	—	—
Stock-based compensation expense	—	—	9,999	—	—	9,999
Unrealized gain on marketable securities	—	—	—	165	—	165
Foreign currency translation adjustment	—	—	—	(57)	—	(57)
Net loss	—	—	—	—	(44,765)	(44,765)
Balance—September 30, 2023	61,858,044	$ 6	$ 962,515	$ (184)	$ (915,620)	$ 46,717

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)

	Nine Months Ended September 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (195,856)	$ (239,439)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	573	462
Non-cash lease expense	266	237
Amortization of intangible assets	563	125
Acquired in-process research and development	—	29,630
Net (accretion) amortization on marketable securities	(5,517)	89
Non-cash interest expense	3,014	1,590
Stock-based compensation expense	30,056	23,418
Changes in operating assets and liabilities:		
Accounts receivable, net	(10,959)	(2,431)
Inventories	(6,399)	(4,307)
Prepaid expenses and other current assets	(10,087)	2,299
Accounts payable	4,345	1,383
Accrued liabilities	(323)	577
Operating lease liabilities	(489)	(283)
Net cash used in operating activities	(190,813)	(186,650)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(107,660)	(377,301)
Proceeds from maturities of marketable securities	350,500	271,061
Purchases of property and equipment	(422)	(210)
Acquisition of in-process research and development	—	(15,450)
Milestone payment for intangible	—	(7,500)
Net cash provided by (used in) investing activities	242,418	(129,400)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon exercise of stock options	1,041	1,000
Proceeds from issuance of shares under ATM, net of issuance costs	—	14,455
Proceeds from issuance of common stock, net of issuance costs	—	161,592
Proceeds from issuance of common stock pursuant to employee stock purchase plan	993	976
Proceeds from long-term debt	—	125,000
Payment of debt issuance costs	—	(2,187)
Net cash provided by financing activities	2,034	300,836
Effect of exchange rate changes on cash	(118)	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	53,521	(15,214)
Cash, cash equivalents, and restricted cash at beginning of period	54,875	97,991
Cash, cash equivalents, and restricted cash at end of period	$ 108,396	$ 82,777
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Interest expense paid in cash	$ 18,862	$ 6,923
Acquired in-process research and development in exchange for the issuance of common stock	$ —	$ 12,468

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 an early commercial-stage biopharmaceutical company focused on developing and commercializing treatments for dermatological diseases with high unmet medical needs. The Company received U.S. Food and Drug Administration (FDA) approval of its first product, ZORYVE® (roflumilast) cream 0.3%, on July 29, 2022, for the treatment of plaque psoriasis, including intertriginous psoriasis, in individuals 12 years of age and older, and began U.S. commercialization in August 2022. The Company also received Health Canada approval of ZORYVE in plaque psoriasis on April 28, 2023 and began Canadian commercialization in June 2023. The Company's current portfolio is comprised of what management believes to be highly differentiated topical and systemic treatments with significant potential to treat immune-mediated dermatological diseases and conditions. The Company believes it has built the industry's leading platform for dermatologic product development. 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 believes this strategy uniquely positions it to rapidly advance its goal of bridging the treatment innovation gap in dermatology, while maximizing its probability of technical success.

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 and August 2022, receiving aggregate net proceeds of $ 93.4 million, $ 207.5 million, and $ 161.6 million, respectively. In October 2020, the Company also sold shares of common stock in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, receiving net proceeds of $ 35.0 million. On October 24, 2023, the Company completed a public offering of its common stock and prefunded warrants to purchase shares of its common stock and received aggregate net proceeds of $ 94.0 million. See Note 12.

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.

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 $ 915.6 million and $ 719.8 million as of September 30, 2023 and December 31, 2022, respectively. Management expects to continue to incur operating losses. The Company had cash, cash equivalents, restricted cash, and marketable securities of $ 228.0 million and $ 410.8 million as of September 30, 2023 and December 31, 2022, respectively. On October 24, 2023, the Company completed a public offering of its common stock and prefunded warrants to purchase shares of its common stock and received net proceeds of $ 94.0 million. The Company has $ 200.0 million outstanding under the Loan Agreement as of September 30, 2023. See Note 8.

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, amounts available under the Loan Agreement 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.

Segments

To date, the Company has viewed its financial information on an aggregate basis for the purposes of evaluating financial performance and allocating the Company's resources. Accordingly, the Company has determined that it operates in one segment.

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated balance sheet as of September 30, 2023, 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 and nine months ended September 30, 2023 and 2022 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 and nine month periods are also unaudited. The condensed consolidated results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the results to be expected for the year ending

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

December 31, 2023 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2022 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, 2022.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of money market funds, commercial paper, U.S. Treasury securities, and short-term corporate debt securities.

Restricted Cash

As of September 30, 2023 and December 31, 2022, the Company held $ 0.9 million and $ 1.2 million, respectively, of restricted cash as collateral for a letter of credit related to the Company's amended office space lease. See Note 7.

Marketable Securities

Marketable securities consist of investment grade short to intermediate-term fixed income investments that have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in fixed income securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase, including those that have maturity dates beyond one year from the balance sheet date, are classified as current assets on the condensed consolidated balance sheets due to their highly liquid nature and availability for use in current operations.

Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive income (loss) on the condensed consolidated balance sheets Realized gains and losses as well as credit losses, if any, on marketable securities are included in other income, net. Interest on marketable securities is included in other income, net. The Company evaluated the underlying credit quality and credit ratings of the issuers during the period. To date, no such credit losses have occurred or have been recorded. The cost of investments sold is based on the specific-identification method.

Trade Receivables, net

The Company's trade accounts receivable consists of amounts due primarily from pharmaceutical wholesalers and specialty pharmacy providers in the United States and Canada (collectively, its "Customers") related to sales of ZORYVE and have standard payment terms. For certain Customers, the trade accounts receivable for the Customer is net of distribution service fees, prompt pay discounts, and other adjustments. The Company monitors the financial performance and creditworthiness of its Customers so that it can properly assess and respond to changes in their credit profile. The Company will reserve against trade accounts receivable for estimated credit losses that may arise and any amounts determined to be uncollectible will be written off against the reserve when it is probable that the receivable will not be collected. The reserve amount for estimated losses was not material as of September 30, 2023 and December 31, 2022.

Inventory

The Company values its inventories at the lower-of-cost or net realizable value. The Company determines the cost of its inventories, which includes costs related to products held for sale in the ordinary course of business, products in process of production for such sale, and items to be currently consumed in the production of goods to be available for sale, on a first-in, first-out (FIFO) basis. Due to the nature of the Company's supply chain process, inventory that is owned by the Company is physically stored at third-party warehouses, logistics providers, and contract manufacturers. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and writes down any excess and obsolete inventories to their net realizable value in the period in which the impairment is first identified. If they occur, such charges are recorded as a component of cost of sales in the condensed consolidated statements of operations. The Company capitalizes inventory costs associated

with products following regulatory approval when future commercialization is considered probable and the future economic benefit is expected to be realized. Products that may be used in clinical development programs are excluded from inventory and their costs are charged to research and development expense in the condensed consolidated statement of operations as incurred, as long as they do not have an alternative use. Prior to the initial date regulatory approval is received, costs related to the production of inventory were recorded as research and development expense on the Company's condensed consolidated statements of operations in the period incurred.

Intangible Assets, net

The Company paid a milestone payment of $ 7.5 million to AstraZeneca in the third quarter of 2022 related to the FDA approval and launch of ZORYVE. This milestone payment was capitalized as an intangible asset and will be amortized to cost of sales over its useful life of 10 years from the date of first commercial sale, as this is the minimum amount of time that the related License Agreement will be in effect. See Note 6. Amortization expense for the three and nine months ended September 30, 2023 was $ 188,000 and $ 563,000 , respectively. Amortization expense for the three and nine months ended September 30, 2022 was $ 125,000 .

Estimated future amortization expense for the intangible assets subsequent to September 30, 2023 is as follows (in thousands):

		Amounts
2023 (October through December)	$	188
2024		750
2025		750
2026		750
2027		750
Thereafter		3,438
Total amortization	$	6,626

The Company evaluates its long-lived assets, including intangibles, for impairment whenever events or changes in circumstance indicate that the carrying value of an asset might not be fully recoverable. To do so, the Company compares the carrying value of the intangible asset to the undiscounted net cash flows over its remaining useful life, and if not recoverable, will estimate the fair value of the asset. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

Valuation of Other Investments

The Company reviews agreements it enters into with third-party entities, pursuant to which the Company may have a variable interest in the entity, in order to determine if the entity is a variable interest entity (VIE). If the entity is a VIE, the Company assesses whether or not it is the primary beneficiary of that entity. In determining whether the Company is the primary beneficiary of an entity, the Company applies a qualitative approach that determines whether it has both (i) the power to direct the economically significant activities of the entity and (ii) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. If the Company determines it is the primary beneficiary of a VIE, it consolidates that VIE into the Company's condensed consolidated financial statements. The Company's determination about whether it should consolidate such VIEs is made continuously as changes to existing relationships or future transactions may result in a consolidation or deconsolidation event. The Company currently does not consolidate any VIEs.

The Company accounts for its equity interest in common stock in Iolyx Therapeutics Inc. ("Iolyx", formerly known as Hawkeye Therapeutics, Inc.) in accordance with Accounting Standards Codification ("ASC") 321, Investments – Equity Securities ("ASC 321"). Under ASC 321, the Company elects to utilize the allowed "measurement alternative", and measures the investment at cost, minus impairment and any changes, plus or minus, resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. The carrying value is included in Other assets and changes are recognized in Other income (expense). See Note 6.

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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 3, 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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation on property and equipment is calculated using the straight-line method over the estimated useful lives of the assets which range from two to five years . Leasehold improvements are depreciated on a straight-line basis over the shorter of their estimated useful lives or lease terms. Maintenance and repairs are expensed as incurred. The Company reviews the carrying values of its property and equipment for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. There were no impairments recognized during the three and nine months ended September 30, 2023 and 2022.

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Leases

The Company determines if an arrangement is or contains a lease at inception. Right-of-use (ROU) assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The classification of the Company's leases as operating or finance leases, along with the initial measurement and recognition of the associated ROU assets and lease liabilities, is performed at the lease commencement date. The measurement of lease liabilities is based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate, based on the information available at commencement date, to determine the present value of lease payments when its leases do not provide an implicit rate. The Company uses the implicit rate when readily determinable. The ROU asset is based on the measurement of the lease liability, includes any lease payments made prior to or on lease commencement and is adjusted for lease incentives and initial direct costs incurred, as applicable. Lease expense for the Company's operating leases is recognized on a straight-line basis over the lease term. The Company considers a lease term to be the non-cancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The Company's lease agreements includes lease and non-lease components and the Company has elected to not separate such components for all classes of assets. Further, the Company elected the short-term lease exception policy, permitting it to not apply the recognition requirements of this standard to leases with terms of 12 months or less (short-term leases) for all classes of assets.

Accrued and Prepaid Nonclinical and Clinical Costs

The Company records accrued liabilities for estimated costs and prepaid costs for research and development activities conducted by third-party service providers, which include the conduct of nonclinical studies, clinical trials, and contract manufacturing activities. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities and prepaid costs balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. For the three and nine months ended September 30, 2023 and 2022, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Revenues

Pursuant to Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when a customer obtains control of promised goods or services. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

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Product Revenue, Net

The Company sells its product to its Customers in the United States and Canada. The Company's Customers subsequently resell the products to pharmacies, health care providers, and patients. In accordance with ASC 606, the Company recognizes net product revenue from sales when the Customers obtain control of the Company's products, which typically occurs upon delivery to the Customer. The Company's payment terms are generally between 31 - 65 days.

Revenue from product sales are recorded at the net sales price, or "transaction price," which includes estimates of variable consideration that result from (a) invoice discounts for prompt payment and distribution service fees, (b) government and private payer rebates, chargebacks, discounts and fees, (c) product returns and (d) costs of co-pay assistance programs for patients, as well as other incentives. Reserves are established for the estimates of variable consideration based on the amounts earned or to be claimed on the related sales. The reserves are classified as reductions to trade receivables, net if payable to a Customer or accrued liabilities if payable to a third party. Where appropriate, the Company utilizes the expected value method to determine the appropriate amount for estimates of variable consideration based on factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Distribution Service Fees: The Company engages with wholesalers and specialty pharmacies to distribute its products to end customers. The Company pays the wholesalers and certain specialty pharmacies a fee for services such as: data reporting, inventory management, chargeback administration, and service level commitment. The Company estimates the amount of distribution services fees to be paid to the Customers and adjusts the transaction price with the amount of such estimate at the time of sale to the Customer.

Prompt Pay Discounts: The Company provides its Customers with a percentage discount on their invoice if the Customers pay within the agreed upon timeframe. The Company estimates the probability of Customers paying promptly based on the percentage of discount outlined in the purchase agreement between the two parties, and deducts the full amount of these discounts from its gross product revenue and accounts receivable at the time such revenue is recognized.

Product Returns: The Company provides Customers a return credit in the amount of the purchase price paid by Customers for all products returned in accordance with the Company's returned goods policy. In the initial sales period, the Company estimates its provision for sales returns based on industry data and adjusts the transaction price for such estimate at the time of sale to the Customer. Once sufficient history has been collected for product returns, the Company will utilize that history to inform its returns estimate. Once the product is returned, it is destroyed. The Company does not record a right-of-return asset.

Chargeback: A chargeback is the difference between the manufacturer's invoice price to the wholesaler and the wholesaler's customer's contract price. The wholesaler tracks these sales and "charges back" the manufacturer for the difference between the negotiated prices paid between the wholesaler's customers and wholesaler's acquisition cost. The Company estimates the percentage of goods sold that are eligible for chargeback and adjusts the transaction price for such discount at the time of sale to the Customer.

Co-payment Assistance: Patients who meet certain eligibility requirements may receive co-payment assistance. The Company records contra-revenue for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

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Rebates and Discounts: The Company accrues rebates for contractually agreed-upon discounts with commercial insurance companies and mandated discounts under government programs such as the Medicaid Drug Rebate Program in the United States. The Company's estimates for expected utilization of commercial insurance rebates are based on data received from its customers. The Company's estimates for rebates under government programs are based on statutory discount rates and expected utilization as well as historical data it has accumulated since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters' unpaid rebates. If actual rebates vary from estimates, the Company may need to adjust accruals, which would affect revenue in the period of adjustment.

Other Revenues

Other revenues is related to the Huadong License and Collaboration Agreement. See Note 6. The Company evaluated the agreement with Huadong and determined that it is within the scope of ASC 606. The Company applied the five-step model as required by ASC 606 to determine revenue recognition.

The nonrefundable upfront payment that the Company received in September 2023 in connection with the transfer of the license and related know-how to Huadong was determined to be a distinct performance obligation, and therefore was recognized in Other revenues.

The Company evaluated whether the development and regulatory milestones are considered probable of being reached and determined that their achievement is highly dependent on factors outside of the Company's control. Therefore, these payments are subject to significant revenue reversal and are therefore not included in the transaction price. At the end of each reporting period, the Company will re-evaluate the probability of achievement of each milestone and, if necessary, adjust its estimate of the overall transaction price and accordingly recognize the related revenue once the probability of significant reversal of revenue is low. Any such adjustments are recorded on a cumulative catch-up basis, and would be reported in Other revenues in the period of adjustment.

The sales milestones and royalties will be recognized in Other revenues when the related sales occur.

Cost of Sales

Cost of sales includes direct and indirect costs related to the manufacturing and distribution of ZORYVE, including raw materials, third-party manufacturing costs, packaging services, freight-in, third-party royalties payable on the Company's net product revenue, and amortization of certain intangible assets associated with ZORYVE. Cost of sales may also include period costs related to certain inventory warehouse and distribution operations and inventory adjustment charges. The Company began capitalizing inventory costs upon FDA approval of ZORYVE on July 29, 2022. As a result, manufacturing and other inventory costs incurred prior to FDA approval of ZORYVE were expensed and, therefore, are not included in cost of sales.

Research and Development

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, license fees, stock-based compensation expense, materials, supplies, and the cost of services provided by outside contractors. All costs associated with research and development are expensed as incurred. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods are received or services are rendered. Such payments are evaluated for current or long-term classification based on when they will be realized.

The Company has entered into, and may continue to enter into, license agreements to access and utilize certain technology. In each case, the Company evaluates if the license agreement results in the acquisition of an asset or a business. To date, none of the Company's license agreements have been considered an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval that do not meet the definition of a derivative, are immediately recognized as research and development expense when paid or become payable, provided there is no alternative future use of the rights in other research and development projects.

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Stock-Based Compensation

The Company accounts for share-based payments at fair value. The fair value of stock options is measured using the Black-Scholes option-pricing model. For share-based awards that vest subject to the satisfaction of a service requirement, the fair value measurement date for such awards is the date of grant and the expense is recognized on a straight-line basis, over the expected vesting period. For share-based awards that vest subject to a performance condition, the Company will recognize compensation cost for awards if and when the Company concludes that it is probable that the awards with a performance condition will be achieved on an accelerated attribution method. The Company accounts for forfeitures as they occur.

Income Taxes

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. The Company records a valuation allowance to reduce deferred tax assets to an amount for which realization is more likely than not. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes the tax benefit from an uncertain tax position if it is more likely than not that the tax position will be sustained upon examination by the tax authorities, based on the merits of the position. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties incurred in relation to the unrecognized tax benefits.

Income tax expense of $ 3.0 million and $ 3.1 million for the three and nine months ended September 30, 2023, respectively, were primarily due to income tax expense related to withholding tax on the Huadong License and Collaboration Agreement. See Note 6.

Foreign Currency Translation

The Company translates the assets and liabilities of its foreign subsidiaries where the local currencies have been determined to be the functional currencies into U.S. dollars using current exchange rates. Adjustments for foreign currency translation adjustments are recognized in other comprehensive income (loss) in the condensed consolidated statements of operations and comprehensive loss. The earnings or loss of these subsidiaries are translated in U.S. dollars using average exchange rates in effect during each reporting period.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive. Shares of common stock subject to repurchase are excluded from the weighted-average shares.

Recently Adopted Accounting Pronouncements

There have been no new accounting pronouncements issued or effective that are expected to have a material impact on the Company's condensed consolidated financial statements.

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3. 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):

	September 30, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 107,471	$ —	$ —	$ 107,471
Commercial paper	—	26,516	—	26,516
U.S. Treasury securities	93,126	—	—	93,126
Total assets	$ 200,597	$ 26,516	$ —	$ 227,113

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

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 53,641	$ —	$ —	$ 53,641
Commercial paper	—	177,099	—	177,099
Corporate debt securities	—	13,821	—	13,821
U.S. Treasury securities	165,028	—	—	165,028
Total assets	$ 218,669	$ 190,920	$ —	$ 409,589

(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.

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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):

	September 30, 2023			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 107,471	$ —	$ —	$ 107,471
Total cash and cash equivalents	$ 107,471	$ —	$ —	$ 107,471
Marketable securities:				
Commercial paper	$ 26,516	$ —	$ —	$ 26,516
U.S. Treasury securities	93,195	5	(74)	93,126
Total marketable securities	$ 119,711	$ 5	$ (74)	$ 119,642

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

	December 31, 2022			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 53,641	$ —	$ —	$ 53,641
Corporate debt securities	—	—	—	—
Total cash and cash equivalents	$ 53,641	$ —	$ —	$ 53,641
Marketable securities:				
Commercial paper	$ 177,099	$ —	$ —	$ 177,099
Corporate debt securities	13,890	—	(69)	13,821
U.S. Treasury securities	166,045	7	(1,024)	165,028
Total marketable securities	$ 357,034	$ 7	$ (1,093)	$ 355,948

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

Realized gains or losses on investments for the three and nine months ended September 30, 2023 and 2022 were no t material. As of September 30, 2023, 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 September 30, 2023 and December 31, 2022, 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.

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4. Balance Sheet Components

Inventories

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

	September 30, 2023	December 31, 2022
Raw materials	$ 11,200	$ 5,659
Work in progress	367	395
Finished goods	2,346	1,460
Total inventories	$ 13,913	$ 7,514

Prepaid Expenses and Other Current Assets

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

	September 30, 2023	December 31, 2022
Prepaid co-pay assistance program	$ 4,948	$ 3,226
Prepaid insurance	852	956
Prepaid clinical trial costs	4,196	172
Other prepaid expenses and current assets	10,184	6,257
Total prepaid expenses and other current assets	$ 20,180	$ 10,611

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued compensation	$ 13,741	$ 14,000
Accrued sales deductions	7,308	1,567
Clinical trial accruals	4,629	7,896
Accrued expenses and other current liabilities	2,317	4,860
Total accrued liabilities	$ 27,995	$ 28,323

5. Property and Equipment, net

Property and equipment, net consists of the following (in thousands):

	September 30, 2023	December 31, 2022
Computer hardware	$ 1,128	$ 983
Furniture and fixtures	661	379
Software	104	104
Leasehold improvements	1,568	1,568
Property and equipment, gross	3,461	3,034
Less accumulated depreciation	(1,726)	(1,153)
Property and equipment, net	$ 1,735	$ 1,881

Depreciation expense was $ 200,000 and $ 573,000 for the three and nine months ended September 30, 2023, respectively, and $ 157,000 and $ 462,000 for the three and nine months ended September 30, 2022. Leasehold improvements are depreciated over the term of the lease, which is the shorter of the improvements' expected useful lives and the lease term. All other fixed asset depreciation is recorded using the straight-line method over the estimated useful lives of the assets (two to five years).

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6. License Agreements & Acquisition

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. The Company may also potentially receive additional payments: (i) up to an aggregate amount of $ 24.0 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.

Other revenue and related income tax expense recognized under the Huadong agreement was $ 30.0 million and $ 3.0 million, respectively, for the three and nine months ended September 30, 2023. See Note 2.

AstraZeneca License Agreement

In July 2018, the Company entered into an exclusive license agreement, or the AstraZeneca License Agreement, with AstraZeneca AB (AstraZeneca), granting the Company a worldwide exclusive license, with the right to sublicense through multiple tiers, under certain AstraZeneca-controlled patent rights, know-how and regulatory documentation, to research, develop, manufacture, commercialize and otherwise exploit products containing roflumilast in topical forms, as well as delivery systems sold with or for the administration of roflumilast, or collectively, the AZ-Licensed Products, for all diagnostic, prophylactic and therapeutic uses for human dermatological indications, or the Dermatology Field. Under this agreement, the Company has sole responsibility for development, regulatory, and commercialization activities for the AZ-Licensed Products in the Dermatology Field, at its expense, and it shall use commercially reasonable efforts to develop, obtain and maintain regulatory approvals for, and commercialize the AZ-Licensed Products in the Dermatology Field in each of the United States, Italy, Spain, Germany, the United Kingdom, France, China, and Japan.

The Company paid AstraZeneca an upfront non-refundable cash payment of $ 1.0 million and issued 484,388 shares of Series B convertible preferred stock, valued at $ 3.0 million on the date of the AstraZeneca License Agreement, which were both recorded in research and development expense. The Company subsequently paid AstraZeneca the first milestone cash payment of $ 2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product, which was recorded in research and development expense. In the third quarter of 2022, the Company paid $ 7.5 million to AstraZeneca as a result of the approval of ZORYVE, which was recorded as an intangible asset. The Company is amortizing the intangible asset to cost of sales over its useful life of 10 years from

the date of first commercial sale as this is the minimum amount of time that the related License Agreement will be in effect. Amortization expense during the three and nine months ended September 30, 2023 was not material.

The Company has agreed to make additional cash payments to AstraZeneca of up to an aggregate of $ 5.0 million upon the achievement of specified regulatory approval milestones with respect to the AZ-Licensed Products, and payments up to an additional aggregate amount of $ 15.0 million upon the achievement of certain aggregate worldwide net sales milestones, of which $ 5.0 million will become payable when the Company achieves $ 100.0 million in worldwide sales. With respect to any AZ-Licensed Products the Company commercializes under the AstraZeneca License Agreement, it will pay AstraZeneca a low to high single-digit percentage royalty rate on the Company's, its affiliates' and its sublicensees' net sales of such AZ-Licensed Products, subject to specified reductions, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country. As a result of the commercialization of ZORYVE in August 2022, the Company began accruing royalties payable to AstraZeneca, which are recorded in cost of sales and accrued liabilities. Royalty expense during the three and nine months ended September 30, 2023 was not material.

There were no milestone payments made or payable in connection with AZ-Licensed Products for the three and nine months ended September 30, 2023 and 2022.

Hengrui Exclusive Option and License Agreement

In January 2018, the Company entered into an exclusive option and license agreement, or the Hengrui License Agreement, with Jiangsu Hengrui Medicine Co., Ltd. (Hengrui), whereby Hengrui granted the Company an exclusive option to obtain certain exclusive rights to research, develop, and commercialize products containing the compound designated by Hengrui as ivarmacitinib, a Janus kinase type 1 inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Japan, and the European Union (including for clarity the United Kingdom). The Company made a $ 0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui Option and License Agreement, which was recorded as research and development expense. In December 2019, the Company exercised its exclusive option under the agreement, for which it made a $ 1.5 million cash payment, which was recorded in research and development expense, and also contemporaneously amended the agreement to expand the territory to additionally include Canada. In addition, the Company has agreed to make cash payments of up to an aggregate of $ 20.5 million upon achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional aggregate of $ 200.0 million in sales-based milestones based on certain aggregate annual net sales volumes with respect to a licensed product.

With respect to any products the Company commercializes under the Hengrui License Agreement, it will pay tiered royalties to Hengrui on net sales of each licensed product by the Company, or its affiliates, or its sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. The Company is obligated to pay royalties until the later of (1) expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, the Company is obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income it receives from sublicensees of its rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance.

In June 2022, the Company entered into a side letter agreement with Hengrui and one of its subsidiaries to extend certain rights and obligations under the Hengrui License Agreement to the subsidiary under specified circumstances, including a change of control of such subsidiary.

There were no payments made or due in connection with Hengrui for the three and nine months ended September 30, 2023 and 2022.

Iolyx Collaboration Agreement

In June 2019, the Company entered into a collaboration agreement, or Iolyx Agreement, with Iolyx, a related party with common ownership, for the development of clinical compounds, including roflumilast. The Iolyx

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Agreement grants Iolyx an exclusive license to certain intellectual property developed under the agreement as it relates to the development of new applications of such compounds.

Contemporaneously with the execution of the Iolyx Agreement, the Company entered into a stock purchase agreement, purchasing 995,000 shares of Iolyx's common stock at $ 0.0001 per share, representing 19.9 % of the outstanding common stock of Iolyx at the time of the purchase.

In accordance with the Iolyx Agreement and in conjunction with Iolyx's sale and issuance of Series A convertible preferred stock, Iolyx issued 4,256,686 fully-paid fully-vested shares of common stock to the Company. As a result of this issuance of common stock, the Company recorded $ 0.4 million in Other revenue in the three months ended June 30, 2023. Also, in conjunction with the issuance of the Series A convertible preferred stock, the Company revalued its common stock acquired with the execution of the Iolyx agreement, resulting in $ 0.1 million recognized in Other income.

There are no other upfront payments, milestones, or royalties pursuant to the Iolyx Agreement. The Company determined that Iolyx is a VIE for which consolidation is not required as it is not the primary beneficiary.

Ducentis Biotherapeutics LTD Acquisition

On September 7, 2022, the Company entered into a Share Purchase Agreement with Ducentis Biotherapeutics LTD (Ducentis), pursuant to which the Company acquired (the "Acquisition") all of the outstanding equity interests in Ducentis for (i) 610,258 shares of the Company common stock valued at approximately $ 12.5 million and $ 15.9 million in cash, inclusive of liabilities acquired, and (ii) contingent payments, the amount of which is indeterminable until achieved, which may become payable upon the achievement of certain development, regulatory, and commercial milestones. The Company currently estimates that these contingent payments may be up to an aggregate of approximately $ 400 million (although the actual amount may differ depending on whether the applicable milestones are achieved). In addition, if applicable, the Company will make payments amounting to a mid-single-digit percentage of any annual net sales of Ducentis's products exceeding $ 1.5 billion. As of September 30, 2023, none of the milestones were probable of achievement and, accordingly, no amounts have been recognized in the accompanying unaudited condensed consolidated financial statements with respect to these contingent payments.

Under the terms of the Share Purchase Agreement, the Company will develop and seek FDA approval of a therapeutic product containing Ducentis's DS-234 product candidate, now ARQ-234, for an atopic dermatitis indication, and if FDA approval of ARQ-234 is obtained by the Company, to launch it in the United States.

The Company accounted for this purchase as an in-process research and development asset acquisition and in the third quarter of 2022 recorded a charge to research and development expense in the amount of $ 29.6 million, which was not tax deductible.

7. Commitments and Contingencies

Operating Lease

The Company leases a facility in Westlake Village, California under an operating lease that commenced in February 2019 and was amended in April 2020 in order to relocate to a new expanded space comprising 22,643 square feet, for which the Company recognized the ROU asset and lease liability. The lease terminates 91 months after December 31, 2020, with a renewal option for a term of five years . The Company will have a one-time option to cancel the lease after month 67 .

The amended lease agreement also required the Company to have an available letter of credit of $ 1.5 million upon occupying the space, which is allowed to be reduced throughout the lease period as rent obligations are met. Accordingly, in November 2020, the Company entered into a letter of credit for $ 1.5 million, which it secured with a restricted cash account in the same amount. In March 2022 and 2023, the Company reduced the letter of credit and related restricted cash account to $ 1.2 million and $ 0.9 million, respectively.

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The minimum annual rental payments of the Company's operating lease liability as of September 30, 2023 are as follows (in thousands):

		Amounts
2023 (October through December)	$	241
2024		995
2025		1,024
2026		1,054
2027		1,087
2028		653
Total minimum lease payments	$	5,054
Less: Amounts representing interest		(769)
Present value of future minimum lease payments	$	4,285
Current portion operating lease liability		715
Operating lease liability, noncurrent		3,570
Total operating lease liability	$	4,285

Straight-line rent expense recognized for operating leases was $ 184,000 and $ 551,000 for the three and nine months ended September 30, 2023, and $ 186,000 and $ 530,000 for the three and nine months ended September 30, 2022, respectively. There were no significant variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases for the three and nine months ended September 30, 2023 and 2022.

The following information represents supplemental disclosure for the condensed consolidated statements of cash flows related to the Company's operating lease (in thousands):

	Nine Months Ended September 30,			
	2023		2022	
Cash flows from operating activities				
Cash paid for amounts included in the measurement of lease liabilities	$	723	$	547

The following summarizes additional information related to the operating lease:

	September 30, 2023	
Weighted-average remaining lease term (in years)	4.8	
Weighted-average discount rate	7.0	%

Manufacturing Agreements

The Company has entered into manufacturing supply agreements for the commercial supply of ZORYVE which include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately $ 1.2 million within the next three months, and then approximately $ 0.8 million per year for 2024 and 2025. This amount does not represent all of the Company's anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

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Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless, and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by the provisions of the Company's Bylaws and the Delaware General Corporation Law. The Company currently has directors' and officers' insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes any potential loss exposure under these indemnification agreements in excess of applicable insurance coverage is minimal.

License Agreements

The terms of certain of the Company's license agreements require us to pay potential future milestone payments based on product development success. The amount and timing of such obligations are unknown or uncertain. See Note 6.

8. 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.

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 on July 29, 2022, the tranche B term loans were funded and the Company received $ 125.0 million on August 2, 2022. The tranche C term loan is available following the achievement of a net product revenue milestone of $ 110.0 million, calculated on a trailing six month basis. The tranche C term loan will remain available for funding until September 30, 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. On September 30, 2023, the rate was 12.88 %. Starting in July 2023, the Secured Overnight Financing Rate (SOFR) for a term of one month was substituted for the benchmark rate. 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 (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.

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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 has 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; provided, however, that such financial covenant shall not apply if the Company's average market capitalization over the trailing five day period prior to the last day of any measurement month is equal to or in excess of $ 400.0 million. The Company was in compliance with all financial covenants under the Loan Agreement as of September 30, 2023.

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 and at each balance sheet date through September 30, 2023, the fair value of the embedded derivative was determined to be immaterial and will be remeasured at fair value each reporting period with any future changes in fair value reported in earnings.

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.

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 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 September 30, 2023. See Note 12 for additional information.

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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 September 30, 2023 and December 31, 2022, the effective interest rate was 14.79 % and 13.79 %, respectively. Interest expense relating to the term loan for the three and nine months ended September 30, 2023 was $ 7.6 million and $ 22.0 million, respectively. Interest expense relating to the term loan for the three and nine months ended September 30, 2022 was $ 4.9 million and $ 8.7 million, respectively.

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

	September 30, 2023	December 31, 2022
Principal loan balance	$ 200,000	$ 200,000
Accrued final fee	4,118	1,871
Unamortized debt issuance costs	(3,335)	(4,102)
Long-term debt, net	$ 200,783	$ 197,769

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.

9. Stockholders' Equity

Common Stock

The holders of the Company's common stock have one vote for each share of common stock. Common stockholders are entitled to dividends when, as, and if declared by the board of directors. The holders have no preemptive or other subscription rights and there are no redemption or sinking fund provisions with respect to such shares. As of September 30, 2023, no dividends had been declared by the board of directors.

The Company reserved the following shares of common stock for issuance as follows:

	September 30, 2023	December 31, 2022
Options issued and outstanding	8,228,270	7,476,223
Common stock awards available for grant under employee incentive plans	3,927,638	3,784,386
Restricted stock units outstanding	2,924,356	1,576,529
Total common stock reserved	15,080,264	12,837,138

Authorized Share Capital

On February 4, 2020, the Company's certificate of incorporation was amended and restated to provide for 300,000,000 authorized shares of common stock with a par value of $ 0.0001 per share and 10,000,000 authorized shares of preferred stock with a par value of $ 0.0001 per share. There were no shares of preferred stock outstanding as of September 30, 2023 and December 31, 2022.

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10. Stock-Based Compensation

In January 2020, the Company's board of directors approved the 2020 Equity Incentive Plan (2020 Plan), which became effective January 30, 2020 in connection with the IPO. The 2020 Plan serves as the successor incentive award plan to the Company's 2017 Equity Incentive Plan (2017 Plan) and initially reserved 2,134,000 shares of common stock available for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit (RSU) awards, and other stock-based awards, plus 1,550,150 shares of common stock that were reserved for issuance pursuant to future awards under the 2017 Plan at the time the 2020 Plan became effective, plus shares represented by awards outstanding under the 2017 Plan that are forfeited or lapsed unexercised and which following the effective date of the 2020 Plan are not issued under the 2017 Plan. In addition, the 2020 Plan reserve will increase on January 1 of each year beginning in 2021 through 2030, by an amount equal to the lesser of (a) four percent of the shares of stock outstanding (on an as converted basis) on the day immediately prior to the date of increase and (b) such smaller number of shares of stock as determined by the Company's board of directors; provided, however, that no more than 11,000,000 shares of stock may be issued upon the exercise of incentive stock options. Accordingly, on January 1, 2023, 2022 and 2021, the 2020 Plan reserve increased by 2,442,090 , 2,013,830 and 1,747,112 shares, respectively. As of September 30, 2023, the Company had 1,487,426 shares available for future grant under the 2020 Plan.

The 2020 Plan provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors, and consultants of the Company under terms and provisions established by the board of directors. Under the terms of the 2020 Plan, options may be granted at an exercise price not less than fair market value. The Company generally grants stock-based awards with service conditions. Options granted typically vest over a four-year period but may be granted with different vesting terms.

Following the Company's IPO and in connection with the effectiveness of the Company's 2020 Plan, the 2017 Plan terminated and no further awards will be granted under that plan. However, all outstanding awards under the 2017 Plan will continue to be governed by their existing terms.

In December 2021, the Company's board of directors approved the 2022 Employment Inducement Incentive Plan (2022 Plan). The 2022 Plan initially reserved 1,250,000 shares of common stock available for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, RSU awards, and other stock-based awards. In November 2022, the 2022 Plan reserve was increased by 1,500,000 . As of September 30, 2023, the Company had 915,425 shares available for future grant under the 2022 Plan.

Stock Option Activity

The following summarizes option activity (in thousands, except share amounts):

	Number of Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance—December 31, 2022	7,476,223	$ 19.93	7.98	$ 18,667
Granted	1,608,110	$ 12.67		
Exercised	(239,517)	$ 4.45		
Forfeited	(479,288)	$ 20.48		
Expired	(137,258)	$ 26.75		
Balance—September 30, 2023	8,228,270	$ 18.81	7.51	$ 3,269
Exercisable—September 30, 2023[1]	4,571,413	$ 18.62	6.59	$ 3,269

(1) Options exercisable includes early exercisable options.

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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 September 30, 2023. The intrinsic value of options exercised for the nine months ended September 30, 2023 was $ 1.2 million.

The total grant-date fair value of the options vested during the nine months ended September 30, 2023 was $ 22.1 million. The weighted-average grant-date fair value of employee options granted during the nine months ended September 30, 2023 was $ 8.76 .

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, 2022	1,576,529	$ 20.73
Granted	2,029,000	$ 14.36
Vested	(414,523)	$ 21.21
Forfeited	(266,650)	$ 18.81
Unvested Balance—September 30, 2023	2,924,356	$ 18.47

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 . There were no RSU grants prior to January 1, 2020.

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 4,058	$ 3,448	$ 11,966	$ 9,437
Selling, general, and administrative	5,941	5,341	18,090	13,981
Total stock-based compensation expense	$ 9,999	$ 8,789	$ 30,056	$ 23,418

As of September 30, 2023, there was $ 46.2 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 September 30, 2023, there was $ 40.0 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 3.0 years.

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In determining the fair value of the stock options granted, the Company uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment.

Fair value of common stock — The Company uses its closing stock price as reported on Nasdaq on the grant date for the fair value of its stock.

Expected Term — The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding. The Company uses the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to determine the expected term.

Expected Volatility — Beginning in 2022, having over two years of trading history, the Company began using solely its own historical stock price for expected volatility.

Risk-Free Interest Rate —The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Dividend Yield —The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero .

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:

	Nine Months Ended September 30, 2023	Year Ended December 31, 2022
Expected term (in years)	5.3 – 6.1	5.4 – 6.1
Expected volatility	75.2 – 77.1 %	77.9 – 82.1 %
Risk-free interest rate	3.5 – 4.7 %	1.4 – 4.2 %
Dividend yield	— %	— %

2020 Employee Stock Purchase Plan

The Company adopted the 2020 Employee Stock Purchase Plan, or the ESPP, which became effective on January 30, 2020 in connection with the IPO. The ESPP is designed to allow the Company's eligible employees to purchase shares of the Company's common stock, at semi-annual intervals, with their accumulated payroll deductions. Under the ESPP, participants are offered the option to purchase shares of the Company's common stock at a discount during a series of successive offering periods. The option purchase price will be the lower of 85 % of the closing trading price per share of the Company's common stock on the first trading date of an offering period in which a participant is enrolled or 85 % of the closing trading price per share on the purchase date, which will occur on the last trading day of each offering period.

The ESPP is intended to qualify under Section 423 of the U.S. Internal Revenue Service Code of 1986, as amended. The maximum number of the Company's common stock which will be authorized for sale under the ESPP is equal to the sum of (a) 351,000 shares of common stock and (b) an annual increase on the first day of each year beginning in 2021 and ending in 2030, equal to the lesser of (i) 1 % of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such number of shares of common stock as determined by the Company's board of directors; provided, however, no more than 5,265,000 shares of the Company's common stock may be issued under the ESPP. Accordingly, on January 1, 2023, 2022 and 2021, the ESPP reserve increased by 610,522 , 503,457 , and 436,778 shares, respectively. As of September 30, 2023, the Company had 1,524,787 shares available for future grant under the ESPP.

Stock-based compensation expense related to the ESPP was $ 234,000 and $ 781,000 for the three and nine months ended September 30, 2023, respectively, and $ 216,000 and $ 637,000 for the three and nine months ended September 30, 2022, respectively.

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11. Net Loss Per Share

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 September 30,	
	2023	2022
Stock options to purchase common stock	8,228,270	7,480,040
Early exercised options subject to future vesting	3,698	18,573
RSUs subject to future vesting	2,924,356	1,567,946
ESPP shares subject to future issuance	73,252	55,735
Total	11,229,576	9,122,294

12. Subsequent Events

Financing

On October 24, 2023, the Company completed an offering relating to the sale of securities consisting of: (i) 32,500,000 shares of the Company's common stock at $ 2.50 per share, and (ii) 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.

The aggregate net proceeds to the Company was $ 94.0 million after deducting underwriting discounts, commissions and estimated offering expenses payable by the Company.

The Company has granted the underwriters an option to purchase up to an additional 6,000,000 shares of the Company's common stock at $ 2.50 per share. This option is exercisable, in whole or in part, for a period of 30 days from the date of the underwriting agreement executed in connection with the offering.

Loan Agreement Amendment

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 remove the market capitalization threshold, and (iii) include an additional minimum financing covenant. 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 September 30, 2023.

Pursuant to the amendment, the modified financial covenant requires the Company to generate a minimum net product revenue equal to 75 % of each month's 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. Any failure by the Company to raise such net cash proceeds during the specified period shall be an immediate event of default.

See Note 8 for additional information regarding the Loan Agreement.

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, 2022 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, 2022, 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 an early 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 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, in August 2022 after obtaining our original 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 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. In addition, we had our first commercial launch outside of the United States after receiving regulatory approval from Health Canada of ZORYVE in April 2023 for the treatment of plaque psoriasis in individuals 12 years or age or older. ZORYVE 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 addition to the approval of ZORYVE for plaque psoriasis, we are also developing roflumilast cream for the treatment of atopic dermatitis. In atopic dermatitis, we have successfully completed three pivotal Phase 3 clinical studies: 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 also initiated INTEGUMENT-OLE, an open label extension study of the long-term safety of roflumilast cream 0.15% in individuals 6 years of age or older and roflumilast 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 also submitted a supplemental new drug application ("sNDA") for topical roflumilast 0.15% for the treatment of mild-to-moderate atopic dermatitis in individuals 6 years of age or older, creating potential for FDA action as early as the third quarter of 2024. Based on the positive results from the INTEGUMENT-PED study in September 2023, we expect to submit a subsequent sNDA for children ages 2 to 5 years of age following the potential initial approval of roflumilast cream 0.15% for treatment of mild-to-moderate atopic dermatitis in individuals 6 years of age or older.

We are also developing a topical foam formulation of roflumilast and have successfully completed pivotal Phase 3 clinical trials in both seborrheic dermatitis and scalp and body psoriasis. In seborrheic dermatitis, the FDA accepted our New Drug Application (NDA) for the treatment of moderate-to-severe seborrheic dermatitis in April 2023 with a target action date of December 16, 2023. If approved, we would expect to launch roflumilast foam for the treatment of seborrheic dermatitis in the first quarter of 2024. In scalp and body psoriasis, we announced positive topline data in September 2022 and we expect the data to be a sufficient basis for an sNDA submission following the potential approval of roflumilast foam for treatment of seborrheic dermatitis.

Beyond topical roflumilast, 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 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 roflumilast cream in that indication, if approved. ARQ-234 could potentially be used to treat other inflammatory conditions as well.

Since our inception in 2016, we have invested a significant portion of our efforts and financial resources in clinical development activities. We only recently started generating revenue from product sales and have historically funded our operations primarily with the net proceeds from equity and debt offerings. Prior to 2023, we received approximately $827.2 million in net cash proceeds through equity offerings, approximately $195.2 million in net proceeds under the Loan Agreement with SLR, and $14.5 million in net proceeds related to shares issued under our ATM. See Notes 1 and 8 to the condensed consolidated financial statements for additional information.

We have incurred net losses in each year since inception, including net losses of $44.8 million and $107.7 million for the three months ended September 30, 2023 and 2022, respectively, and net losses of $195.9 million and $239.4 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $915.6 million and cash, cash equivalents, restricted cash, and marketable securities of $228.0 million. On October 24, 2023, we completed a public offering of shares of our common stock and prefunded warrants to purchase shares of our common stock, and received net proceeds of $94.0 million. As of September 30, 2023, we had $200.0 million outstanding under the Loan Agreement.

We expect to continue to incur losses and significant expenses as we commercialize ZORYVE in psoriasis 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, 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.

License Agreements & Acquisition

AstraZeneca License Agreement

In July 2018, we entered into the AstraZeneca License Agreement with AstraZeneca, granting us a worldwide exclusive license, with the right to sublicense through multiple tiers, under certain AstraZeneca-controlled patent rights, know-how and regulatory documentation, to research, develop, manufacture, commercialize, and otherwise exploit products containing roflumilast in topical forms, as well as delivery systems sold with or for the administration of roflumilast, or collectively, the AZ-Licensed Products, for all diagnostic, prophylactic and therapeutic uses for human dermatological indications, or the Dermatology Field. Under this agreement, we have sole responsibility for development, regulatory, and commercialization activities for the AZ-Licensed Products in the Dermatology Field, at our expense, and we shall use commercially reasonable efforts to develop, obtain, and maintain regulatory approvals for, and commercialize the AZ-Licensed Products in the Dermatology Field in each of the United States, Italy, Spain, Germany, the United Kingdom, France, China, and Japan.

We paid AstraZeneca an upfront non-refundable cash payment of $1.0 million and issued 484,388 shares of our Series B convertible preferred stock, valued at $3.0 million on the date of the AstraZeneca License Agreement. We subsequently paid AstraZeneca the first milestone cash payment of $2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product. We also paid AstraZeneca $7.5 million upon ZORYVE's FDA approval in plaque psoriasis. We have agreed to make additional cash payments to AstraZeneca of up to an aggregate of $5.0 million upon the achievement of specific regulatory approval milestones with respect to the AZ-Licensed Products, and payments up to an additional aggregate amount of $15.0 million upon the achievement of certain aggregate worldwide net sales milestones, of which $5.0 million will become payable when we achieve $100.0 million in worldwide sales. With respect to any AZ-Licensed Products we commercialize under the AstraZeneca License Agreement, we will pay AstraZeneca a low to high single-digit percentage royalty rate on our, our affiliates' and our sublicensees' net sales of such AZ-Licensed Products, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and ten years from the first commercial sale of such AZ-Licensed Product in such country. We began making quarterly royalty payments in the first quarter of 2023. See Note 6 to the condensed consolidated financial statements for additional information.

Hengrui Exclusive Option and License Agreement

In January 2018, we entered into the Hengrui License Agreement, with Hengrui, whereby Hengrui granted us an exclusive option to obtain certain exclusive rights to research, develop, and commercialize products containing the compound designated by Hengrui as ivarmacitinib, a JAK 1 inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Japan, and the European Union (including for clarity the United Kingdom). We made a $0.4 million upfront non-refundable cash payment to Hengrui upon execution of the Hengrui Option and License Agreement. In December 2019, we exercised our exclusive option under the agreement, for which we made a $1.5 million cash payment, and also contemporaneously amended the agreement to expand the territory to additionally include Canada. In addition, we have agreed to make cash payments of up to an aggregate of $20.5 million upon our achievement of specified clinical development and regulatory approval milestones with respect to the licensed products and cash payments of up to an additional aggregate of $200.0 million in sales-based milestones based on achieving certain aggregate annual net sales volumes with respect to a licensed product. With respect to any products we commercialize under the Hengrui License Agreement, we will pay tiered royalties to Hengrui on net sales of each licensed product by us, or our affiliates, or our sublicensees, ranging from mid single-digit to sub-teen percentage rates based on tiered annual net sales bands subject to specified reductions. We are obligated to pay royalties until the later of (1) expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (2) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis. Additionally, we are obligated to pay Hengrui a specified percentage, ranging from the low-thirties to the sub-teens, of certain non-royalty sublicensing income we receive from sublicensees of our rights to the licensed products, such percentage decreasing as the development stage of the licensed products advance.

The agreement continues in effect until the expiration of our obligation to pay royalties as described above, unless earlier terminated in accordance with the following: (1) by either party upon written notice for the other party's material breach or insolvency event if such party fails to cure such breach or the insolvency event is not dismissed within specified time periods; and (2) by us for convenience upon 90 days prior written notice to Hengrui and having discussed and consulted any potential cause or concern with Hengrui in good faith.

In June 2022, we entered into a side letter agreement with Hengrui and one of its subsidiaries to extend certain rights and obligations under the Hengrui License Agreement to the subsidiary under specified circumstances, including a change of control of such subsidiary. See Note 6 to the condensed consolidated financial statements for additional information.

Ducentis Acquisition

On September 7, 2022, we entered into a Share Purchase Agreement with Ducentis, pursuant to which we acquired all of the outstanding equity interests in Ducentis for (i) 610,258 shares of our common stock valued at approximately $12.5 million and $15.9 million in cash, inclusive of liabilities acquired, and (ii) contingent payments, the amount of which is indeterminable until achieved, which may become payable upon the achievement of certain development, regulatory, and commercial milestones. We currently, estimate that these contingent payments may be up to an aggregate of approximately $400 million (although the actual amount may differ depending on whether the applicable milestones are achieved). In addition, if applicable, we will make payments amounting to a mid-single-digit percentage of any annual net sales of Ducentis's products exceeding $1.5 billion. As of September 30, 2023, none of the milestones were probable of achievement and, accordingly, no amounts have been recognized in the accompanying condensed consolidated financial statements with respect to these contingent payments.

Under the terms of the Share Purchase Agreement, we will develop and seek FDA approval of a therapeutic product containing Ducentis's DS-234 product candidate, now ARQ-234, for an atopic dermatitis indication, and if FDA approval of ARQ-234 is obtained by us, to launch it in the United States.

Huadong License and Collaboration Agreement

In August 2023, we entered into a license and collaboration agreement ("Huadong Agreement") with Hangzhou Zhongmei Huadong Pharmaceutical Co ("Huadong"), a wholly owned subsidiary of Huadong Medicine Co., Ltd., whereby Huadong received an exclusive license for the development, manufacture, and commercialization of both the cream and foam formulations of topical roflumilast 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 Licensed Products"). 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 our approval and oversight rights.

Pursuant to the terms of the agreement, upon closing in September 2023, we 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 $3.0M, and may potentially receive additional payments (i) up to an aggregate amount of $24.0 million upon the achievement of certain development and regulatory milestones and (ii) up to an aggregate amount of $40.3 million upon the achievement of certain sales milestones. In addition, we will receive tiered low double-digit to high-teen double-digit percentage royalties on Huadong's, its affiliates' and sublicensees' total net sales of the Huadong Licensed Products, subject to certain royalty reductions.

The agreement term continues on a Licensed Product-by-Licensed Product and country-by-country and Region-by-Region basis until the expiration of the last Royalty Term for the last Licensed Product in the Territory. The Royalty Term is 10 years after the first commercial sale of such Licensed Product in such country or region, subject to certain termination clauses in the agreement. See Note 6 to the condensed consolidated financial statements.

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, we began to recognize revenue from product sales, net of rebates, chargebacks, discounts, and other adjustments. 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 Iolyx 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, 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 over the next two years approximately, due to inventory that was previously expensed. As of September 30, 2023 and December 31, 2022, the value of this inventory, mostly at the raw materials stage, was approximately $10.0 million and $14.1 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 substantial research and development expenses in the future as we develop our product candidates. In particular, we expect to incur substantial research and development expenses for the ongoing pediatric and open label extension Phase 3 trials of roflumilast cream for atopic dermatitis, ARQ-255 for alopecia areata, and 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 roflumilast cream, roflumilast 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. 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.

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 September 30, 2023 and 2022

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

	Three Months Ended September 30,		Change	
	2023	2022	$	%
	(in thousands)			
Revenues:				
Product revenue, net	$ 8,109	$ 725	$ 7,384	1018 %
Other revenue	30,000	—	30,000	*
Total revenues	38,109	725	37,384	5156 %
Operating expenses:				
Cost of sales	1,182	269	913	339 %
Research and development	26,236	69,731	(43,495)	(62) %
Selling, general, and administrative	47,595	35,473	12,122	34 %
Total operating expenses	75,013	105,473	(30,460)	(29) %
Loss from operations	(36,904)	(104,748)	67,844	(65) %
Other income (expense):				
Other income, net	2,721	1,938	783	40 %
Interest expense	(7,559)	(4,899)	(2,660)	54 %
Loss before income taxes	(41,742)	(107,709)	65,967	(61) %
Provision for income taxes	3,023	—	3,023	*
Net loss	$ (44,765)	$ (107,709)	$ 62,944	(58) %

*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 in August 2022, and Canada product revenue in the second quarter of 2023 following the Health Canada approval and subsequent commercial launch of ZORYVE in June 2023. Net product revenue increased by $7.4 million for the three months ended September 30, 2023 compared to three months ended September 30, 2022. The increase in revenue was primarily driven by end customer demand.

Other revenue

Other revenue is a result of license revenues 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 $0.9 million for the three months ended September 30, 2023 compared to three months ended September 30, 2022. The increase is related primarily to additional ZORYVE product costs incurred. Prior to the date on which the initial regulatory approval was received, 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 two years. See Note 6 to the condensed consolidated financial statements for additional information.

Research and Development Expenses

	Three Months Ended September 30,		Change	
	2023	2022	$	%
	(in thousands)			
Direct external costs:				
Topical roflumilast program	$ 6,020	$ 21,901	$ (15,881)	(73) %
Topical JAK inhibitor program	978	1,113	(135)	(12) %
Other early stage programs	2,026	132	1,894	1435 %
In-process research and development	—	29,630	(29,630)	(100) %
Indirect costs:				
Compensation and personnel-related	12,289	11,251	1,038	9 %
Other	4,923	5,704	(781)	(14) %
Total research and development expense	$ 26,236	$ 69,731	$ (43,495)	(62) %

Research and development expenses decreased by $43.5 million, or 62%, for the three months ended September 30, 2023 compared to the three months ended September 30, 2022. The decrease was primarily due to IPR&D expense as a result of the acquisition of ARQ-234 from Ducentis, as well as the completion of Phase 3 studies of roflumilast cream in atopic dermatitis and roflumilast foam in seborrheic dermatitis and scalp and body psoriasis. Additionally, manufacturing costs recorded as research and development expenses decreased as we began capitalizing such costs to inventory upon FDA approval of ZORYVE in July 2022. The increase in compensation and personnel related expense is mainly due to accrued severance related to headcount reductions implemented in September 2023.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by $12.1 million, or 34%, for the three months ended September 30, 2023 compared to the three months ended September 30, 2022. The increase was primarily due to higher compensation and personnel-related expenses of $5.3 million, higher sales and marketing expenses of $4.0 million, and higher professional services of $1.4 million. These increases were primarily due to our commercialization efforts, including the hiring of our full sales force for ZORYVE.

Other Income, Net

Other income, net increased by $0.8 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022, primarily due to the impact of higher interest rates, partially offset by a lower marketable securities balance.

Interest Expense

Interest expense increased by $2.7 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022, due to an increase in our long-term debt balance and the impact of higher interest rates. See Note 8 to the condensed consolidated financial statements for additional information.

Provision for Income Taxes

Income tax expense of $3.0 million for the three months ended September 30, 2023 was primarily due to income tax expense related to withholding tax on the Huadong License and Collaboration Agreement.

Comparison of the Nine Months Ended September 30, 2023 and 2022

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

	Nine Months Ended September 30,		Change	
	2023	2022	$	%
	(unaudited)			
	(in thousands)			
Revenues:				
Product revenue, net	$ 15,660	$ 725	$ 14,935	2060 %
Other revenue	30,420	—	30,420	*
Total revenues	46,080	725	45,355	6256 %
Operating expenses:				
Cost of sales	2,741	269	2,472	919 %
Research and development	86,800	148,558	(61,758)	(42) %
Selling, general, and administrative	136,471	85,101	51,370	60 %
Total operating expenses	226,012	233,928	(7,916)	(3) %
Loss from operations	(179,932)	(233,203)	53,271	(23) %
Other income (expense):				
Other income, net	9,114	2,501	6,613	264 %
Interest expense	(21,950)	(8,737)	(13,213)	151 %
Loss before income taxes	(192,768)	(239,439)	46,671	(19) %
Provision for income taxes	3,088	—	3,088	*
Net loss	$ (195,856)	$ (239,439)	$ 43,583	(18) %

*Not applicable

Product revenue, net

We began recording product revenue in the third quarter of 2022 following the approval of ZORYVE by the FDA and our subsequent commercial launch in the United States in August 2022, and Canada product revenue in the second quarter of 2023 following the Health Canada approval and subsequent commercial launch of ZORYVE in June 2023. Net product revenue increased by $14.9 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, which was driven by an increase in end customer demand.

Other revenue

Other revenue is a result of shares of common stock acquired in connection with the Iolyx Agreement and license revenues received in relation to 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 nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. The increase is primarily related to increased product costs associated with the sales of ZORYVE. Prior to the date on which the initial regulatory approval was received, 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 two years.

Research and Development Expenses

	Nine Months Ended September 30,		Change	
	2023	2022	$	%
	(unaudited)			
	(in thousands)			
Direct external costs:				
Topical roflumilast program	$ 28,974	$ 68,214	$ (39,240)	(58) %
Topical JAK inhibitor program	2,832	2,505	327	13 %
Other early stage programs	3,869	625	3,244	519 %
In-process research and development	—	29,630	(29,630)	(100) %
Indirect costs:				
Compensation and personnel-related	34,784	30,880	3,904	13 %
Other	16,341	16,704	(363)	(2) %
Total research and development expense	$ 86,800	$ 148,558	$ (61,758)	(42) %

Research and development expenses decreased by $61.8 million, or 42%, for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. The decrease was primarily due to IPR&D expense as a result of the acquisition of ARQ-234 from Ducentis, as well as the completion of Phase 3 studies of roflumilast cream in atopic dermatitis and roflumilast foam in seborrheic dermatitis and scalp and body psoriasis.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by $51.4 million, or 60%, for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. The increase was primarily due to an increase in compensation and personnel-related expenses of $26.3 million, an increase in sales and marketing expenses of $17.4 million, and an increase in professional services of $4.8 million. These increases were primarily related to commercialization efforts for ZORYVE.

Other Income, Net

Other income, net increased by $6.6 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, primarily due to the impact of higher interest rates, partially offset by a lower marketable securities balance.

Interest Expense

Interest expense increased by $13.2 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, due to an increase in our average long-term debt balance and the impact of higher interest rates. See Note 8.

Provision for Income Taxes

Income tax expense of $3.1 million for the nine months ended September 30, 2023 was primarily due to income tax expense related 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 as of September 30, 2023 have been private placements of preferred stock, our IPO completed in January 2020, our follow-on financings in October 2020, February 2021, and August 2022, our Loan Agreement, our ATM, and revenue from the sale of our approved product. 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 September 30, 2023, we had cash, cash equivalents, restricted cash, and marketable securities of $228.0 million, and an accumulated deficit of $915.6 million. On October 24, 2023, we completed a public offering of shares of our common stock and prefunded warrants to purchase shares of our common stock, and received net proceeds of $94.0 million. We maintain cash balances with financial institutions in excess of insured limits. As of September 30, 2023, we had $200.0 million outstanding under the Loan Agreement. See Notes 1 and 8 to the condensed consolidated financial statements for additional information.

We believe that our existing capital resources will be sufficient to meet the projected operating requirements for at least 12 months from the date of issuance of our financial statements.

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 roflumilast cream in plaque psoriasis and atopic dermatitis, roflumilast 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 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. Pursuant 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.

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. See Notes 1 and 8 to the condensed consolidated financial statements for additional information. The tranche C term loan is available following the achievement of a net product revenue milestone of $110.0 million, calculated on a trailing six month basis. The tranche C term loan will remain available for funding until September 30, 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. On September 30, 2023, the rate was 12.88%. Starting in July 2023, the Secured Overnight Financing Rate (SOFR) for a term of one month was substituted for the benchmark rate.

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.

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.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, restrictions on our ability to merge or consolidate with any other entity, to incur additional indebtedness, or to pay any dividends or other distributions on capital stock. We have 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; provided, however, that such financial covenant shall not apply if our average market capitalization over the trailing five day period prior to the last day of any measurement month is equal to or in excess of $400.0 million. We were in compliance with all covenants under the Loan Agreement as of September 30, 2023.

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.

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 amended Loan Agreement provides for term loans in aggregate principal amount of up to $200.0 million, which amounts were fully drawn as of September 30, 2023. Pursuant to the amendment, the modified financial covenant requires us to generate a minimum net product revenue equal to 75% of each month's 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. Any failure by us to raise such net cash proceeds during the specified period shall be an immediate event of default.

Cash Flows

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

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Cash used in operating activities	$ (190,813)	$ (186,650)
Cash provided by (used in) investing activities	242,418	(129,400)
Cash provided by financing activities	2,034	300,836
Effect of exchange rate changes on cash	(118)	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 53,521	$ (15,214)

Net Cash Used in Operating Activities

During the nine months ended September 30, 2023, net cash used in operating activities was $190.8 million, which consisted of a net loss of $195.9 million and a change in net operating assets and liabilities of $23.9 million, partially offset by net non-cash charges of $29.0 million. The net non-cash charges were primarily related to stock-based compensation expense of $30.1 million.

During the nine months ended September 30, 2022, net cash used in operating activities was $186.7 million, which consisted of a net loss of $239.4 million and a change in net operating assets and liabilities of $2.8 million, partially offset by net non-cash charges of $55.6 million. The net non-cash charges were primarily related to acquired in-process research and development of $29.6 million and stock-based compensation expense of $23.4 million.

Net Cash Provided by (Used in) Investing Activities

During the nine months ended September 30, 2023, net cash provided by investing activities was $242.4 million, which was comprised primarily of proceeds from the maturities of marketable securities of $350.5 million, partially offset by purchases of marketable securities of $107.7 million.

During the nine months ended September 30, 2022, net cash used in investing activities was $129.4 million, which was comprised primarily of purchases of marketable securities of $377.3 million, cash paid for IPR&D related to the acquisition of Ducentis of $15.5 million and a milestone payment made to AstraZeneca of $7.5 million, partially offset by the proceeds from the maturities of marketable securities of $271.1 million.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2023, net cash provided by financing activities was $2.0 million, which was comprised of $1.0 million in proceeds from the issuance of common stock upon the exercise of stock options and $1.0 million in proceeds from the issuance of common stock as part of our ESPP.

During the nine months ended September 30, 2022, net cash provided by financing activities was $300.8 million, which was comprised primarily of the net cash proceeds received from our August 2022 public stock offering of $161.6 million, our August 2022 debt facility draw down of $125.0 million, and our March 2022 sale of stock under our ATM facility of $14.5 million.

Contractual Obligations and Contingent Liabilities

The following summarizes our significant contractual obligations as of September 30, 2023.

Facility Operating Lease

In April 2020, we amended our lease agreement for our facility in Westlake Village, California to relocate to a new expanded space including 22,643 square feet. The lease payment term for the new space began on December 30, 2020 and will terminate 91 months thereafter, with a renewal option term of five years. We have a one-time option to cancel the lease after month 67.

The lease is subject to fixed rate escalation increases with an initial base rent of $76,000 per month and includes rent free periods aggregating approximately one year. The amended lease agreement required that we deliver a letter of credit to the landlord of $1.5 million upon occupying the space, which is allowed to be reduced throughout the lease period as rent obligations are met. Accordingly, as of September 30, 2023, we have a letter of credit and related restricted cash account of $0.9 million. The total commitment under the operating lease agreement is $5.1 million, including $0.3 million for the remaining three months of 2023, $1.0 million for each of the years 2024 through 2025, $1.1 million for each of the years 2026 through 2027, and $0.6 million for the year 2028. See Note 7 to the condensed consolidated financial statements for additional information.

Long-Term Debt Obligations

As of September 30, 2023, we had $200.0 million outstanding under our Loan Agreement. See Notes 1 and 8 to the condensed consolidated financial statements for additional information. The total commitment under the Loan Agreement as of September 30, 2023 is $298.9 million, including $6.6 million for the remaining three months of 2023, $26.2 million for the year 2024, $26.1 million for each of the years 2025 through 2026, and $213.9 million for the year 2027. These amounts do not represent or include any future draw downs, but instead represent only the contractually obligated minimum payments of interest, principal, and loan fees related to the funding of the $75.0 million tranche A term loan on December 22, 2021 and the $125.0 million tranche B term loan on August 2, 2022.

License Agreements & Acquisition

The terms of certain of our license agreements and our acquisition of Ducentis require us to pay potential future milestone payments based on product development and commercial success. The amount and timing of such obligations are unknown or uncertain. These potential obligations are further described in Note 6 to the condensed consolidated financial statements.

Manufacturing Agreements

We have entered into manufacturing supply agreements for the commercial supply of ZORYVE, which include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately $1.2 million within the next three months, and approximately $0.8 million per year for 2024 and 2025. This amount does not represent all of our anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our certificate of incorporation and bylaws, we have indemnification obligations to our officers and directors for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date, and we have director and officer insurance that may enable us to recover a portion of any amounts paid for future potential claims.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Use of Estimates

The preparation of our 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 the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2022. There were no material changes to our critical accounting policies during the nine months ended September 30, 2023.

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements.

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 September 30, 2023, we had cash and cash equivalents of $107.5 million, restricted cash of $0.9 million, and marketable securities of $119.6 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 September 30, 2023, 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 September 30, 2023, 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 September 30, 2023 we had cash balances denominated in Canadian dollars of $4.0 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 September 30, 2023, 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 September 30, 2023.

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 nine months ended September 30, 2023 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

We may from time to time be involved in various legal proceedings of a character normally incident to the ordinary course of our business. We are not currently a party to any material litigation or other material legal proceedings.

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, 2022 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023. Other than the risk factors set forth below, 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, 2022 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations. We may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC.

The terms of our loan and security agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

As of September 30, 2023, we had $200.0 million outstanding under our Loan Agreement. On November 1, 2023, we entered into an amendment to the Loan Agreement, pursuant to which the terms 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 amended Loan Agreement provides for term loans to the Company in an aggregate principal amount of up to $200.0 million, which amount was fully drawn on September 30, 2023. 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.

The Loan Agreement contains a number of representations and warranties and affirmative and restrictive covenants, including financial covenants, and the terms may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry, or take future actions. The Loan Agreement includes a financial covenant whereby, beginning with the month ending December 31, 2023, we must generate minimum net product revenue for applicable measuring periods. Pursuant to the amendment to the Loan Agreement, this financial covenant requires us to generate a minimum net product revenue equal to 75% of each month's 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. Each annual plan shall be approved by our board of directors and SLR, in its capacity as collateral agent, in its reasonable discretion. Failure to deliver such annual plan on or before December 15 of the prior year will result in an event of default. In addition, pursuant to the amendment to the Loan Agreement, we agreed to a minimum financing covenant 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 (i) the sale or issuance of equity interests, (ii) business development or collaboration agreements (including upfront, milestone, royalty and other payments), or (iii) subordinated debt, in each case as permitted pursuant to the terms of the Loan Agreement. Failure by the Company to satisfy this minimum financing covenant will result in an event of default. We may not be able to raise such amounts on favorable terms, or at all.

If the debt under the Loan Agreement were accelerated due to an event of default or otherwise, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition. If we do not have or are unable to generate sufficient cash to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern. Moreover, regardless of a potential event of default, the debt under the Loan Agreement matures and is due on January 1, 2027. As a result, we may need to refinance or secure separate financing in order to repay amounts outstanding when due, however, no assurance can be given that an extension will be granted, that we will be able to renegotiate the terms of the agreement with the lender or that we will be able to secure separate debt or equity financing on favorable terms, if at all.

In order to service our indebtedness, we need to generate cash from our operating activities or additional equity or debt financings. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This may place us at a competitive disadvantage compared to our competitors that have less indebtedness.

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

On October 12, 2023 , Howard G. Welgus , M.D., a member of our board of directors , terminated a Rule 10b5-1 trading plan , which plan was previously adopted on August 29, 2023 and intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The plan provided for the potential sale of up to 120,000 shares of Common Stock held by Mr. Welgus between December 1, 2023 and November 29, 2024. Prior to its termination, no shares were sold under the plan.

Amendment to Loan Agreement

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 amended Loan Agreement provides for term loans in aggregate principal amount of up to $200.0 million, which amounts were fully drawn as of September 30, 2023. Pursuant to the amendment, the modified financial covenant requires us to generate a minimum net product revenue equal to 75% of each month's 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. Any failure by us to raise such net cash proceeds during the specified period shall be an immediate event of default.

This description of the amendment to the Loan Agreement does not purport to be complete, and is subject to and qualified in its entirety by reference to the full text of the amendment, which is attached as Exhibit 10.2 to this Quarterly Report on Form 10-Q and incorporated herein by reference.

Employment Matters

On October 31, 2023, David W. Osborne, Ph.D., Senior Vice President and Chief Technical Officer, notified the Company of his intention to retire from the Company effective as of December 31, 2023. Dr. Osborne has served as an executive officer of the Company since April 2017 and is one of the Company's co-founders. In connection with Dr. Osborne's retirement, Bethany Dudek, Vice President, Quality, will succeed to Dr. Osborne's responsibilities commencing in November 2023. Dr. Osborne has agreed to enter into a consulting agreement with the Company at a later date following this transition period.

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†	Licensee Agreement, dated August 10, 2023, by and between the Registrant and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.				X
10.2	First Amendment to Amended and Restated Loan and Security Agreement, dated November 1, 2023, by and among the Registrant, Arcutis Canada, Inc., SLR Investment Corp., and the lenders party thereto.				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

† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K, and/or certain of the exhibits and schedules to this exhibit have been omitted in accordance with Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

* 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: November 03, 2023

By: /s/ Todd Franklin Watanabe

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

Date: November 03, 2023

By: /s/ John W. Smither

John W. Smither
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

[***] 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

Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd

Dated as of August 10, 2023

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Schedules

LICENSE AGREEMENT

This LICENSE AGREEMENT (this "Agreement") is made as of August 10, 2023 (the "Effective Date") by and among Arcutis Biotherapeutics, Inc., a Delaware corporation, having a place of business at 3027 Townsgate Road, Suite 300, Westlake Village, CA 91361 ("Licensor") and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., a limited company registered under the laws of China, having a place of business at No.866, Moganshan Road, Hangzhou, China ("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, and commercialization of pharmaceutical products in the greater China region; and

WHEREAS, the Parties desire to enter into a license pursuant to which Licensee would together Exploit Licensed Products in the Territory, 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 1.29 (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; provided, however, notwithstanding the foregoing, neither China Grand Enterprises,

Inc. nor any direct or indirect subsidiary controlled by China Grand Enterprises, Inc., except for Huadong Medicine Co., Ltd. and its subsidiaries, will be deemed an Affiliate of Licensee for the purposes of this Agreement.

1.4 "Agreement" has the meaning set forth in the Preamble.

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 "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 UK Bribery Act 2010, the Anti-Unfair Competition Law of the People's Republic of China, the Criminal Law of the People's Republic of China.

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

1.9 "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, Directive (EU) 2018/843 of the European Parliament and of the Council of 30 May 2018 amending Directive (EU) 2015/849 ("AML 5") and all national and international laws enacted to implement AML 5, the Luxembourg Law of 12 November 2004 on the fight against money laundering and terrorist financing, as amended, the UK Proceeds of Crime Act 2002, the UK Terrorism Act 2000, as amended, the Anti-Unfair Competition Law of the People's Republic of China, the Criminal Law of the People's Republic of China, 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.

1.10 "Applicable Law" means all applicable laws, statutes, rules, regulations, treaties (including Tax treaties), orders, judgments or ordinances having the effect of law of any Governmental Authority, including, to the extent applicable, the Drug Administration Law of the People's Republic of China, the Biosafety Law of the People's Republic of China, the People's Republic of China's Regulation of Human Genetic Resources, and any Anti-Corruption Laws, Anti-Money Laundering Laws, and Global Trade Laws and Regulations.

1.11 "Arising Joint IP" has the meaning set forth in Section 14.1.2(b) (Ownership of Arising Intellectual Property).

1.12 "Arising Licensee IP" has the meaning set forth in Section 14.1.2(a) (Ownership of Arising Intellectual Property).

1.13 "Arising Licensor IP" has the meaning set forth in Section 14.1.2(b) (Ownership of Arising Intellectual Property).

1.14 "ARQ-151" means ZORYVE™ cream, a topical form of Roflumilast formulated as a cream, in the formulation set forth in Schedule 1.14 (ARQ-151) alone or in combination with one or more other active ingredients and in (a) the concentration(s) set forth in Schedule 1.14 (ARQ-151), and (b) any concentration for which Licensor or its Affiliates obtains Regulatory Approval outside the Territory.

1.15 "ARQ-154" means topical Roflumilast foam, a topical form of Roflumilast formulated as a foam, in the formulation set forth in Schedule 1.15 (ARQ-154) alone or in combination with one or more other active ingredients and in (a) the concentration(s) set forth in Schedule 1.15 (ARQ-154), and (b) any concentration for which Licensor or its Affiliates obtains Regulatory Approval outside the Territory.

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

1.17 "Automatic Licensed Product Improvement" means (a) any new concentration, formulation, upgrade, improvement, or line extension to ARQ-151 or ARQ-154 ("Product Improvement") for which no additional Clinical Trial is required to promote, market, secure approval for, or sell ARQ-151 or ARQ-154, as applicable, with such new concentration, upgrade, improvement or line extension or (b) Product Improvements that (i) require a Clinical Trial to implement and (ii) (A) Licensor desires to include subjects or patients in the Territory in any such Clinical Trial and Licensee elects to participate in such Clinical Trial through the management of such Clinical Trial in the Territory and contributes up to [***]% of all patients of such Clinical Trial from the Territory, or such larger percentage as Licensor requests in writing, subject to Licensee's approval, at Licensee's sole expense or (B) Licensor does not desire to include subjects or patients in the Territory in any such Clinical Trial or (C) Licensor does desire to include subjects or patients in the Territory in any such Clinical Trial and Licensee elects to not participate in such Clinical Trial but, in either case (B) or (C), Licensee reimburses an amount equal to [***]% of the cost of such Clinical Trial to Licensor in accordance with Article 10 (Financial Terms). In addition to the requirements under subclause (a) and (b) above, as applicable, if Licensor has acquired or licensed any Know-How or Patent Rights from a Third Party, such Product Improvement will only be an Automatic Licensed Product Improvement if Licensee reimburses Licensor for [***]% of all payments made to such Third Party to acquire or license such Product Improvement, provided that such additional Know-How or Patent Rights acquired or licensed also cover the Territory.

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

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

1.20 "Blocking IP" means any (i) Arising Licensor IP, (ii) Product Inventions, and (iii) Arising Joint IP, that is, in the case of clauses (i) – (iii), 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 Territory Development Plan, perform Medical Affairs with respect to in accordance with the Territory Medical Affairs Plan, Manufacture, Commercialize or otherwise Exploit, one or more Licensed Products in the Territory in the Field.

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

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

1.23 "Calendar Quarter" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, and December 31, provided, that the first Calendar Quarter of the Term will begin on the Effective Date and end on the earlier of March 31, June 30, September 30 or December 31, immediately thereafter.

1.24 "Calendar Year" means the respective periods of 12 months ending on December 31, provided, that the first Calendar Year of the Term will begin on the Effective Date and end on December 31 of that same year.

1.25 "CBP" has the meaning set forth in Section 1.84 (Global Trade Laws and Regulations).

1.26 "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, including, in Chinese Mainland, Good Laboratory Practices established through the NMPA.

1.27 "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, including, in Chinese Mainland, Good Clinical Practices established through the NMPA.

1.28 "cGMP" or "GMP" means all applicable then-current good manufacturing practice standards relating for fine chemicals, intermediates, bulk products, or finished pharmaceutical or biological products, as are required by applicable Regulatory Authorities or Applicable Law in the relevant country or jurisdiction, including, as applicable (a) all applicable requirements detailed in the NMPA's Good Manufacturing Practice for Drugs, and (b) all Applicable Law promulgated by any Governmental Authority having jurisdiction over the Manufacture of the applicable compound or pharmaceutical or biological product, as applicable.

1.29 "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.

1.30 "China" means the People's Republic of China, including the Hong Kong Special Administrative Region ("Hong Kong SAR"), the Macau Special Administrative Region ("Macau SAR") and the Taiwan Region ("Taiwan Region").

1.31 "Chinese Mainland" means all of China excluding Hong Kong SAR, Macau SAR and Taiwan Region.

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

1.33 "Clinical Development" has the meaning set forth in Section 1.62 (Development).

1.34 "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.

1.35 "Clinical Trial Issue" means that there has occurred, or Licensor determines in its reasonable discretion that deficiencies in Clinical 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 reasonably likely to occur any failure to materially comply with the terms of the AZ License, this Agreement, the applicable Territory Development Plan, cGLP, cGMP, cGCP, or Applicable Law.

1.36 "CMO" means a contract manufacturing organization.

1.37 "CNIPA" means the China National Intellectual Property Administration or any successor entity thereto.

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

1.39 "Combination Product" means a product that is sold in the form of a combination containing or comprising a Licensed Product together with one or more other therapeutically active pharmaceutical agents that are each not a Licensed Product (whether coformulated or copackaged or otherwise sold for a single price).

1.40 "Combination Sale" has the meaning set forth in Section 1.141 (Net Sales).

1.41 "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 accordingly.

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

1.43 "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.

1.44 "Competing Generic" means, any topically delivered product in a given country or Region in the Territory, that contains a different active pharmaceutical ingredient as a Licensed Product and (a) is approved in reliance, in whole or in part, on a prior Regulatory Approval of a product other than the Licensed Product ("Other Reference Product"), (b) is otherwise approved under any then-existing laws and regulations in the applicable country or Region pertaining to approval of generic products, as a "generic" version of the Other Reference Product, which approval relies, in whole or in part, on a prior Regulatory Approval of such Other Reference Product or (c) is otherwise recognized by the applicable Regulatory Authority as an interchangeable product to the Other Reference Product and in each case (a) through (c), has received Regulatory Approval for the treatment of any Indication.

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

1.46 "Competitive Activities" has the meaning set forth in Section 2.8.2 (Business Combinations).

1.47 "Competitive Infringement" means any infringement of the Licensed Patent Rights that arises as a result of the making, using, offering to sell, selling, or importing of a product in the Field in the Territory that would be competitive with the Commercialization of a Licensed Product in the Field in the Territory.

1.48 "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.

1.49 "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).

1.50 "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.

1.51 "Confidentiality Disclosure Agreement" means the Mutual Confidential Disclosure Agreement by and between the Parties dated April 26, 2023 (as amended from time to time).

1.52 "Continuous Licensed Know-How Transfer" has the meaning set forth in Section 2.2 (Licensed Know-How Transfer).

1.53 "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, 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 Patent 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.

1.54 "Cost Reimbursement" has the meaning set forth in Section 10.11.2 (Withholding Tax).

1.55 "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.

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

1.57 "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.

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

1.59 "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 of OFAC sanctions or on the OFAC list of specially designated nationals, or the subject of any similar sanction of any Governmental Authority in the Territory.

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

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

1.62 "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 any country or Region in the Territory to support or maintain Regulatory Approval for a product in such country or Region). "Develop," "Developing," and "Developed" will be construed accordingly.

1.63 "Development Activities" has the meaning set forth in Section 4.1 (Development Diligence and Responsibilities).

1.64 "Development and Regulatory Milestone Event" has the meaning set forth in Section 10.2.1 (Regulatory Milestones).

1.65 "Development and Regulatory Milestone Payment" has the meaning set forth in Section 10.2.1 (Regulatory Milestones).

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

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

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

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

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

1.71 "Effective Date" has the meaning set forth in the Preamble.

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

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

1.74 "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.

1.75 "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).

1.76 "Field" means all therapeutic uses of a Licensed Product solely for all Indications in humans.

1.77 "First Commercial Sale" means, with respect to an applicable product in a country or Region, 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 or Region following Regulatory Approval of such product in such country or Region. 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.

1.78 "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.

1.79 "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.

1.80 "Fully Burdened Manufacturing Cost" means, with respect to the Licensed Product, in each case, supplied by or on behalf of the applicable Party or its Affiliates to the other Party or its Affiliates hereunder:

(a) if and to the extent the Licensed Product (or any precursor or intermediate thereof), as applicable, is Manufactured by a Third Party manufacturer, (i) the actual Third Party costs of such Manufacturing invoiced to the supplying Party by the Third Party manufacturer, plus (ii) any reasonable internal costs incurred by or on behalf of such supplying Party or its Affiliates incurred directly in connection with such Manufacturing; or

(b) if and to the extent the Licensed Product (or any precursor or intermediate thereof), as applicable, is Manufactured by a Party or its Affiliate, the actual, fully burdened costs that are directly attributable to and reasonably allocated to such Manufacturing, including the cost of raw materials and costs of materials, direct labor, ordinary course quality assurance costs, documented payments other than in respect of any of the foregoing made by the relevant Party to any Third Party manufacturer in respect of the acquisition of the Licensed Product, including the cost of freight into or between manufacturing sites in the supply chain and related insurance, but excluding any profit made by the relevant Party or its Affiliates through the application of transfer pricing. Such fully burdened costs will be calculated in accordance with applicable Accounting Standards, consistently applied.

1.81 "GAAP" means United States generally accepted accounting principles, consistently applied.

1.82 "Generic Product" means, with respect to a given Licensed Product in a given country or Region in the Territory, 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 the applicable country or Region 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 such country or Region 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.

1.83 "Global Brand Elements" has the meaning set forth in Section 14.11.1 (Global Brand Elements).

1.84 "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 UK Export Control Act 2002; UK Export Control Order 2008/3231; EU Council Regulation 428/2009 (as maintained by the EU or retained by the UK); EU Council sanctions regulations, as implemented in EU Member States; sanctions regimes implemented under the UK Sanctions and Anti-Money Laundering Act 2018; Canadian sanctions policies; United Nations sanctions policies; all relevant regulations made under any of the foregoing; and other similar economic and trade sanctions or export or import control laws (except to the extent inconsistent with U.S. law).

1.85 "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).

1.86 **"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.

1.87 "Gross Combination Sale Amount" has the meaning set forth in Section 1.141 (Net Sales).

1.88 "Hong Kong SAR" has the meaning set forth in Section 1.30 (China).

1.89 "ICC" has the meaning set forth in Section 16.4 (Arbitration).

1.90 "ICC Rules" has the meaning set forth in Section 16.4 (Arbitration).

1.91 "IDL" has the meaning set forth in Section 1.135 (Marketing Authorization Application).

1.92 "IFRS" means International Financial Reporting Standards, consistently applied.

1.93 "Importation Model" has the meaning set forth in Section 6.1.1 (Importation Model).

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

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

1.96 "Independent Price" has the meaning set forth in Section 1.141 (Net Sales).

1.97 "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 2.9 (Right of First Negotiation) or for which Licensee develops a Licensed Product pursuant to Section 4.8 (Development of New Formulations, Concentrations, or Indications).

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

1.99 "Initial Licensed Know-How Transfer" has the meaning set forth in Section 2.2 (Licensed Know-How Transfer).

1.100 "Invoicing Entity" has the meaning set forth in Section 1.141 (Net Sales).

1.101 "Inventions" has the meaning set forth in Section 14.1.2 (Ownership of Arising Intellectual Property).

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

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

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

1.105 "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.

1.106 "Knowledge" means, with respect to a Party, the actual knowledge of those Persons listed for such Party on Schedule 1.106 (Knowledge) after due inquiry of such Person's direct reports.

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

1.108 "Licensed 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 Territory Development Plan, perform Medical Affairs in accordance with the Territory Medical Affairs Plan, Manufacture, Commercialize or otherwise Exploit one or more Licensed Products in the Territory in the Field.

1.109 "Licensed Patent Rights" means any Patent Right that is (a) (i) Controlled by Licensor or any of its Affiliates as of the Effective Date and (ii) 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 Territory Development Plan, perform Medical Affairs in accordance with the Territory Medical Affairs Plan, Manufacture, Commercialize or otherwise Exploit, one or more Licensed Products in the Territory in the Field, and (b) any Patent Rights within the Blocking IP. Schedule 1.109 (Licensed Patent Rights) sets forth the Licensed Patent Rights existing as of the Effective Date.

1.110 "Licensed Patent Right Infringement" has the meaning set forth in Section 14.5.1 (Notice).

1.111 "Licensed Product" means either (a) ARQ-151 or (b) ARQ-154 and any Automatic Licensed Product Improvements.

1.112 "Licensed Product Trademarks" has the meaning set forth in Section 14.11.2 (Licensed Product Trademarks in the Territory).

1.113 "Licensed Technology" means the Licensed Know-How, Licensed Patent Rights, and Blocking IP, but excluding any Know-How or Patent Right to the extent related to any active

ingredient included in a Licensed Product other than the active ingredient included in ARQ-151 and ARQ-154.

1.114 "Licensee" has the meaning set forth in the Preamble.

1.115 "Licensee Collaboration Know-How" means any Know-How 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 (other than Licensor or its licensees), Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Know-How to Licensee or any Affiliate of Licensee, including any Know-How included in Arising Licensee IP.

1.116 "Licensee Collaboration Patent Right" means any Patent Right that (a) has a priority date on or after the Effective Date (b) Covers any invention included in the Licensee Collaboration Know-How, and (c) does not cover any Product Invention.

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

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

1.119 "Licensee Manufacturer" has the meaning set forth in Section 6.1.2 (Localization Model).

1.120 "Licensee ROFN" has the meaning set forth in Section 2.9 (Licensee Right of First Negotiation).

1.121 "Licensee ROFN Negotiation Notice" has the meaning set forth in Section 2.9 (Licensee Right of First Negotiation).

1.122 "Licensee ROFN Negotiation Period" has the meaning set forth in Section 2.9 (Licensee Right of First Negotiation).

1.123 "Licensee ROFN Notice Period" has the meaning set forth in Section 2.9 (Licensee Right of First Negotiation).

1.124 "Licensee ROFN Trigger Notice" has the meaning set forth in Section 2.9 (Licensee Right of First Negotiation).

1.125 "Licensor" has the meaning set forth in the Preamble.

1.126 "Licensor Blocking IP" means any Know-How, and all intellectual property rights therein, that is conceived, reduced to practice, discovered, developed, or made by or on behalf of either Licensor or any Third Parties acting on Licensor's behalf (or any of its Representatives, Affiliates, licensees, or sublicensees) using Licensee Collaboration Technology under the license granted to Licensor under Section 2.4 (License Grant to Licensor) that is necessary for Licensee (or, with respect to patent applications, would be necessary if such patent applications were to issue as patents) to practice or use such Licensee Collaboration Technology.

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

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

1.129 "Localization Effective Date" has the meaning set forth in Section 6.1.2 (Localization Model).

1.130 "Localization Model" has the meaning set forth in Section 6.1.2 (Localization Model).

1.131 "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).

1.132 "Macau SAR" has the meaning set forth in Section 1.30 (China).

1.133 "Major Markets" means those countries labeled as Major Markets on Schedule 1.190 (Territory), provided that notwithstanding Schedule 1.190 (Territory), the Major Markets will exclude all Restricted Countries.

1.134 "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 accordingly.

1.135 "Marketing Authorization Application" or "MAA" means any new drug application, biologics license application, or other marketing authorization application, in each case, filed with the applicable Regulatory Authority in a country or other regulatory jurisdiction, which application is required to commercially market or sell a pharmaceutical or biologic product in such country or jurisdiction (and any amendments thereto). In the context of imported drugs in China, MAA is also known as the Import Drug License ("IDL") application.

1.136 "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.

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

1.138 "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.

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

1.140 "Mono Product" has the meaning set forth in Section 1.141 (Net Sales).

1.141 "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 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;

(f) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to the Licensed Product;

(g) 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);

(h) that portion of the annual fee on prescription drug manufacturers imposed by the U.S. Patient Protection and Affordable Care Act, or similar Applicable Law, that the applicable Invoicing Entity reasonably allocates to sales of the Licensed Product in accordance with its standard policies and procedures; and

(i) any consideration actually paid or payable for, or reasonably allocable to, any delivery system related to the invoiced sale of the Licensed Product.

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 the relevant country or Region 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.

In the event that the Licensed Product is sold as a Combination Product (a "Combination Sale"), the Net Sales amount for the Licensed Product sold in such a Combination Sale will be determined as follows:

(A) Except as provided below, the Net Sales amount for a Combination Sale in any period and country or Region will be calculated by multiplying the gross amount invoiced for the Combination Sale (the "Gross Combination Sale Amount"), less all deductions in (a)-(g) above ("Permitted Deductions"), by the fraction, the numerator of which is the wholesale acquisition cost charged by the applicable Invoicing Entity in such period and country or Region for a Licensed Product which is not a Combination Product (the "Mono Product"), if such Mono Product is sold

separately by the applicable Invoicing Entity in such period and country or Region (the "Independent Price"), and the denominator is the Independent Price plus the wholesale acquisition cost charged by the applicable Invoicing Entity for product(s) containing as their sole active ingredients those active ingredients that are not Licensed Products ("Other Product(s)") if such Other Product(s) are sold separately by the applicable Invoicing Entity in such period and country or Region; provided that if any of such Other Product(s) are not sold separately by the applicable Invoicing Entity, but are independently marketed by one or more Third Parties, in such period and country or Region, then such product(s) will be deemed to be separately sold by the applicable Invoicing Entity at the average wholesale acquisition costs charged by such Third Parties for purposes of the calculations in this clause.

(B) In the event an Invoicing Entity sells a Mono Product in such period and country or Region, but does not separately sell all of the Other Product(s) and such Other Product(s) are not independently marketed by one or more Third Parties, as the case may be, in such period and country or Region, the calculation of Net Sales resulting from such Combination Sale will be determined by multiplying the Gross Combination Sale Amount, less all Permitted Deductions, by the fraction, the numerator of which is the Independent Price, and the denominator of which is the wholesale acquisition cost charged by the applicable Invoicing Entity for such Combination Product in such period and country or Region.

(C) In the event that an Invoicing Entity does not sell a Mono Product in such country or Region and period, but does separately sell all of the Other Products included in the Combination Sale in such period and country or Region, the calculation of Net Sales resulting from such Combination Sale will be determined by multiplying the Gross Combination Sale Amount, less all Permitted Deductions, by a fraction, the numerator of which is the wholesale acquisition cost charged by the applicable Invoicing Entity for such Combination Product in such period and country or Region (the "Wholesale Price") minus the aggregate of the wholesale acquisition cost charged by the applicable Invoicing Entity of such Other Product(s) in such period and country or Region, and the denominator of which is the Wholesale Price; provided, if any of the Other Product(s) are not sold separately by the applicable Invoicing Entity, but are independently marketed by one or more Third Parties, in such period and country or Region, then such Other Product(s) will be deemed to be separately sold by the applicable Invoicing Entity at the average wholesale acquisition costs charged by such Third Parties for purposes of the calculations in this clause.

If the calculation of Net Sales resulting from a Combination Sale cannot be determined by any of the foregoing methods, the calculation of Net Sales for such Combination Sale will be calculated based upon the relative fair market value of the active components of such Combination Product as reasonably determined in good faith by the Invoicing Entity.

1.142 "NMPA" means the National Medical Products Administration of the People's Republic of China, and local counterparts thereto, and any successor agency or authority thereto having substantially the same function.

1.143 "OFAC" has the meaning set forth in Section 1.84 (Global Trade Laws and Regulations).

1.144 "Optional Licensed Product Improvement" has the meaning set forth in Section 2.9 (Licensee Right of First Negotiation).

1.145 "Other Product(s)" has the meaning set forth in Section 1.141 (Net Sales).

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

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

1.148 "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.

1.149 "Patent Rights" means: any (a) patent or patent application in any country, Region, or supranational jurisdiction worldwide, including provisional applications, priority applications, and international applications; (b) substitution, divisional, provisional, continuation, continuation-in-part, reissue, renewal, registration, confirmation or the like of any such patent or patent application; (c) 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; and (d) patents that have issued or in the future issue from the foregoing patent applications.

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

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

1.152 "Permitted Deductions" has the meaning set forth in Section 1.141 (Net Sales).

1.153 "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.

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

1.155 "Post-Change of Control Party" has the meaning set forth in Section 2.8.2 (Business Combinations).

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

1.157 "Product Improvement" has the meaning set forth in Section 1.17 (Automatic Licensed Product Improvement).

1.158 "Product Inventions" has the meaning set forth in Section 14.1.2(b) (Ownership of Arising Intellectual Property).

1.159 "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; (e) a Politically Exposed Person (PEP) as defined by the Financial Action Task Force (FATF), Groupe d'action Financière sur le Blanchiment de Capitaux (GAFI), or AML 5; or (f) any person acting in an official capacity for any government or Governmental Entity, or other government entity, enterprise, or organization identified above.

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

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

1.162 "Region" has the meaning set forth on Schedule 1.190 (Territory).

1.163 "Regulatory Approval" means, with respect to a 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.

1.164 "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 NMPA, and any corresponding national or regional regulatory authorities.

1.165 "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 a particular country or other regulatory jurisdiction, but in all cases excluding Patent Rights and Patent Term Extensions.

1.166 "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).

1.167 "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 the Territory.

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

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

1.170 "Restricted Country" means any country or geographic region subject to comprehensive economic sanctions administered by OFAC, which as of the Effective Date includes: Crimea, Cuba, Iran, North Korea, Syria, and the so-called Donetsk and Luhansk People's Republics.

1.171 "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.

1.172 "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, and all other lists 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.

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

1.174 "Right of Reference" means a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) or any analogous Applicable Law recognized outside of the United States.

1.175 "Roflumilast" means 3-cyclopropylmethoxy-N-(3,5-dichloropyridin-4-yl)-4-(difluoromethoxy) benzamide, as set forth in Schedule 1.175 (Roflumilast).

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

1.177 "Royalty Term" means, on a Licensed Product-by-Licensed Product and country-by-country, or, as applicable, Region-by-Region basis, the period of time that commences upon the First Commercial Sale of such Licensed Product in such country or Region and ends upon the latest of: [***].

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

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

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

1.181 "Status Quo Item" has the meaning set forth in Section 3.5.2(b) (No Change; Status Quo).

1.182 "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 Third Party that would otherwise be deemed a Subcontractor of Licensee under this definition will instead be deemed a Sublicensee for purposes of this Agreement if such Third Party 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.

1.183 "Sublicense" has the meaning set forth in Section 2.6.1 (Right to Sublicense).

1.184 "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).

1.185 "Supply Election Date" has the meaning set forth in Section 6.1 (Clinical and Commercial Supply).

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

1.187 "Taiwan Region" has the meaning set forth in Section 1.30 (China).

1.188 "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.

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

1.190 "Territory" means those countries and Regions set forth on Schedule 1.190 (Territory), provided that notwithstanding Schedule 1.190 (Territory), the Territory will exclude all Restricted Countries.

1.191 "Territory Development Plan" has the meaning set forth in Section 4.2 (Territory Development Plans).

1.192 "Territory Medical Affairs Plan" has the meaning set forth in Section 7.1 (Territory Medical Affairs Plans).

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

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

1.195 "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).

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

1.197 "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.

1.198 "Wholesale Price" has the meaning set forth in Section 1.141 (Net Sales).

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

1.200 [***].

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 (a) an exclusive (subject to Licensor's retained rights under Section 2.5 (No Implied Licenses; Retained Rights)), royalty-bearing license, with the right to grant sublicenses through multiple tiers, solely in accordance with Section 2.6 (Sublicensing and

Subcontractors), under its interest in the Licensed Technology to Develop, have Developed, perform Medical Affairs with respect to, Manufacture, have Manufactured, Commercialize and otherwise Exploit Licensed Products in the Field in the Territory solely in accordance with the terms of this Agreement, including the terms of each applicable Territory Development Plan and Territory Medical Affairs Plan and (b) a non-exclusive, perpetual, irrevocable, fully paid up, royalty-free, worldwide license to Licensor Blocking IP solely to practice or use the Licensee Collaboration Technology for any purpose.

2.2 Licensed Know-How Transfer. Within [***] days of the Effective Date ("Initial Licensed Know-How Transfer") and thereafter ("Continuous Licensed Know-How Transfer") during the Term, upon Licensee's reasonable request no more often than [***] or otherwise as needed to perform the activities set forth in the Territory Development Plan in a timely manner, Licensor will make available and deliver to Licensee (or a designated Affiliate thereof) any and all of the Know-How within the Licensed Technology in Licensor's possession and control that has not been previously provided under this Agreement, in the format and form such Know-How exists as of such date, for use in accordance with the terms of Licensee's exclusive license under Section 2.1 (License Grant to Licensee). To assist with the transfer of such Know-How, Licensor will make its personnel reasonably available to Licensee and its designated Affiliates during normal business hours for the transfer of such Know-How. The Initial Licensed Know-How Transfer is [***]. For the Continuous Licensed Know-How Transfer, Licensee will reimburse Licensor for (a) all out-of-pocket expenses, and (b) internal costs of Licensor exceeding [***] hours of FTE time of such transfer activities provided by Licensor at the FTE Rate, in each case (a) and (b) incurred by Licensor in connection with the obligations under this Section 2.2 (Licensed Know-How Transfer).

2.3 Affiliate Rights. The rights licensed to Licensee under Section 2.1 (License Grant to Licensee) may be extended as a Sublicense pursuant to Section 2.6.1 (Right to Sublicense) 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 material violation of any Applicable Law in relation to its performance under this Agreement. .

2.4 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 (subject to

Section 15.3.2(a) (Termination of this Agreement), perpetual, irrevocable, transferable license, with the right to grant sublicenses through multiple tiers, under the Licensee Collaboration Technology solely to Develop, perform Medical Affairs with respect to, Manufacture, Commercialize and otherwise Exploit Licensed Products (a) during the Term, both (i) outside the Territory, and (ii) inside the Territory but outside the Field, and (b) after the Term, worldwide in all fields.

2.5 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 Licensed 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 Licensed Technology to Develop Licensed Products in the Field in the Territory for seeking and obtaining Regulatory Approval and for Commercialization outside of the Territory and, subject to the terms of this Agreement, outside of the Field in the Territory, and (b) on behalf of itself and its Affiliates and Subcontractors, the right under the Licensed Technology to Manufacture Licensed Products in the Field in the Territory for Development worldwide and for seeking and obtaining Regulatory Approval and for Commercialization outside of the Territory and, subject to the terms of this Agreement, outside of the Field in the Territory. Neither Party will practice the Licensed Technology in violation of this Agreement and the rights granted in this Article 2 (Licenses; Exclusivity; Right of First Negotiation).

2.6 Sublicensing and Subcontractors.

2.6.1 Right to Sublicense. Subject to the terms of this Agreement, Licensee will have the right to grant sublicenses, through multiple tiers, of the rights granted under Section 2.1 (License Grant to Licensee) to Third Parties or Affiliates (each a "Sublicense") (a) with the prior written consent of Licensor in the Major Markets, which consent may not be unreasonably withheld, conditioned, or delayed, and (b) [***]. 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 2.6.2 (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.

2.6.2 Sublicense Survival. Upon 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, then Licensee will promptly provide written notice of termination to all Sublicensees. Within [***] days of the effective date of termination pursuant to the preceding sentence, any Sublicensee who is not then in breach of its Sublicense or the terms of this Agreement, may elect, by providing written notice to Licensor, for the Sublicense

to become a direct license with Licensor, provided, however, that (a) such Sublicensee will be required to pay to Licensor the same amounts in consideration for such direct grant as Licensee would have otherwise received from such Sublicensee pursuant to such Sublicense and (b) 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.

2.6.3 Terms of Sublicenses to Third Parties. Within [***] days of granting any Sublicense, Licensee will provide a true and complete copy of such Sublicense to Licensor, provided that Licensee may redact any financial terms contained therein that are not necessary for Licensor to determine the scope of the rights granted under such Sublicense and compliance with the requirements of this Agreement and the AZ License. For the avoidance of doubt, upon 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, Licensee will provide to Licensor an unredacted copy of all Sublicenses. Each Sublicense 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 (Licensee Covenants), 12.5 (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 2.4 (License Grant to Licensor) and assignment of Product Inventions set forth in Section 14.1.2(b) (Ownership of Arising Intellectual Property) 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 the Territory in accordance with Section 2.8.1 (Licensee Exclusivity); and

(f) is subject to those provisions in the AZ License that are applicable to sublicensees.

2.6.4 Right to Subcontract. Subject to the terms of this Agreement, Licensee will have the right to engage Subcontractors, without requiring Licensor's prior written consent, for the sole purpose of performing Licensee's obligations with respect to the Manufacturing, Development, performance of Medical Affairs activities with respect to, or Commercialization of the Licensed Products in the Territory 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 (Licensee Covenants), 12.5 (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 2.4 (License Grant to Licensor) with respect to such Licensee Collaboration Know-How and Licensee Collaboration Patent Rights and assignment of Product Inventions set forth in Section 14.1.2(b) (Ownership of Arising Intellectual Property). Licensee will conduct appropriate risk-based due diligence to assess the capabilities, compliance, and reputation of Subcontractors that it engages. Licensee will not engage any Subcontractor that is Debarred/Excluded.

2.6.5 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 that are applicable to such Third Parties. 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.

2.7 AZ License.

2.7.1 Licensor. Licensor covenants and agrees that it (a) will not enter into any amendment of or waive any rights under the AZ License that would materially adversely impact or otherwise modify the rights of Licensee under this Agreement or Licensee's rights to Exploit

the Licensed Products in accordance with the terms of this Agreement; and (b) will comply with the terms of the AZ License and will not take any action that would result in Licensor's breach of the AZ License that would give rise to a right of termination that remains uncured beyond the applicable cure period under the AZ License. In the event that the AZ License is terminated, Licensor will use Commercially Reasonable Efforts to secure direct license rights for Licensee on substantially similar terms as set forth in the AZ License.

2.7.2 Licensee. 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 Licensed 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 that portion of the Licensed Technology that is being sublicensed to Licensee under this Agreement, 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 terms of the AZ License applicable to Licensee as a sublicensee thereunder.

2.8 Exclusivity Covenants.

2.8.1 Licensee Exclusivity. On a Licensed Product-by-Licensed Product basis, (i) Licensee will not, and will cause its Affiliates and Sublicensees not to, and (ii) Licensor will not, and will cause its Affiliates and Sublicensees not to, directly or indirectly, [***]; provided that [***].

2.8.2 Business Combinations. Neither Party will be in breach of the restrictions set forth in this Section 2.8 (Exclusivity Covenants) if such Party or any of its Affiliates or licensees or Sublicensees undergo 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 2.8.1 (Licensee Exclusivity) (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 the Territory, as long as (i) no Licensed 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.

2.8.3 Acquisition of a Competing Product. Neither Party will be in breach of the restrictions set forth in this Section 2.8 (Exclusivity Covenants) if such Party or any of its Affiliates or licensees or Sublicensees acquires a Competing Product that is being Exploited in the Territory in a manner that would otherwise breach Section 2.8 (Exclusivity Covenants), 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 such Party or the applicable Affiliate, licensee or Sublicensee (a) enters into a definitive agreement with a Third Party to divest (whether by exclusive out-license or otherwise) such Competing Product throughout the Territory and closes such transaction within [***] days after the closing of such acquisition or merger or (b) terminates the further Exploitation of such Competing Product throughout the Territory within [***] days after the closing of such acquisition or merger, and, until the completion of such divestiture or termination, (i) no Licensed Technology or Licensee Collaboration Technology is used by or on behalf of such Party or its Affiliates, licensees or Sublicensees, as applicable, in connection with any subsequent Exploitation of such Competing Products in the Territory and (ii) such Party and its Affiliates, licensees or Sublicensees, as applicable, 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.

2.9 Licensee Right of First Negotiation. Licensee will have the right to negotiate a definitive license agreement with respect to each Optional Licensed Product Improvement in the Territory on the terms set forth in this Section 2.9 (Licensee Right of First Negotiation) (such negotiation right, the "Licensee ROFN"). During the Term, if Licensor makes the decision, in accordance with its standard practice, that it is interested in licensing the right to develop any Product Improvement that is not an Automatic Licensed Product Improvement, (each an "Optional Licensed Product Improvement"), then Licensor will promptly provide notice of such Optional Licensed Product Improvements to Licensee (each such notice, a "Licensee ROFN Trigger Notice"). If, within [***] Business Days following its receipt of a Licensee ROFN Trigger Notice (the "Licensee ROFN Notice Period"), Licensee provides a written notice to Licensor exercising the Licensee ROFN with respect to the Optional Licensed Product Improvement that is the subject of such Licensee ROFN Trigger Notice (each such notice from Licensee to Licensor, a "Licensee ROFN Negotiation Notice"), then during the period commencing on the date of Licensor's receipt of the Licensee ROFN Negotiation Notice and ending [***] days thereafter (or such longer period as is mutually agreed by the Parties) (the "Licensee ROFN Negotiation Period"), Licensor and its Affiliates will exclusively negotiate in good faith with Licensee 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 Optional Licensed Product Improvements in the Territory. If (a) Licensee does not deliver a Licensee ROFN Negotiation Notice to Licensor during the applicable Licensee ROFN Notice Period or (b) Licensee delivers a Licensee ROFN Negotiation Notice to Licensor during the applicable Licensee ROFN Notice Period, but the Parties fail to enter into a definitive license agreement (or amendment to this Agreement) with respect to the applicable Optional Licensed Product Improvement during the applicable Licensee ROFN Negotiation Period, then in each case ((a) or (b)), Licensor will be free to negotiate any transaction with respect to the applicable Optional Licensed Product Improvement with any Third Party and will have no further obligation to enter into an agreement with Licensee with respect to such Optional Licensed Product Improvement, provided if Licensee had delivered a Licensee ROFN Negotiation Notice for such Optional Licensed Product Improvement, during the [***] months following the expiry of the Licensee ROFN Negotiation Period Licensor may only license such Optional Licensed Product Improvement to Third Parties on terms no less favorable to Licensor in the aggregate than

the terms last offered to Licensee during the Licensee ROFN Negotiation Period, and provided further, if after, after the [***]-month anniversary of the expiry of the Licensee ROFN Negotiation Period, Licensor has not entered into a definitive agreement to license such Optional Licensed Product Improvement with a Third Party, then the Licensee Right of First Negotiation will automatically reset and will apply for the next round of negotiation of a definitive license agreement with respect to each Optional Licensed Product Improvement in the Territory.

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 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 the Territory. The JSC will be composed 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") until the first anniversary of the Effective Date. Thereafter, a Licensee representative will become the JSC Chairperson for the next [***] months of the Term and then the role of JSC Chairperson will rotate between the Parties every [***] months during the Term. 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 five 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) [***] any amendment to a Territory Development Plan, as described in Section 4.2 (Territory Development Plans);

(c) [***] approve any Clinical Trials, as described in Section 4.3 (Clinical Trial Design; Protocols);

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

(e) discuss material Development Data and Clinical Data generated by or on behalf of either Party;

(f) [***] any Proposed New Formulations, Concentrations, or Indications, as described in Section 4.8 (Development of New Formulations, Concentrations, or Indications);

(g) discuss any regulatory developments related to the Licensed Products in each country and Region in the Territory;

(h) [***] any Territory Medical Affairs Plan or amendment thereto, as described in Section 7.1 (Territory Medical Affairs Plans);

(i) [***] of Medical Affairs activities inside and outside the Territory;

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

(k) discuss the Licensed Product Trademarks, as described in Section 14.11.2 (Licensed Product Trademarks in the Territory)

(l) 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

(m) 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 Territory Development Plan or Territory Medical Affairs Plan so long as such obligations 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.

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 those matters within the jurisdiction of the JSC pursuant to Section 3.2 for the following matters: [***].

(b) No Change; Status Quo. Neither Party will have final decision-making authority over with respect to the final resolution of any other disagreement regarding a matter delegated under this Agreement to the JSC for decision, including approval of: [***].

(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 mutually agree in writing 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 of this Agreement, including Article 9 (Diligence), as between the Parties, Licensee will be solely responsible for and will conduct all Development under the Territory Development Plan ("Development Activities") at its sole cost.

4.2 Territory Development Plans. All Development 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 (Territory Development Plans), a "Territory Development Plan"). The initial Territory Development Plan for each Licensed Product is set forth on Schedule 4.2 (Initial Territory Development Plans) attached hereto and the Parties will use reasonable efforts through the JSC to approve a more detailed Territory Development Plan complying with the terms of this Section 4.2 (Territory Development Plans) within [***] days of the Effective Date or such longer period as mutually agreed by the Parties in writing. Each Territory Development Plan and all updates thereto will contain in reasonable detail (a) a description of the scope and breadth of initial Development Activities for the applicable Licensed Product in the Field in the Territory, including Clinical Development activities reasonably necessary to support Regulatory Approval of such Licensed Product in the Field in the Territory, including a description of all protocols of planned Clinical Trials, (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, and (d) an estimated timeline for submission of MAAs for the applicable Licensed Product in each country and Region in the Territory. From time to time during the Term, but at least [***], the JSC will discuss the status of

activities under each Territory Development Plan. The JSC will review, discuss, and determine whether to approve any and all updates to a Territory Development Plan. Once approved by the JSC, each update to a Territory Development Plan will become effective and supersede the then-current Territory 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 Territory 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 of a Clinical Trial Issue, then upon at least [***] days' notification by Licensor and at Licensor's cost and expense, Licensor may conduct an audit of Licensee and its Affiliates, Sublicensees, and Subcontractors, and those Clinical Trial sites engaged by Licensee or its Affiliates or Sublicensees to perform Licensee's obligations under any Territory Development Plan and affected by the Clinical Trial Issue, in each case, to determine whether the applicable Clinical Trials are being conducted in compliance with the terms of the AZ License, the terms of this Agreement relevant to Clinical Trials (i.e., not the focus of audits pursuant to Section 5.7 (Regulatory Audits), Section 10.10 (Financial Records and Audits) or Section 12.8.2 (Compliance Audits)), the applicable Territory Development Plan, cGLP, cGMP, cGCP, and Applicable Law. After preparing or receiving an audit report, Licensor will provide Licensee with a written summary of Licensor's findings of any material deficiencies from such standards that Licensor identifies during any such audit. Notwithstanding any provision to the contrary in this Agreement, Licensor may provide any such reports to the counterparty to the AZ License. Licensee will remediate any such undisputed deficiencies no later than [***] days after Licensee's receipt of such report, at Licensee's cost and expense or, if such remediation is anticipated to take longer than [***] days, then Licensee will coordinate with the JSC to implement a plan to complete such remediation as soon as practicable. If any undisputed deficiencies or areas of remediation, that have or could reasonably be expected to have a Material Adverse Impact, are identified in the course of such audit, then Licensee will reimburse Licensor for Licensor's costs and expenses relating to the conduct of such audit within [***] days after receiving Licensor's invoice therefor. To the extent not inconsistent with the AZ License, if Licensee disputes any of Licensor's findings of deficiencies, then either Party may refer the issue to an independent Third Party regulatory compliance consultant expert agreed by both Parties for resolution. The decision of such independent expert will be final and binding and all fees and expenses of such independent expert will be borne by the Party against which the decision is rendered by the independent Third Party expert.

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 any audit of a Clinical Trial site conducted pursuant to Section 4.4.1 (Conduct of Audits) identifies any non-compliance by such Clinical Trial site with the AZ License, this Agreement, the applicable Territory Development Plan, 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, then, without prejudice to any other remedies available to Licensor under this Agreement, 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 will 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 the Territory 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 will be compliant in all respects with Applicable Law (including cGLP, cGMP, and cGCP, as applicable). In addition, if any audit of any Sublicensee conducted pursuant to Section 4.4.1 (Conduct of Audits) identifies that any Sublicensee or Subcontractor is not performing its activities in accordance with the terms of the AZ License, this Agreement, the applicable Territory Development Plan, 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, without prejudice to any other remedies available to Licensor under this Agreement, Licensee will require that Deficient Sublicensee/Subcontractor promptly remedy any such deficiency to Licensor's reasonable satisfaction, and if such remedy is not completed in a timely fashion, the Licensee will take action to prohibit such Deficient Sublicensee/Subcontractor from performing further activities under the applicable Territory Development Plan and replace such Deficient Sublicensee/Subcontractor with a new Sublicensee engaged in accordance with Section 2.6 (Sublicensing and Subcontractors) to perform the applicable Development Activities at Licensee's sole cost and expense.

4.4.3 Licensee Audits. Licensee will promptly notify Licensor of all upcoming audits, including those conducted by health authorities, ethics boards, or institutional review boards as well as those that Licensee or its Affiliates or Sublicensees plan to conduct of any Sublicensee, Subcontractor, or Clinical Trial site that Licensee or its Affiliates or Sublicensees have engaged to fulfill Licensee's obligations under each Territory Development Plan. Upon (a) the reasonable request of Licensor or (b) such audit revealing any Critical Findings, Licensee will prepare, or cause to be prepared, a report detailing the findings of such audit and provide such report to Licensor within [***] days of (a) or (b), as applicable. 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 validated computer systems that are compliant with Applicable Law (including cGLP, cGMP, and cGCP, as applicable). 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 [***] 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 Territory 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. Each such report will contain sufficient detail to enable Licensor to reasonably assess Licensee's compliance with the Territory Development Plan and Licensee's diligence obligations under this Agreement, including Licensee's, or its Affiliates' or its or their Sublicensees' activities with respect to achieving Regulatory Approvals of Licensed Products in the Territory and clinical study results and results of other Development activities. 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. To the extent permitted by the Applicable Law and the Licensor having duly cooperated with the Licensee to complete the procedural requirements under Applicable Law in each case, 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 (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 the Territory under a Territory 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 Territory Development Plan (collectively, "Clinical Data") to Licensor no later than [***] days after the tables, figures, and listings for such Clinical Trial first become available. Licensor and its Affiliates and its and their

designees will have the exclusive right to use and reference such Development Data provided by Licensee, solely 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 the Territory. Notwithstanding anything to the contrary contained herein, Licensee has the full ownership of all Development Data and Clinical Data generated by Licensee or its designee.

4.8 Development of New Formulations, Concentrations, or Indications. Except as set forth in this Section 4.8 (Development of New Formulations or 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 1.14 (ARQ-151) and Schedule 1.15 (ARQ-154), (b) concentrations for the applicable Licensed Product which Licensor or its Affiliates obtains Regulatory Approval for outside the Territory, or (c) in the Indications, as applicable (the "Approved Formulations, Concentrations, and Indications"). 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 (a "Proposed New Formulation, Concentration, or Indication"), then upon notice from Licensee, the Parties, through the JSC, will discuss and determine whether to approve Licensee Developing the Licensed Products for such Proposed New Formulation, Concentration, or Indication. If the Parties agree on Licensee conducting such Development, then Licensee will submit to the JSC an amendment to the Territory 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 Territory Development Plan for the Proposed New Formulation, Concentration, or Indication, then (i) Schedule 1.14 (ARQ-151) or Schedule 1.15 (ARQ-154), as applicable, will be amended to include 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. Notwithstanding anything to the contrary contained herein, Licensee has the full ownership of all data made, collected, or otherwise generated under or in connection with the Proposed New Formulation, Concentration, or Indication.

4.9 Licensor Data and Documentation. Licensor will use Commercially Reasonable Efforts to provide, in a timely manner, to a Regulatory Authority in the Territory, any data or other documentation that (a) Licensor Controls, (b) is in existence as of the Effective Date, or, with respect to documents and data for (i) Optional Licensed Product Improvements, the date Licensee is granted a license to such Optional Licensed Product Improvements pursuant to the exercise of the Licensee ROFN, 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, and (d) can only be provided by Licensor or its designee, 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**. As between the Parties and subject to Article 9 (Diligence), Licensee will be responsible for preparing and submitting all Regulatory Submissions, including each MAA, for Licensed Products in the Territory in accordance with the applicable Territory Development Plan, including meeting the timelines set forth in the applicable Territory Development Plan. Licensee or its designee will be the Marketing Authorization Holder in the Territory for each Licensed Product. In addition, as between the Parties, Licensee will be responsible for conducting all regulatory activities and interactions with Regulatory Authorities in the Territory in connection with the Development Activities for any Licensed Product in accordance with this Section 5.1 (Licensee's Responsibilities). In the event that it is not feasible for Licensee to own any such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals in its own name according to relevant Applicable Laws in the Territory, then Licensor will hold such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals, as applicable, in its own name for the benefit of and on behalf of Licensee, in which case Licensor with be the Marketing Authorization Holder, and will appoint Licensee as its legal agent in the Territory at the sole expense of Licensee. When feasible and reasonable pursuant to Applicable Law, Licensor will conduct activities and execute documents that are necessary for transferring such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals, as applicable, to Licensee upon Licensee's written request and sole expense.

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. 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 described in this Section 5.1.1(b) (Review and Approval of Regulatory Submissions). Licensee will provide to Licensor (through the JSC) 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, reasonably in advance of any applicable submission deadline (and in no event less than [***] days prior to such submission deadline). Licensee will reasonably consider any comments Licensor may have regarding such Regulatory Submissions. Licensee will, and 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. Licensee will, at its own cost and expense, reasonably cooperate with Licensor in connection with Licensor's regulatory activities with respect to the Licensed Products outside of the Territory, including by providing access to its qualified personnel on a reasonable basis to consult with Licensor with respect to such regulatory activities.

5.1.3 Regulatory Reports. At each meeting of the JSC, (a) Licensee will keep Licensor, through the JSC, informed of regulatory developments related to the Licensed Products in each country and Region in the Territory, and (b) Licensor will keep Licensee informed, through the JSC, of material regulatory developments related to the Licensed Products outside the Territory. Each Party will, as soon as reasonably practicable, notify the other Party in writing of any decision by any Regulatory Authority in the Territory, in the case of Licensee, or outside the Territory, in

the case of Licensor, regarding any Licensed Product, but in any event within [***] Business Days of receipt of such decision.

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 Regulatory Approval for the Licensed Products in the Territory, including by providing access to its qualified personnel on a reasonable basis to consult with Licensee with respect to such regulatory activities. The first [***] hours of such assistance provided by Licensor would be provided without charge, and Licensee would pay for all further assistance in excess of such [***] hours 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. Any such payments will be made through a separate consultation service agreement to be negotiated by the Parties in good faith.

5.3 Costs and Expenses. Except as set forth in Section 5.2 (Licensors 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 the Territory. 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 the Territory 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 the Territory, 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 Regulatory Approvals and Regulatory Submissions pertaining to the Licensed Products in the Territory 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. Licensee will bear its own costs and expenses associated with providing Licensor with 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.

5.5.2 Licensee Right of Reference. 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 and submitted by or on behalf of Licensor to any Regulatory Authority during the Term. Licensee may use such Right of Reference solely to conduct Development Activities in accordance with the terms of the applicable Territory Development Plan, to perform Medical Affairs in accordance with the Territory 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 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.

5.6 Pharmacovigilance and Adverse Events Reporting. The Parties will use Commercially Reasonable Efforts to enter into a mutually agreed-upon pharmacovigilance agreement within [***] days prior to the anticipated initiation of the first Clinical Trial by or on behalf of Licensee or a Sublicensee for a Licensed Product.

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 the Territory, 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 the Territory. 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 Territory Development Plan. Licensor will be responsible for: (a) reporting to the applicable Regulatory Authorities in the Territory, except for Chinese Mainland, all quality complaints, adverse events, and safety data related to such Licensed Product for all Clinical Trials conducted under a Territory Development Plan; and (b) responding to safety issues and to all requests of Regulatory Authorities, except in Chinese Mainland, related to such Licensed Product and any Territory 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 Territory 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, 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 at least [***]days prior notice and no more frequently than once per Calendar Year, 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 (i.e., not the focus of audits pursuant to Section 4.4 (Clinical Trial Audit Rights), Section 10.10 (Financial Records and Audits) or Section 12.8.2 (Compliance Audits) of this Agreement)). 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 [***] 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 of the Territory 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 five Business Days after receipt of such notice (or, if action is taken without notice, within two days of Licensee becoming aware of such action).Licensee will have the final decision-making authority with respect to such responses and will consider and incorporate in good faith Licensor's reasonable comments to any such responses that are received in a timely manner.

ARTICLE 6
MANUFACTURING, SUPPLY AND TECHNOLOGY TRANSFER

6.1 Clinical and Commercial Supply. On a Licensed Product-by-Licensed Product basis, no later than (a) for clinical supply, [***] months after the Effective Date and (b) for commercial supply, [***] months prior to the anticipated First Commercial Sale of such Licensed Product (each date, a "Supply Election Date"), Licensee will elect to obtain supply of Licensed Product via the Importation Model or the Localization Model, as set forth in this Section 6.1 (Clinical and Commercial Supply). Licensee will be allowed to elect either the Importation Model, subject to Licensor's agreement pursuant to 6.1.1 (Importation Model), or Localization Model for both clinical and commercial supply, provided that if Licensee elects the Localization Model for clinical supply, it will be deemed to have also elected the Localization Model for commercial supply.

6.1.1 Importation Model. On a Licensed Product-by-Licensed Product basis, upon Licensee's request, which request must be submitted no later than the applicable Supply Election Date, the Parties will negotiate in good faith to enter into one or more clinical or commercial supply agreements, as applicable, and associated quality agreements that will govern the terms of supply of Licensed Products to Licensee for the either Development or Commercialization, as applicable of Licensed Products in the Territory under this Agreement (the "Importation Model"). Such supply agreement(s) will (a) be consistent with the applicable terms of this Agreement, the AZ License, and, if the agreement is with Licensor, any agreement between Licensor and the applicable CMO(s) related to the Manufacturing and supply of Licensed Products, (b) if the agreement is with Licensor, have a supply price of Licensor's Fully Burdened Manufacturing Costs plus a [***]% markup, with such cost subject to Licensee's customary audit rights and (c) will otherwise be on commercially reasonable terms. The Parties may agree that such commercial supply agreement(s) and associated quality agreement(s) should be between Licensee and Licensor's applicable CMO(s), in which case Licensor will introduce Licensee to the applicable CMO(s) and use Commercially Reasonable Efforts to facilitate and support such negotiation. Any such commercial supply agreement under the Importation Model will include a mechanism based

on forecast and actual demand to allocate available supply of Licensed Product on a pro-rata basis to be set forth in the applicable agreement between Licensee, Licensor, and any other Third Party in the event of a shortage of supply of the Licensed Products.

6.1.2 Localization Model. On a Licensed Product-by-Licensed Product basis, if Licensee has not entered into a supply agreement pursuant to the Importation Model prior to (a) for clinical supply, the initiation of the first Clinical Trial for a Licensed Product by Licensee hereunder, or (b) for commercial supply, the First Commercial Sale of a Licensed Product, Licensor will use Commercially Reasonable Efforts to transfer applicable manufacturing technology and process to Licensee or Licensee's designated Third Party for the Manufacture of such Licensed Product, as set forth in this Section 6.1.2 (Localization Model) (the "Localization Model"). Within [***] days of the date Licensee elects the Localization Model (the "Localization Effective Date"), Licensor will commence transferring to Licensee or its designee (the "Licensee Manufacturer") (i) any Licensed 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, so that Licensee can successfully Manufacture three commercial batches of Licensed Product after the completion of the transfer. Licensee would pay for all internal costs and expenses associated with such transfer activities provided by Licensor and its Affiliates in connection with such transfer at the FTE Rate, and Licensee would pay for all out-of-pocket costs incurred by Licensor in providing such transfer, in each case within [***] days of receipt of an invoice from Licensor for such FTE expenses or out-of-pocket costs. Licensee will be solely responsible for all of its and the Licensee Manufacturer's costs and expenses in connection with such transfer.

ARTICLE 7
MEDICAL AFFAIRS

7.1 Territory 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 (Territory Medical Affairs Plans), a "Territory 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, and in no event later than [***] days prior to the anticipated commercial launch of such Licensed Product in the Territory, the JSC will develop, review, discuss, and determine whether to approve an initial Territory Medical Affairs Plan for such Licensed Product in the Territory. Each Territory 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, and (b) the estimated timelines for performing such activities. Following the approval of a Territory Medical Affairs Plan in accordance with the terms of this Agreement, from time to time during the Term, the either Party may propose updates to such Territory Medical Affairs Plan and submit such proposed updated Territory 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 Territory Medical Affairs Plan will become effective and supersede the then-current Territory 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, no later than [***] days after 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 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) (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 Territory 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 the Territory. 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. Subject to Article 9 (Diligence), Licensee will have the sole and exclusive right (even as to Licensor and its Affiliates) 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. 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 National Reimbursement Drug List (NRDL) of China; (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, no later than [***] days after the end of the Calendar Quarter, Licensee will provide Licensor (through the JSC) a written report (a) summarizing on a country-by-country and Region-by-Region basis the Commercialization activities conducted by or on behalf of Licensee under this Agreement with respect to each Licensed Product in the Territory 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) (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 reasonably assess Licensee's compliance with its diligence obligations set forth in Article 9 (Diligence).

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 the Territory. Any such materials or insight presented to the JSC will be deemed Licensed 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 Regulatory Approval for each Licensed Product [***], and (b) to Commercialize each Licensed Product in each country or Region in the Territory 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 $30,000,000 in immediately available funds by wire transfer, in accordance with wire instructions and invoice to be provided by Licensor to Licensee.

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 "Development and Regulatory Milestone Event," and each respective payment, a "Development and Regulatory Milestone Payment"), in accordance with Section 10.2.3(a) (Regulatory and Commercial Milestone Payments):

Table 10.2.1 – Regulatory Milestones	
Development and Regulatory Milestone Event	Development Regulatory Milestone Payment
FDA CBE-30 or PAS approval of ARQ-151 (0.3% concentration), before [***]	$[***]
FDA CBE-30 or PAS approval of ARQ-154 (0.3% concentration), before [***].	$[***]
Dosing of 1st patient in the first Clinical Trial in China	$[***]
Filing of the first NDA for a Licensed Product in China	$[***]
First Regulatory Approval of a Licensed Product in China for psoriasis	$[***]

Table 10.2.1 – Regulatory Milestones	
Development and Regulatory Milestone Event	Development Regulatory Milestone Payment
First Regulatory Approval of a Licensed Product in China for atopic dermatitis	$[***]
First Regulatory Approval of a Licensed Product in China for seborrheic dermatitis	$[***]

Each Development and Regulatory Milestone Payment will be payable one time only as set forth in the table above, upon achievement of the applicable Development and 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 Total Annual Net Sales such Licensed Product (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 Total Annual Net Sales of all Licensed Products in the Territory equal or exceed $[***]	$[***]
First Calendar Year in which aggregate Total Annual Net Sales of all Licensed Products in the Territory equal or exceed $[***]	$[***]
First Calendar Year in which aggregate Total Annual Net Sales of all Licensed Products in the Territory equal or exceed $[***]	$[***]
First Calendar Year in which aggregate Total Annual Net Sales of all Licensed Products in the Territory equal or exceed $[***]	$[***]
First Calendar Year in which aggregate Total Annual Net Sales of all Licensed Products in the Territory equal or exceed $[***]	$[***]

(b) Achievement of Sales Milestones. Each Sales Milestone Event will be payable one time only based on aggregate sales of all of the Licensed Products as set forth in the table above, upon the first achievement of the applicable Sales Milestone Event for such Licensed Products. For clarity, no Sales Milestone Payment will be due hereunder for any subsequent or repeated achievement of such same Sales Milestone Event.

10.2.3 Invoicing and Payment of Milestone Payments.

(a) Development and Regulatory Milestone Payments. In the event that Licensee, its Affiliates or its Sublicensees under this Agreement achieves a Development and Regulatory Milestone Event, it will notify Licensor thereof within [***] Business Days of such achievement. Following Licensor's receipt of notice from Licensee that Licensee has achieved a Development and Regulatory Milestone Event, Licensor will invoice Licensee for the applicable Development and Regulatory Milestone Payment, and Licensee will pay to Licensor such Development and Regulatory Milestone Payment within [***] Business 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 Total Annual Net Sales of any applicable Licensed Product first achieve a Sales Milestone Event during a particular Calendar Year, Licensee will notify Licensor thereof in the last Royalty Report for such Calendar Year 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 [***] Business 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 Total Annual Net Sales of all Licensed Products during the applicable Royalty Term for each Licensed Product as set forth in the table below in this Section 10.3.1 (Royalty Rates), as may be adjusted in accordance herewith ("Royalties"). Net Sales for a given Licensed Product in a given country or Region for which the Royalty Term has expired will not be included in the Total Annual Net Sales for purposes of calculating the Royalties (and Royalty tiers).

Total Annual Net Sales for a Licensed Product	Royalty Rate
Portion of Total Annual Net Sales up to and including $[***]	[***]%
Portion of Total Annual Net Sales above $[***] up to and including $[***]	[***]%
Portion of Total Annual Net Sales above $[***] up to and including $[***]	[***]%
Portion of Total Annual Net Sales above $[***] up to and including $[***]	[***]%
Portion of Total Annual Net Sales above $[***] up to and including $[***]	[***]%
Portion of Total Annual Net Sales above $[***]	[***]%

For example only, if there is $[***]in the aggregate of Total Annual Net Sales of the Licensed Products in the Territory a given Calendar Year, after conversion to U.S. Dollars of the Net Sales in each country or Region in the Territory, then Licensee would owe a Royalty payment of [***].

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 and country-by-country and Region-by-Region basis, only during the applicable Royalty Term for such Licensed Product in such country or Region. Following the expiration of the applicable Royalty Term for a given Licensed Product in a given country or Region: (a) no further Royalties will be payable with respect to sales of such Licensed Product in such country or Region; and (b) the license granted to Licensee under this Agreement with respect to such Licensed Product in such country or Region will become fully paid-up, perpetual, irrevocable, and royalty-free in accordance with Section 15.3.1 (Expiration of the Royalty Term).

10.3.3 Royalty Reductions.

(a) Absence of Valid Claims. On a Licensed Product-by-Licensed Product and country-by-country and Region-by-Region basis, during the Royalty Term for such Licensed Product, if the composition of matter, method of use, or method of manufacturing of such Licensed Product or a component thereof in such country or Region is not Covered by a Valid Claim of any Patent Right included in the Licensed Patent Rights, then the then-applicable Royalty rate payable with respect to Total Annual Net Sales of such Licensed Product pursuant to this Section 10.3 (Royalties) in such country or Region will be reduced by [***]%.

(b) Generic Competition. On a Licensed Product-by-Licensed Product and country-by-country and Region-by-Region basis, during the Royalty Term for such Licensed Product, (i) if in a Calendar Quarter following the first Calendar Quarter in which the First Commercial Sale of a Generic Product occurs in such country or Region (such first Calendar Quarter, the "Launch Quarter") the Net Sales in such Calendar Quarter of such Licensed Product in such country or Region decline by greater than [***]% but less than [***]% relative to the average quarterly Net Sales of such Licensed Product in such country or Region occurring during the four consecutive Calendar Quarters immediately preceding the Launch Quarter, then, thereafter for so long as such Generic Product is commercially available in such country or Region, the then-applicable Royalty rate of such Licensed Product pursuant to this Section 10.3 (Royalties) in such country or Region will be reduced by [***]%; (ii) if in a Calendar Quarter following the Launch Quarter, the Net Sales in such Calendar Quarter of such Licensed Product in such country or Region decline by [***]% or more relative to the average quarterly Net Sales of such Licensed Product in such country or Region occurring during the four consecutive Calendar Quarters immediately preceding the Launch Quarter, then, thereafter for so long as such Generic Product is commercially available in such country or Region, the then-applicable Royalty rate of such Licensed Product pursuant to this Section 10.3 (Royalties) in such country or Region will be reduced by [***]%:

10.4 Aggregate Limitation on Deduction. Notwithstanding the foregoing, in no event will the deductions set forth in Section 10.3.3 (Royalty Reductions) reduce the royalties payable to Licensor with respect to a particular Calendar Quarter in a given country or Region to less than

[***]% of the royalties that would otherwise be due pursuant to Section 10.3.1 (Royalty Rates); provided, that Licensee will be entitled to carry forward to subsequent Calendar Quarters any amounts with respect to which Licensee would have been entitled to make a deduction pursuant to Section 10.3.3 (Royalty Reductions), but is unable to take such deduction as a result of the limitation set forth in this Section 10.4, until such reduction is fully realized.

10.5 Royalty Payments and Reporting. Licensee will calculate, on a Licensed Product-by-Licensed Product and country-by-country and Region-by-Region 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 each country or Region in the Territory) 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 [***] Business 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 [***] Business 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, Licensee will provide written notice to Licensor of such change.

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 exchange rate between each currency of origin and Dollars as reported by The Wall Street Journal, Eastern Addition, or an equivalent resource as agreed by the Parties, on the last Business Day of the Calendar Quarter with respect to which such payment became 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. Notwithstanding the foregoing, nothing in this Section 10.8 (Blocked Payments) will be interpreted to require either Party to violate Applicable Law.

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. Each Party 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 the other Party to confirm the accuracy of the amounts paid, reimbursed, credited, offset, or shared (or required to be paid, reimbursed, credited, offset, or shared) by such Party 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 the auditing Party and reasonably acceptable to the audited Party or its applicable Affiliate for the sole purpose of verifying for the auditing Party the accuracy of (a) the financial statements, reports, or notices (the "Financial Documents") furnished by the audited Party or such Affiliate pursuant to this Agreement or (b) the Amounts (i.e., not the focus of the audits pursuant to Section 4.4 (Clinical Trial Audit Rights), Section 5.7 (Regulatory Audits) or Section 12.8.2 (Compliance Audits)). Such Auditor will subject to written obligations of confidentiality and non-use applicable to each Party's Confidential Information that are at least as stringent as those set forth in this Agreement. Such audit will not (a) be performed more frequently than [***]during the Term, (b) be performed more frequently than [***]after the expiration or termination of this Agreement, (c) conducted for any Calendar Year more than [***] years after the end of such year, or (d) repeated for any Calendar Year or with respect to the same set of records (unless a material discrepancy with respect to such records is discovered during a prior audit). Any such audit will not disclose the audited Party's or its Affiliates' or Sublicensees' or Subcontractors' Confidential Information to the auditing Party, 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 receipt of 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 the audited Party, 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). The auditing Party will bear the full cost and expense of such audit unless such audit reveals an overpayment to, or an underpayment by, the audited Party or its Affiliates that resulted from a discrepancy in a Financial Document that the audited Party or its Affiliates provided to the other Party 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 the audited Party or its applicable Affiliate will bear the full cost and expense of such audit. Each Party, at the request of the other Party, will make available to the other Party the results of any audit performed by the non-requesting Party on such non-requesting Party'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. [***] (a "Cost Reimbursement") by Licensee to Licensor not be subject to any deduction or withholding for Taxes. To the extent that any Taxes will be required by Applicable Law to be deducted or withheld from any Cost Reimbursement, (i) the amount payable by Licensee for such Cost Reimbursement will be increased as may be necessary so that after making all required deductions or withholdings of Taxes, Licensor will receive an amount equal to the amount it would have received for such Cost Reimbursement had no such deductions or withholdings of Taxes been made and (ii) Licensee will make such deductions and withholdings of Taxes and pay the full amount deducted and withheld to the relevant Governmental Authority in accordance with Applicable Law. Licensor will provide reasonable assistance to enable the recovery of the withholding Tax resulting from the payment of Cost Reimbursement, and to the extent that Licensor recovers any Taxes withheld by Licensee or receives Tax credits that would otherwise have reduced the amount by which Licensee had to increase the payment to Licensor under Section 10.11.2 (Withholding Tax), then Licensee will receive a credit for such amount, which credit Licensee may set off against future payments of amounts due to Licensor hereunder.

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 (a) the withholding Party, a reasonable amount of time prior to making any payment that is subject to withholding, (i) notifying the other Party in writing that (A) such payment is subject to withholding, (B) the amount that will be withheld or rate of withholding, and (C) a reasonable description of the provision of Applicable Law that requires

such withholding and (ii) 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 and (b) each Party providing 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. 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 will 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 will 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, transfer, sales, purchase, turnover, or similar tax as may be applicable in any relevant jurisdiction.

10.11.5 No Partnership. Nothing contained in this Agreement will 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) will, 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.

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 Licensed Know-How and Product Inventions 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 (other than Product Inventions) 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 (not to be unreasonably withheld, conditioned or delayed) 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 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, would have a Material Adverse Impact on 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. Notwithstanding any provision to contrary set forth in this Agreement, Licensor will delete any Confidential Information of Licensee that Licensee identifies for deletion in Licensee's written comments.

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 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 each issue a press release announcing this Agreement, as set forth on Schedule 11.7.1 (Press Releases), on such date and time as may be agreed by the Parties. Other than the press releases set forth on Schedule 11.7.1 (Press Releases) 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 Section 4.7 (Data Exchange 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 releases set forth on Schedule 11.7.1 (Press Releases) 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 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 Releases) 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 Releases) 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 It has the right under the Licensed Technology to grant to Licensee the licenses set forth in this Agreement, and it has not granted any license or other right under the Licensed Technology that is inconsistent with the licenses granted to Licensee hereunder.

12.2.2 Schedule 1.109 (Licensed Patent Rights) lists all Licensed 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 the Territory in the Field, and Licensor owns or Controls all rights, title and interests in and to such Licensed Patent Rights.

12.2.3 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.

12.2.4 There are no pending or, to Licensor's Knowledge, threatened, adverse actions, suits, or proceedings against Licensor or any of its Affiliates involving the Licensed Technology (including to invalidate Licensed Patent Rights).

12.2.5 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.

12.2.6 To Licensor's Knowledge, Licensor has not withheld from Licensee any information with respect to the Licensed Technology that would be reasonably likely to result in a Material Adverse Impact on the Development, Manufacture, or Commercialization of the Licensed Product in the Territory as contemplated under this Agreement. To Licensor's Knowledge, (a) true, complete, and correct copies of all portions of Regulatory Documentation that has been requested by Licensee have been provided or made available to Licensee prior to the Effective Date and (b) all other the information provided by Licensor to Licensee regarding the Licensed Technology is true, correct and complete in all material respects.

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 Licensed Technology licensed to Licensee under this Agreement.

12.2.8 The AZ License is a valid binding agreement, enforceable in accordance with the terms and neither Licensor nor, to Licensor's knowledge, the counterparty to the AZ License (a) is in breach of the AZ License; (b) has alleged or threatened that the other party has breached the AZ License (which has not been cured) or, (c) has threatened to terminate the AZ License.

12.2.9 Neither the execution, delivery, and performance by Licensor of this Agreement, nor the consummation by Licensor of the transactions contemplated hereby, will require Licensor 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 Exchange Act of 1934 (as amended), the Financial Industry Regulatory Authority, Inc., Nasdaq, Inc., and applicable state securities law).

12.2.10 To its Knowledge, neither Licensor nor any of its 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, Anti-Money Laundering Laws, or Global Trade Laws and Regulations;

(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 (at a time when such party or country was 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) improperly 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) improperly 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 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 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 the Territory.

12.3.6 To its Knowledge, neither Licensee nor any of its Affiliates, nor 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, Anti-Money Laundering Laws, or Global Trade Laws and Regulations;

(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 (at a time when such party or country was 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) improperly 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) improperly 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's publicly-filed financial statements have been prepared in accordance with IFRS .

12.3.8 Except as otherwise disclosed by Licensee, 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 the applicable country or jurisdiction in the Territory; (d) includes a waiver of pre-emption rights under any Applicable Law in such country or jurisdiction, including in the case of an employee in China, Article 847 of the Civil Code of the People's Republic of China to the effect that the employee will confirm that such employee will not have any right or claim with respect to any Licensee Collaboration Technology derived from such employee's work, except for the reward and remuneration that such employee is entitled to under the invention and patent reward and remuneration policy; 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 relating to the obligations as a Sublicensee.

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

12.4.3 Licensee will require Clinical Trial sites engaged by Licensee or its Affiliates under a Territory 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 the country or jurisdiction in the Territory in which such Clinical Trial site is located. Licensee will, and will require 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 applicable local country or Region codes and guidelines with respect to the promotion of the Licensed Product in the Territory.

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, to the extent applicable, the Data Security Law of the People's Republic of China, and the Personal Information Protection Law of the People's Republic of China (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 Territory Development Plan or Territory 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 Territory Development Plan or Territory Medical Affairs Plan. Without limiting the generality of the foregoing, with respect to all activities performed by or on behalf of Licensee under the Agreement or under a Territory Development Plan or Territory 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 Territory Development Plan or Territory 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 Territory Development Plan or Territory 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 and its 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 and its 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 and its 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 and its 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 to be in violation of any such laws.

(e) It and its 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 the 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 it will exercise its termination rights set in Section 9.2.4 (Termination by Licensee) under the AZ License in good faith, provided that (a) without the prior written notification from the Licensee, it will not send any

termination notice to the counterparty under the AZ License; and (b) in the event that the Licensor terminates the AZ License, the Licensor will use reasonable efforts to assist the Licensee to will enter into a direct license agreement with the licensor under the AZ License on the same terms as this Agreement, taking into account any difference in license scope, territory, and duration of the applicable license granted under the AZ License.

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 the Territory, 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 [***] days' 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 Territory Development Plan or Territory 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. Licensee and its Affiliates will, and will cause its Sublicensees and Subcontractors to, provide Licensor with reasonable access to their respective facilities and personnel during regular business hours 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, provided that Licensor may not exercise its rights under this Section 12.8.2 (Compliance Audits) more than [***] unless such audit reveals an instance of non-compliance by Licensee and

such Affiliates, Sublicensees, and Subcontractors, in which case Licensor may audit Licensee again during the same [***] solely as to such matters of non-compliance discovered under the initial audit. 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.

12.10 Time for Claims. Except in the case of any fraud, claim for indemnification under Article 13 (Indemnification), or intentional misrepresentation by a Party: (a) the representations and warranties of the Parties contained in Section 12.1 (Representations and Warranties of Each Party), Section 12.2 (Representations and Warranties of Licensor), and Section 12.3 (Representations and Warranties of Licensee) will survive until the date that is [***] months after the Effective Date, (b) no claim may be made or suit instituted by a Party alleging breach of, or inaccuracy in, any representation or warranty contained in Section 12.1 (Representations and Warranties of Each Party), Section 12.2 (Representations and Warranties of Licensor), and Section 12.3 (Representations and Warranties of Licensee) unless a written notice is provided to the other Party at any time prior to the date that is [***] months following the Effective date, and (c) after such [***] month period, no Party may bring any claim against the other Party arising from or relating to such other Party's breach of such representations and warranties.

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 Indemnitees") 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 the Territory, including to the extent arising out of Licensor holding Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals for the benefit of Licensee pursuant to Section 5.1, 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 Indemnitees") 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, and (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. Each of Licensor and Licensee will procure and maintain in full force and effect during the Term of this Agreement insurance required by Applicable Law in each country or Region where the Party performs any activities under this Agreement. Without limiting the foregoing, each of Licensor and 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 Representatives, Affiliates, licensees, or Sublicensees) in the course of performing activities under this Agreement ("Inventions") will be as follows:

(a) Licensee will solely own (or retain ownership of) all Inventions, other than Product Inventions, that are conceived, reduced to practice, discovered, developed, or made solely by or on behalf of Licensee or any Third Party acting on its behalf (or any of its Representatives, Affiliates, or Sublicensees but excluding, for the avoidance of doubt, Licensor and its sublicensees), and all intellectual property rights therein ("Arising Licensee IP").

(b) Licensor will solely own (or retain ownership of) (i) all Inventions that are 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 Representatives, Affiliates, or licensees or Sublicensees), and all intellectual property rights therein, directed to the composition of matter of Licensed Products, including improvements thereof, or methods of use of Licensed Products, including combinations of active ingredients or other products using Licensed Products and improvements thereof, or methods of manufacturing Licensed Products and improvements thereof (the "Product Inventions") and (ii) all other Inventions that are conceived, reduced to practice, discovered, developed, or made solely by or on behalf of Licensor (or any of its Representatives or Affiliates), and all intellectual property rights therein (collectively, "Arising Licensor IP").

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

14.2 Assignments of Intellectual Property Rights.

14.2.1 Inventor Assignment Obligation. Licensee and its Affiliates will, and will require 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 a particular country or jurisdiction in the Territory 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 require its Sublicensees and Subcontractors to, enter into a written agreement or employment policy with each of its employees performing activities under this Agreement that [***].

14.2.2 Assignment of Product Inventions and Arising Joint IP. Licensee (on behalf of itself and its Affiliates) will and does hereby assign to Licensor (a) its right, title, and interest in and to the Product Inventions and (b) its right, title and interest outside of the Territory in and to the Arising Joint IP outside the Territory.

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

14.2.4 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.

14.2.5 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 Licensed Patent Rights, any Patent Rights claiming Arising Joint IP ("Arising Joint Patent Rights"), and any Patent Rights claiming Product Inventions worldwide. Such Patent Prosecution will be at Licensor's sole expense outside the Territory and at Licensee's sole expense within the Territory, and Licensee will reimburse Licensor for such costs within [***] days after receiving an invoice with reasonable supporting documentation for such costs.

(b) Review and Consult on Arising Joint Patent Rights. Licensor will consult with Licensee and keep Licensee reasonably informed regarding the Patent Prosecution of any Arising Joint Patent Rights in the Territory and will provide Licensee with all substantive correspondence received from any patent authority in the Territory in connection therewith. In addition, Licensor will provide Licensee with drafts of all proposed substantive filings in the Territory and correspondence to any patent authority in the Territory in connection with the Patent Prosecution of the Arising Joint Patent Rights in the Territory 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 Arising Joint Patent Rights in the Territory. Licensor will consider in good faith Licensee's reasonable comments on Patent Prosecution of the Arising Joint Patent

Rights in the Territory, 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).

(c) Licensee Step-In Right. If Licensor elects not to continue to prosecute or maintain a given Licensed Patent Right or Arising Joint Patent Right inside the Territory pursuant to Section 14.4.1(a) (Right to Prosecute) and Licensor does not determine in its reasonable discretion that the continued prosecution or maintenance of such Licensed Patent Right or Arising Joint Patent Right would adversely affect Licensor's overall patent strategy, then Licensor will give Licensee notice thereof within a reasonable period (but not less than [***] days) prior to allowing such Licensed Patent Right or Arising Joint Patent Right to lapse or become abandoned or unenforceable, and Licensee will have the right to prosecute or maintain such Licensed Patent Right or Arising Joint Patent Right inside the Territory. Licensee will have the right, but not the obligation, to assume responsibility for continuing the prosecution of such Licensed Patent Right or Arising Joint Patent Right inside the Territory and paying any required fees to maintain such Licensed Patent Right or Arising Joint Patent Right inside the Territory or defending such Licensed Patent Right or Arising Joint Patent Right, all at Licensee's sole expense, through patent counsel or agents of its choice. Licensee will not become an assignee of any such Licensed Patent Right or Arising Joint Patent Right as a result of its assumption of any such responsibility. Upon transfer of Licensor's responsibility for filing, prosecuting and maintaining any of the Licensed Patent Right or Arising Joint Patent Right under this Section 14.4.114.4.2(c) (Licensee Step-In Right), Licensor will promptly deliver to Licensee copies of all necessary files related to the Licensed Patent Right or Arising Joint Patent Right with respect to which responsibility has been transferred and will take all actions and execute all documents reasonably necessary for Licensee to assume such prosecution.

14.4.2 Licensee Collaboration Patent Rights.

(a) Right to Prosecute. As between the Parties, Licensee will have (i) the sole right to control the Patent Prosecution of all Licensee Collaboration Patent Rights inside the Territory, and (ii) the first right to control the Patent Prosecution of all Licensee Collaboration Patent Rights outside the Territory[***].

(b) Review and Consult. Licensee will consult with Licensor and keep Licensor reasonably 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. Licensee will consider in good faith Licensor's reasonable comments on Patent Prosecution, but Licensee will have final decision-making authority regarding Patent Prosecution of such Patent Rights under this Section 14.4.1(b) (Review and Consult).

(c) Licensor Step-In Right. If Licensee elects not to continue to prosecute or maintain a given Licensee Collaboration Patent Right outside the Territory pursuant to Section 14.4.2(a) (Right to Prosecute) and Licensee does not determine in its reasonable discretion that the

continued prosecution or maintenance of such Licensee Collaboration Patent Right would adversely affect Licensee's overall patent strategy, then Licensee will give Licensor notice thereof within a reasonable period (but not less than [***] days) prior to allowing such Licensee Collaboration Patent Rights to lapse or become abandoned or unenforceable, and Licensor will have the right to prosecute or maintain such Licensee Collaboration Patent Right outside the Territory. Licensor will have the right, but not the obligation, to assume responsibility for continuing the prosecution of such Licensee Collaboration Patent Rights outside the Territory and paying any required fees to maintain such Licensee Collaboration Patent Rights outside the Territory or defending such Licensee Collaboration Patent Rights, all at Licensor's sole expense, through patent counsel or agents of its choice. Licensor will not become an assignee of any such Licensee Collaboration Patent Rights as a result of its assumption of any such responsibility. Upon transfer of Licensee's responsibility for filing, prosecuting and maintaining any of the Licensee Collaboration Patent Rights to Licensor under this Section 14.4.2(c) (Licensor Step-In Right), Licensee will promptly deliver to Licensor copies of all necessary files related to the Licensee Collaboration Patent Rights with respect to which responsibility has been transferred and will take all actions and execute all documents reasonably necessary for Licensor to assume such prosecution.

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 the Territory and (b) within [***] days after becoming aware of any other suspected, threatened, or actual infringement by a Third Party product in the Territory of any of the Licensed Patent Rights, Arising Joint Patent Rights or Licensee Collaboration Patent Rights in the Territory or any related declaratory judgment or equivalent action alleging the invalidity, unenforceability, or non-infringement of such Patent Rights (collectively "Licensed Patent Right Infringement"). For clarity, Licensed Patent Right Infringement excludes any adversarial Patent Prosecution proceedings.

14.5.2 Enforcement Rights.

(a) Licensee First Right. Licensee will have the first right to bring and control any legal action to enforce the Licensed Patent Rights, Arising Joint Patent Rights or Licensee Collaboration Patent Rights against Competitive Infringement in the Territory as it reasonably determines appropriate; provided that, with respect Licensed Patent Rights and Arising Joint Patent Right, such enforcement would not in Licensor's reasonable determination adversely affect Licensor's patent rights strategy, and Licensee will consider the interests of Licensor in such enforcement of the Licensed Patent Rights or Licensee Collaboration 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 abate such Competitive Infringement in the Territory or to file an action to abate such Competitive Infringement in the Territory within [***] months after a written request from Licensor to do so, 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, 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 the Territory 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 the Territory 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 a country or jurisdiction in the Territory or under Applicable Law (including (a) in China, under Article 76 of the Patent Law of the People's Republic of China and its implementing measures and interpretations promulgated by relevant China Governmental Authorities, including NMPA, CNIPA, and the Supreme People's Court, and (b) other equivalents thereof in the Territory), for Licensed Patent Rights, the Parties will discuss and agree which Licensed Patent Rights to list in such patent listing in such country or jurisdiction (the "Listing Patent Rights") (i) prior to the submission of the first and any subsequent MAA for such Licensed Product in such country or jurisdiction 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 such country or jurisdiction 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 such country or jurisdiction 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 the applicable countries or jurisdictions in the Territory. 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 a country or jurisdiction in the Territory 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 the Territory or supplementary protection certificates and any other extensions that are now or become available in the future under Applicable Laws in any country or jurisdiction in the Territory, 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 any country or jurisdiction in the Territory (a "Patent Term Extension"), or adjusting the term of Patent Rights in the Territory due to the time needed to prosecute and obtain a grant of a Patent Right under Applicable Laws in any country or jurisdiction in the Territory (a "Patent

Term Adjustment"), as between the Parties, (a) 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 Licensed Patent Rights and that become available for a patent included in the Licensed Patent Rights, provided that Licensor will consult with Licensee with respect to such decisions and consider the reasonable comments and concerns raised by Licensee. Licensee will make the appropriate filings and applications in the Territory in order to effectuate Licensor's decisions regarding Patent Term Extensions or Patent Term Adjustments in the Territory 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 Filing of Agreement with CNIPA. The Parties will file a redacted copy of this Agreement with the CNIPA as required by Applicable Law in the Territory no later than the date required under such Applicable Law.

14.10 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.

14.11 Product Trademarks.

14.11.1 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").

14.11.2 Licensed Product Trademarks in the Territory. [***]. Licensee and its Affiliates, Sublicensees, and Subcontractors will not use any trademark, trade dress, or logo except for the Licensed Product Trademarks in connection with the Commercialization of the Licensed Products in the Territory, 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.

14.11.3 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.

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 and country-by-country and Region-by-Region basis, on the expiration of the Royalty Term for such Licensed Product in such country or Region and will finally expire in its entirety upon the expiration of the last Royalty Term for the last Licensed Product in the Territory. (the "Term"). Upon expiry of the Term on a Licensed Product-by-Licensed Product and country-by-country and Region-by-Region basis, all rights and licenses granted by Licensor to Licensee under this Agreement with respect to a Licensed Product in such country or Region 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 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 Licensed 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 (a) Licensee regarding a violation of Anti-Corruption Laws, Anti-Money Laundering Laws, or Global Trade Laws and Regulations, or (b) against Licensee's Representatives, Affiliates, Sublicensees, or Subcontractors regarding a violation of Anti-Corruption Laws, Anti-Money Laundering Laws, or Global Trade Laws and Regulations in relation to the performance of this Agreement, then in each case ((a) or (b)) Licensor may terminate this Agreement in its entirety by providing written notice to Licensee.

15.2.6 Cessation of Development and Commercialization in the Territory. If Licensee and its Affiliates and Sublicensees do not conduct any material Development or Commercialization activities with respect to a Licensed Product in the Territory for a continuous period of longer than [***] months, and such suspension of activity is not: (a) contemplated in a Territory 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 or Region, 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 or Region. 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 or Region: (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 Territory 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 a country or Region, 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 such country or Region.

15.3.2 Termination of this Agreement. Upon the termination 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 Licensed Technology will terminate. All licenses and other rights, including the license grant in Section 2.4 (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, provided that if this Agreement is terminated by Licensee's pursuant to Section 15.2.3 (Termination for Material Breach), [***].

(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, except to the extent Sublicenses continue pursuant to Section 2.6.2 (Sublicense Survival), (a) no later than [***] days after the effective date of termination or expiration 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, at its cost and expense, 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 expiration or termination of this Agreement is after Regulatory Approval for any Licensed Product in the Territory, Licensee will no longer serve as the legal agent, as described in Article 38 of the Drug Administration Law of the People's Republic of China or any corresponding regulation in the applicable country or jurisdiction, for such Licensed Product in the Territory as of the effective date of such expiration or 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 the Territory 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 or expiration 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 or the date that this Agreement expires, Licensee will promptly (and in any event within [***] days after the effective date of termination or expiration):

(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 the Territory 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) Licensee 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.

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 the Territory. 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.

15.3.10 **Termination by Licensee for Licensor's Breach or Insolvency**. Notwithstanding any provision to the contrary in this Article 15 (Term and Termination), if Licensee terminates this Agreement pursuant to Section Error! Reference source not found.15.2.3 (Termination for M aterial Breach) or Section 15.2.7 (Termination for Insolvency), then Licensor will be responsible for the reasonable out-of-pocket costs incurred by Licensee directly in connection with the performance of the activities set forth in this Section 15.3 (Effects of Termination) other than the activities set forth in Section 15.3.2(a) (Licenses). Licensee will invoice Licensor quarterly for the foregoing costs incurred by or on behalf of Licensee in such Calendar Quarter, and Licensor will pay the undisputed invoiced amounts within [***] days after the date of any such invoice.

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 2.1(b) (License Grant to Licensee), Section 2.4 (License Grant to Licensor), Section 2.5 (No Implied Licenses; Retained Rights); Section 2.6.2 (Sublicense Survival),; 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 with respect to amounts that come due during the Term); 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 12.10 (Time for Claims) (solely for the time period set forth therein); 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); 14.11.3 (Ownership); Section 15.1 (Term); 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 Continuance of Rights and Obligations During Pendency of Dispute Resolution. If the alleged breaching Party disputes in good faith the existence of a breach specified in a notice provided by the other Party in accordance with Section 15.2.3 (Termination for Material Breach) and such alleged breaching Party provides the other Party notice of such Dispute within the applicable cure period with respect to such breach, then the cure period set forth in Section 15.2.3 (Termination for Material Breach) will be tolled during the pendency of the dispute resolution process as set forth in Article 16 (Dispute Resolution) and the non-breaching Party will not have the right to terminate this Agreement under Section 15.2.3 (Termination for Material Breach) unless and until such dispute resolution process has been completed and such process results in a determination that the alleged breaching Party has materially breached this Agreement and failed to cure such breach within the applicable cure period. During the pendency of such dispute, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder, provided that 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.

16.3 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 16.4 (Arbitration) to resolve the matter by providing the other Party written notice.

16.4 Arbitration. If any Dispute that was subject to Section 16.3 (Negotiation; Escalation) remains open [***] days after such Dispute is referred to the Executive Officers, then such Dispute will be finally resolved by arbitration administered by the International Chamber of Commerce ("ICC") in accordance with its arbitration rules in effect at the time of submission (the "ICC Rules"). The arbitration will be conducted before an arbitral tribunal composed of three arbitrators. Each of the Licensor, on the one hand, and the Licensee, on the other hand, will appoint an arbitrator in writing, in accordance with the ICC Rules. The two arbitrators thus appointed will choose the third arbitrator, who will act as the presiding arbitrator of the arbitral tribunal. If either Party fails to appoint an arbitrator, the Party not in default may request the ICC to appoint that arbitrator. The ICC, after inviting consultation with the Parties, will proceed to appoint the arbitrator within [***] days of the party's request. If, within [***] days after the appointment of the second arbitrator, the two arbitrators have not agreed on the choice of the presiding arbitrator, the presiding arbitrator will promptly be appointed by the ICC. If, however, the aggregate award sought by the Parties is less than $[***] and equitable relief is not sought, then, unless otherwise

agreed by the Parties a single arbitrator will be appointed by agreement of the Parties, or, failing such agreement, in accordance with the ICC Rules. Unless otherwise agreed by the Parties, all such arbitration proceedings will be held in New York, New York, USA, provided that proceedings may be conducted remotely with the consent of the Parties and the arbitrator(s). All arbitration proceedings will be conducted in the English language. In addition to the authority conferred upon the arbitral tribunal by the ICC Rules, the arbitral tribunal will conduct the arbitration taking guidance from the IBA Rules on the Taking of Evidence in International Arbitration as current on the date of the commencement of the arbitration. The Parties hereby agree that the arbitrator(s) have authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator(s) deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. Rulings will be issued by written order summarizing the arbitration proceedings no more than [***] days after the final submissions of the Parties. All rulings by the arbitrator(s) will be final and binding on the Parties. The award will be final and binding upon the Parties and will be the sole and exclusive remedy between the Parties regarding any claims, counterclaims, issues, or requests for declaratory, accounting, or other relief presented to the arbitral tribunal. The arbitral tribunal will have the power to grant any remedy or relief that the arbitrator(s) deem appropriate, including specific performance in the event of non-compliance of its orders or awards as well as interim, conservatory, or provisional measures, and any such measures may be enforced in a court of competent jurisdiction, provided that the arbitrator(s) will have no authority to award punitive damages. 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(s) and other related costs of the arbitration will be shared equally by the Parties, unless the arbitrator(s) determine that a Party has incurred unreasonable expenses due to vexatious or bad faith positions taken by the other Party, in which event the arbitrator(s) may make an award of all or any portion of such expenses (including legal fees and expenses) so incurred. The provisions of this Section 16.4 (Arbitration) may be enforced and judgment on the award (including without limitation equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment, or other interim order in aid of arbitration proceedings, or to issue order(s) in connection with the enforcement of any award. The Parties retain the right to seek interim measures from any court of competent jurisdiction, and any such request will not be deemed incompatible with the agreement to arbitrate set forth herein or be deemed a waiver of the right to arbitrate.

16.5 Confidentiality. All arbitration proceedings pursuant to Section 16.4 (Arbitration) will be confidential and will not be disclosed except as required by Applicable Law or required in connection with any court application for interim relief or post-arbitration or enforcement proceedings. Any documentary or other evidence given by a party or witness in such an arbitration will be treated as confidential by any party whose access to such evidence arises exclusively as a result of its participation in the arbitration, and, except as may be required by Applicable Law, will not be disclosed to any Third Party (other than a witness or expert, provided that such witness or expert agrees to maintain the confidentiality of the information).

16.6 Patent and Trademark Disputes. Notwithstanding Section 16.4 (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 country or Region in which such Patent Rights, trademark rights, or trade dress rights were granted or arose.

16.7 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 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 16.4 (Arbitration), or the availability of interim measures of protection under ICC rules.

16.8 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.

16.9 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 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), (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 2.8 (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 Region 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
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
Attn: Legal Department
[***]
If to Licensee:
Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.
No.866, Moganshan Road
Hangzhou, People's Republic of China
Attention: YU XI
Email: [***]

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

Greenberg Traurig LLP
3333 Piedmont Road
Suite 2500
Atlanta, Georgia 30305
Attention: Wayne H. Elowe
Email: [***]

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 required 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 Licensee'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 and Collaboration 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: Chief Executive Officer

Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd

By: /s/ Liang Lu

Name: Liang Lu

Title: Chairman & CEO

Exhibit 10.2

Execution Version

FIRST AMENDMENT TO AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT TO AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT (this "Amendment") is entered into as of November 1, 2023, by and among SLR INVESTMENT CORP., a Maryland corporation with an office located at 500 Park Avenue, 3rd Floor, New York, NY 10022 ("SLR"), as collateral agent (in such capacity, together with its successors and assigns, "Collateral Agent"), the Lenders listed on Schedule 1.1 thereto or otherwise a party thereto from time to time including SLR in its capacity as a Lender (each a "Lender" and collectively, the "Lenders"), and ARCUTIS BIOTHERAPEUTICS, INC., a Delaware corporation with offices located at 3027 Townsgate Road, Suite 300, Westlake Village, CA 91361 ("Parent") and ARCUTIS CANADA, INC., a corporation incorporated under the laws of the Province of Ontario ("Arcutis Canada" and together with Parent and any other co-Borrower party hereto from time to time, individually and collectively, jointly and severally, "Borrower").

A. Collateral Agent, Borrower and Lenders have entered into that certain Amended and Restated Loan and Security Agreement dated as of January 10, 2023 (as amended, supplemented or otherwise modified from time to time, the "Loan Agreement") pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

B. Borrower, Collateral Agent and the Required Lenders have agreed to amend certain provisions of the Loan Agreement as provided herein, subject to, and in accordance with, the terms and conditions set forth herein, and in reliance upon the representations and warranties set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, the Required Lenders and Collateral Agent hereby agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. **Amendments to Loan Agreement.**

2.1 Section 1.4 (Definitions). The following terms and their respective definitions hereby are added or amended and restated in their entirety, as applicable, to Section 1.4 of the Loan Agreement as follows:

"Term Loan"	Section 2.2(a)(iii)

"2023 Plan" is Borrower's annual plan outlining Borrower's monthly forecasted Net Product Revenue for its 2023 fiscal year which has been approved by Parent's board of directors and approved in writing by Collateral Agent in its reasonable discretion.

"First Amendment Effective Date" is November 1, 2023.

"Material Adverse Change" is (a) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower and its Subsidiaries, when taken as a whole; or (b) a material impairment of (i) the ability of the Loan Parties to repay any portion of the Obligations, (ii) the legality, validity or enforceability of any Loan Document, (iii) the rights and remedies of Collateral Agent or Lenders under any Loan Document except as the result of the action or inaction of the Collateral Agent or Lenders or (iv) the validity, perfection or priority of any Lien in favor of Collateral Agent for the benefit of the Secured Parties on any of the Collateral except as the result of the action or inaction of the Collateral Agent or Lenders. For the avoidance of doubt, "Material Adverse Change" shall not include, in and of themselves, the non-occurrence of any of the events as described under "Tranche B Term Loan Funding Condition".

"NPR Annual Plan" is Borrower's annual plan outlining Borrower's monthly forecasted Net Product Revenue for its 2024 fiscal year and each fiscal year thereafter (each, a "Plan Year") which has been approved by Parent's board of directors and approved in writing by Collateral Agent in its reasonable discretion.

"Specified License Agreement" means that certain license agreement identified by Parent to Collateral Agent prior to the First Amendment Effective Date.

2.2 Section 1.4 (Definitions). The following terms and their respective definitions hereby removed in their entirety from Section 1.4 of the Loan Agreement, as follows:

"Average Market Capitalization"

"Tranche C Term Loan"

"Tranche C Term Loan Condition"

"Tranche C Term Loan Draw Period"

2.3 Section 2.2(a)(iii) (Tranche B Term Loans). Section 2.2(a)(iii) of the Loan Agreement is hereby amended and restated in its entirety as follows:

"(iii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Tranche B-2 Term Loan Draw Period, to make term loans to Borrower in an aggregate principal amount of up to Seventy-Five Million Dollars ($75,000,000.00), in minimum increments of Fifteen Million Dollars ($15,000,000.00), according to each Lender's Tranche B Term Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "Tranche B-2 Term Loan", and collectively as the "Tranche B-2 Term Loans"; each Tranche B-1 Term Loan or Tranche B-2 Term Loan is hereinafter referred to singly as a "Tranche B Term Loan" and the Tranche B-1 Term Loans and the Tranche B-2 Term Loans are hereinafter referred to collectively as the "Tranche B Term Loans"; each Tranche A Term Loan or Tranche B Term Loan is hereinafter referred to singly as a "Term Loan" and the Tranche A Term Loans and Tranche B Term Loans are hereinafter referred to collectively as the "Term Loans"). After repayment, no Tranche B-2 Term Loan may be re-borrowed."

2.4 Section 2.2(a)(iv) (Tranche C Term Loans). Section 2.2(a)(iv) of the Loan Agreement is hereby deleted in its entirety.

2.5 Section 2.4(d) First Amendment Fee. Section 2.4 of the Loan Agreement is hereby amended by inserting the following new Section 2.4(d):

"(d) First Amendment Fee. A fully earned, non-refundable amendment fee in the amount of Two Hundred Thousand Dollars ($200,000.00), which shall be due and payable on the First Amendment Effective Date, to be shared among the Lenders in accordance with their respective Pro Rata Shares."

2.6 Section 3.2 (Conditions Precedent to all Term Loans). Section 3.2(f) of the Loan Agreement is hereby amended to replace "; and" with a period (.), and Section 3.2(g) of the Loan Agreement is hereby deleted in its entirety.

2.7 Section 6.15 (Minimum Capital Raise). Section 6.15 is hereby added to the end of Section 6 of the Loan Agreement as follows:

"6.15 Minimum Capital Raise. On or before April 1, 2024, Borrower shall provide Collateral Agent with reasonably satisfactory evidence that Parent has received at least Thirty One Million Dollars ($31,000,000.00) 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 Parent's equity interests otherwise permitted hereunder, (b) a business development or collaboration agreement otherwise permitted hereunder (including, for the

avoidance of doubt, any payments or proceeds received by Parent pursuant to the Specified License Agreement), and/or (c) Subordinated Debt."

2.8 Section 7.13 (Financial Covenant). Section 7.13 of the Loan Agreement is hereby amended and restated in its entirety as follows:

"7.13 Financial Covenant. Permit Net Product Revenue: (a) for the fiscal year ending December 31, 2023, to be lower than seventy-five percent (75%) of the projected Net Product Revenue set forth in the 2023 Plan provided to Collateral Agent for such fiscal year, and (b) for the month ending January 31, 2024 and the last day of each month thereafter, to be lower than seventy-five percent (75%) of the projected Net Product Revenue for the trailing six (6) month period then ended set forth in the NPR Annual Plan for such period; provided, however, it shall be an immediate Event of Default if Borrower fails to deliver the NPR Annual Plan on or before December 15th of the year prior to each respective Plan Year (or such later date as may be agreed by the Collateral Agent in its reasonable discretion)."

2.9 Section 8.2(a) (Covenant Default). Section 8.2(a) of the Loan Agreement is hereby amended and restated in its entirety as follows:

"(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Landlord Waivers; Bailee Waivers), 6.10 (Creation/Acquisition of Subsidiaries), 6.14 (Ducentis), 6.15 (Minimum Capital Raise), or Borrower violates any provision in Section 7; or"

2.10 Schedule 1.1 (Lenders and Commitments). Schedule 1.1 of the Loan Agreement is hereby amended and restated in its entirety with Schedule 1.1 attached hereto as Annex I.

2.11 Exhibit E (Compliance Certificate). Exhibit E of the Loan Agreement is hereby amended and restated in its entirety with the Exhibit E attached hereto as Annex II.

3. Limitation of Amendments.

3.1 The amendments set forth in Section 2 above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Collateral Agent and the Required Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and the Required Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date) and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by or on behalf of the Borrower to the Collateral Agent, remain true,

accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not contravene (i) any material law or regulation binding on or affecting Borrower, (ii) any material contractual restriction with a Person binding on Borrower, (iii) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made;

4.6 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Loan Document. Borrower, Lenders and Collateral Agent agree that this Amendment shall be a Loan Document. Except as expressly set forth herein, the Loan Agreement and the other Loan Documents shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.

6. Release by Borrower.

6.1 FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves, releases, and discharges Collateral Agent and each Lender and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the Effective Date through and including the date of execution of this Amendment solely to the extent such claims arise out of or are in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing (collectively "Released Claims"). Borrower hereby waives the provisions of California Civil Code Section 1542 (and any similar provision under the laws of any state), which states:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

6.2 By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected in relation to the Released Claims; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Collateral

Agent or Lenders with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

6.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Collateral Agent and the Lenders to enter into this Amendment, and that Collateral Agent and the Lenders would not have done so but for Collateral Agent's and the Lenders' expectation that such release is valid and enforceable in all events.

7. Effectiveness. This Amendment shall be deemed effective as of the date hereof upon the due execution of this Amendment by the parties thereto.

8. Counterparts. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument. Delivery by electronic transmission (e.g. ".pdf") of an executed counterpart of this Amendment shall be effective as a manually executed counterpart signature thereof.

9. Electronic Execution. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Collateral Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

10. Governing Law. THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAW OTHER THAN THE LAW OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.

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IN WITNESS WHEREOF, the parties hereto have caused this First Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

BORROWER:

ARCUTIS BIOTHERAPEUTICS, INC.

By: /s/ John W. Smither
Name: John W. Smither
Title: Interim Chief Financial Officer

ARCUTIS CANADA, INC.

By: /s/ Masaru Matsuda
Name: Masaru Matsuda
Title: Secretary

COLLATERAL AGENT AND LENDER:

SLR INVESTMENT CORP.

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

LENDERS:

SLR INVESTMENT CORP.
SCP PRIVATE CREDIT INCOME FUND SPV LLC
SCP PRIVATE CREDIT INCOME BDC SPV LLC
SCP PRIVATE CORPORATE LENDING FUND LP
SCP PRIVATE CORPORATE LENDING FUND SPV LLC
SCP CAYMAN DEBT MASTER FUND SPV LLC
SLR CP SF DEBT FUND SPV LLC
SLR HC FUND SPV LLC
SLR HC BDC SPV LLC

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

Annex I

SCHEDULE 1.1

Lenders and Commitments

Tranche A Term Loans

Lender	Tranche A Term Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$25,068,419.41	33.42%
SCP PRIVATE CREDIT INCOME FUND SPV LLC	$12,325,996.08	16.43%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$9,195,136.66	12.26%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$8,379,223.42	11.17%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$3,593,436.84	4.79%
SLR CP SF DEBT FUND SPV LLC	$2,877,005.95	3.84%
SLR HC FUND SPV LLC	$11,202,765.00	14.94%
SLR HC BDC SPV LLC	$2,358,016.64	3.14%
TOTAL	$75,000,000.00	100.00%

Tranche B Term Loans

Lender	Tranche B Term Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$41,780,699.02	33.42%
SCP PRIVATE CREDIT INCOME FUND SPV LLC	$20,543,326.79	16.43%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$15,325,227.77	12.26%
SCP PRIVATE CORPORATE LENDING FUND LP	$13,965,372.36	11.17%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$5,989,061.40	4.79%
SLR CP SF DEBT FUND SPV LLC	$4,795,009.92	3.84%
SLR HC FUND SPV LLC	$18,671,275.01	14.94%
SLR HC BDC SPV LLC	$3,930,027.73	3.14%
TOTAL	$125,000,000.00	100.00%

Aggregate (all Term Loans)

Lender	Term Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$66,849,118.43	33.42%
SCP PRIVATE CREDIT INCOME FUND SPV LLC	$32,869,322.87	16.43%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$24,520,364.43	12.26%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$8,379,223.42	4.19%
SCP PRIVATE CORPORATE LENDING FUND LP	$13,965,372.36	6.98%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$9,582,498.24	4.79%
SLR CP SF DEBT FUND SPV LLC	$7,672,015.87	3.84%
SLR HC FUND SPV LLC	$29,874,040.01	14.94%
SLR HC BDC SPV LLC	$6,288,044.37	3.14%
TOTAL	$200,000,000.00	100.00%

Annex II

EXHIBIT E

Compliance Certificate

TO: SLR INVESTMENT CORP., as Collateral Agent and Lender
and the Lenders listed on Schedule 1.1 of the Loan Agreement

FROM: ARCUTIS BIOTHERAPEUTICS, INC. and ARCUTIS CANADA, INC.

The undersigned authorized officer ("Officer") of ARCUTIS BIOTHERAPEUTICS, INC. and ARCUTIS CANADA, INC. (individually and collectively, jointly and severally, "Borrower"), hereby certifies solely in his/her capacity as an officer of Borrower and not in his/her individual capacity, that in accordance with the terms and conditions of the Amended and Restated Loan and Security Agreement dated as of January 10, 2023, by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the "Loan Agreement;" capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below;

There are no Default or Events of Default, except as noted below;

Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

Borrower, and each of Borrower's Subsidiaries, has timely filed all required tax returns and reports; Borrower, and each of Borrower's Subsidiaries, has timely paid all foreign, federal, state, provincial, territorial and local Taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP)[1] and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under **"Complies" column.**

	Reporting Covenant	Requirement	Actual	Complies		
1)	Monthly financial statements	Monthly within 30 days		Yes	No	N/A
2)	Quarterly financial statements	Quarterly within 45 days		Yes	No	N/A
3)	Annual (CPA Audited) statements	Within 90 days after FYE or 5 days after filing with SEC		Yes	No	N/A
4)	Annual Financial Budget	Annually (within earlier 10 days of approval or Feb 28th of each year), and when revised		Yes	No	N/A
5)	A/R & A/P agings	If applicable		Yes	No	N/A

1 Insert for annual and quarterly financial statements only.

7)	Compliance Certificate	Monthly within 30 days		Yes	No	N/A
8)	IP notice (events reasonably expected to materially and adversely affect value of IP or result in MAC)	When required		Yes	No	N/A
9)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period		$_____	Yes	No	N/A
10)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period		$_____	Yes	No	N/A

Deposit and Securities Accounts
(Please list all accounts; attach separate sheet if additional space needed)

	Institution Name	Account Number	New Account?		Account Control Agreement in place?	
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No

Financial Covenants

Minimum Net Product Revenue	Actual Net Product Revenue (trailing 12 months)	Minimum Net Product Revenue per Section 7.13(a)	Complies		
(period ending _____)	$_____	$[_____]	Yes	No	N/A
	Actual Net Product Revenue (trailing 6 months)	Minimum Net Product Revenue per Section 7.13(b)			
	$_____	$[_____]			

Other Matters

1)	Have there been any changes in Key Persons since the last Compliance Certificate?	Yes	No
2)	Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement?	Yes	No
3)	Have there been any new or pending claims or causes of action against Borrower that involve more than One Million Dollars ($1,000,000.00)?	Yes	No
4)	Have there been any amendments or changes to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No
5)	Has Borrower or any Subsidiary entered into or amended a Material Agreement? If yes, please explain and provide a copy of the Material Agreement(s) and/or amendment(s)	Yes	No
6)	Has Borrower provided the Collateral Agent with all notices required to be delivered under Sections 6.2(a) and 6.2(b) of the Loan Agreement?	Yes	No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

ARCUTIS BIOTHERAPEUTICS, INC.

By: _____
Name: _____
Title: _____

ARCUTIS CANADA, INC.

By: _____
Name: _____
Title: _____

Date:

COLLATERAL AGENT USE ONLY

Received by:_____ Date: _____

Verified by: _____ Date: _____

Compliance Status: Yes No

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: November 3, 2023

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, John W. Smither, 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: November 3, 2023

By: /s/ John W. Smither

John W. Smither
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 September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Todd Franklin Watanabe, Chief Executive Officer of the Company, and John W. Smither, 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: November 3, 2023

By: /s/ Todd Franklin Watanabe

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

Date: November 3, 2023

By: /s/ John W. Smither

John W. Smither
Chief Financial Officer
(Principal Accounting and Financial Officer)