UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2025

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 **Westlake Village, California**	**91361**
(Address of Principal Executive Offices)	**(Zip Code)**

(805) 418-5006

(Registrant's telephone number, including area code)

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 July 31, 2025 was 119,905,078.

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 June 30, 2025. 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)
(unaudited)

	June 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 72,740	$ 71,335
Restricted cash	308	617
Marketable securities	118,083	156,620
Trade receivables, net	106,688	73,066
Inventories	16,324	14,526
Prepaid expenses and other current assets	18,635	19,656
Total current assets	332,778	335,820
Property, plant, and equipment, net	1,394	1,041
Intangible assets, net	15,937	9,479
Operating lease right-of-use asset	1,728	1,953
Other assets	596	596
Total assets	$ 352,433	$ 348,889
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 15,082	$ 14,220
Current portion of long-term debt, net	1,000	—
Accrued and other current liabilities	87,854	66,793
Total current liabilities	103,936	81,013
Operating lease liability, long-term	2,114	2,562
Long-term debt, net	107,049	107,203
Other long-term liabilities	360	570
Total liabilities	213,459	191,348
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at June 30, 2025 and December 31, 2024; no shares issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized at June 30, 2025 and December 31, 2024; 119,797,738 and 117,848,033 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	12	12
Additional paid-in capital	1,301,886	1,279,479
Accumulated other comprehensive loss	(35)	(7)
Accumulated deficit	(1,162,889)	(1,121,943)
Total stockholders' equity	138,974	157,541
Total liabilities and stockholders' equity	$ 352,433	$ 348,889

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues:				
Product revenue, net	$ 81,504	$ 30,858	$ 145,350	$ 52,427
Other revenue	—	—	2,000	28,000
Total revenues	81,504	30,858	147,350	80,427
Operating expenses:				
Cost of sales	7,492	3,464	16,322	6,720
Research and development	19,453	19,298	36,996	42,439
Selling, general and administrative	69,170	58,173	133,172	112,967
Total operating expenses	96,115	80,935	186,490	162,126
Loss from operations	(14,611)	(50,077)	(39,140)	(81,699)
Other income (expense):				
Other income, net	2,096	5,229	4,826	9,273
Interest expense	(3,029)	(7,484)	(6,011)	(14,964)
Loss before income taxes	(15,544)	(52,332)	(40,325)	(87,390)
Provision for income taxes	342	—	621	324
Net loss	$ (15,886)	$ (52,332)	$ (40,946)	$ (87,714)
Other comprehensive income (loss):				
Unrealized loss on marketable securities	(95)	(127)	(232)	(243)
Foreign currency translation adjustment	200	(34)	204	(55)
Total other comprehensive income (loss)	105	(161)	(28)	(298)
Comprehensive loss	$ (15,781)	$ (52,493)	$ (40,974)	$ (88,012)
Per share information:				
Net loss per share, basic and diluted	$ (0.13)	$ (0.42)	$ (0.32)	$ (0.75)
Weighted-average shares used in computing net loss per share, basic and diluted	126,997	123,481	126,519	117,265

See accompanying notes to the condensed consolidated financial statements.

ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(In thousands)
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2024	117,848	$ 12	$ 1,279,479	$ (7)	$ (1,121,943)	$ 157,541
Issuance of common stock upon the exercise of stock options	110	—	395	—	—	395
Issuance of common stock upon the vesting of restricted stock units	1,180	—	—	—	—	—
Stock-based compensation expense	—	—	9,915	—	—	9,915
Unrealized loss on marketable securities	—	—	—	(137)	—	(137)
Foreign currency translation adjustment	—	—	—	4	—	4
Net loss	—	—	—	—	(25,060)	(25,060)
Balance—March 31, 2025	119,138	12	1,289,789	(140)	(1,147,003)	142,658
Issuance of common stock upon the exercise of stock options	19	—	61	—	—	61
Issuance of common stock upon the vesting of restricted stock units	522	—	—	—	—	—
Shares issued pursuant to the employee stock purchase plan	119	—	1,319	—	—	1,319
Stock-based compensation expense	—	—	10,717	—	—	10,717
Unrealized loss on marketable securities	—	—	—	(95)	—	(95)
Foreign currency translation adjustment	—	—	—	200	—	200
Net loss	—	—	—	—	(15,886)	(15,886)
Balance—June 30, 2025	119,798	$ 12	$ 1,301,886	$ (35)	$ (1,162,889)	$ 138,974

See accompanying notes to the condensed consolidated financial statements.

ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(In thousands)
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2023	96,787	$ 9	$ 1,070,558	$ 4	$ (981,904)	$ 88,667
Issuance of shares of common stock net of discount and issuance costs of $10,820	18,158	3	161,679	—	—	161,682
Issuance of common stock upon the exercise of stock options	22	—	82	—	—	82
Issuance of common stock upon the vesting of restricted stock units	538	—	—	—	—	—
Stock-based compensation expense	—	—	10,030	—	—	10,030
Unrealized loss on marketable securities	—	—	—	(116)	—	(116)
Foreign currency translation adjustment	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	(35,382)	(35,382)
Balance—March 31, 2024	115,505	12	1,242,349	(133)	(1,017,286)	224,942
Issuance of common stock upon the exercise of stock options	147	—	806	—	—	806
Issuance of common stock upon the vesting of restricted stock units	443	—	—	—	—	—
Shares issued pursuant to the employee stock purchase plan	384	—	649	—	—	649
Stock-based compensation expense	—	—	12,523	—	—	12,523
Unrealized loss on marketable securities	—	—	—	(127)	—	(127)
Foreign currency translation adjustment	—	—	—	(34)	—	(34)
Net loss	—	—	—	—	(52,332)	(52,332)
Balance—June 30, 2024	116,479	$ 12	$ 1,256,327	$ (294)	$ (1,069,618)	$ 186,427

See accompanying notes to the condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (40,946)	$ (87,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	20,267	22,553
Amortization of intangible assets	3,542	375
Non-cash interest expense	846	2,009
Net accretion on marketable securities	(1,554)	(4,113)
Other non-cash items, net	348	(123)
Changes in operating assets and liabilities:		
Accounts receivable, net	(33,621)	(16,524)
Inventories	(1,433)	(746)
Prepaid expenses and other current assets	1,018	3,369
Accounts payable	863	(4,172)
Accrued liabilities	21,018	8,726
Operating lease liabilities	(404)	(362)
Net cash used in operating activities	(30,056)	(76,722)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(89,262)	(231,727)
Proceeds from maturities of marketable securities	129,121	140,893
Milestone payment for intangible asset	(10,000)	—
Purchases of property and equipment	(686)	—
Net cash provided by (used in) investing activities	29,173	(90,834)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon exercise of stock options	456	888
Proceeds from issuance of common stock pursuant to employee stock purchase plan	1,319	649
Proceeds from issuance of common stock, net of issuance costs	—	161,682
Net cash provided by financing activities	1,775	163,219
Effect of exchange rate changes on cash	204	(99)
Net increase (decrease) in cash, cash equivalents, and restricted cash	1,096	(4,436)
Cash, cash equivalents, and restricted cash at beginning of period	71,952	89,323
Cash, cash equivalents, and restricted cash at end of period	$ 73,048	$ 84,887
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest expense paid in cash	$ 5,164	$ 13,021

See accompanying notes to the condensed consolidated financial statements.

ARCUTIS BIOTHERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Organization and Description of Business

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

The Company received U.S. Food and Drug Administration (FDA) approval of its first product, ZORYVE® (roflumilast) cream 0.3% (ZORYVE cream 0.3%), in July 2022, for the treatment of plaque psoriasis, including intertriginous psoriasis, in individuals 12 years of age and older (subsequently approved down to 6 years old), and began U.S. commercialization in August 2022. The Company also received Health Canada approval of ZORYVE cream 0.3% in plaque psoriasis in April 2023 and began Canadian commercialization in June 2023. The Company received FDA approval of ZORYVE® (roflumilast) topical foam 0.3% (ZORYVE foam), in December 2023, for the treatment of seborrheic dermatitis in individuals 9 years of age and older, and began U.S. commercialization in January 2024. The Company received FDA approval of ZORYVE® (roflumilast) cream 0.15% (ZORYVE cream 0.15%) and began U.S. commercialization, in July 2024, for the treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older. The Company received Health Canada approval of ZORYVE foam for seborrheic dermatitis in October 2024, and began Canadian commercialization in December 2024. The Company received Health Canada approval for ZORYVE cream 0.15% for atopic dermatitis in March 2025, and began Canadian commercialization in April 2025. The Company also received FDA approval of ZORYVE foam 0.3% for the treatment of plaque psoriasis of the scalp and body in adult and adolescents 12 years of age and older in May 2025, and began U.S. commercialization in June 2025.

Initial Public Offering and Follow-On Financings

On February 4, 2020, the Company closed an initial public offering (IPO) issuing and selling shares of 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 addition to the sale of common stock, the offering completed in October 2023 consisted of prefunded warrants to purchase 7,500,000 shares of the Company's common stock at $2.4999 per underlying share of common stock. The exercise price of the warrants is $0.0001 per underlying share of common stock. The prefunded warrants are exercisable at any time on or after their original issuance, and were not exercised as of June 30, 2025.

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

At-the-Market (ATM) Offerings

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

In January 2024, the Company amended and restated its Sales Agreement with Cowen to reset the ATM program and provide for the offer and sale of shares of common stock having an aggregate gross offering price of up to $100.0 million. All other terms of the amended and restated Sales Agreement are substantially the same as the original Sales Agreement. The Company has not yet issued or sold any common stock under the amended and restated Sales Agreement.

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

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $1,162.9 million and $1,121.9 million as of June 30, 2025 and December 31, 2024, respectively. Management expects to continue to incur operating losses. The Company had cash, cash equivalents, restricted cash, and marketable securities of $191.1 million and $228.6 million as of June 30, 2025 and December 31, 2024, respectively. The Company has $100.0 million outstanding under the Loan Agreement as of June 30, 2025. See Note 7.

The Company believes that its existing capital resources will be sufficient to meet the projected operating requirements for at least 12 months from the date of issuance of its financial statements. If the Company's available cash, cash equivalents and marketable securities and anticipated future cash flows from operations are insufficient to satisfy its liquidity requirements, the Company may need to raise additional capital to fund its operations. No assurance can be given as to whether additional financing will be available on terms acceptable to the Company or 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 funds, 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 and Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP), 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. Results of operations for any interim period are not necessarily indicative of future or annual results. 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, 2024.

These condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries and all intercompany balances and transactions have been eliminated.

Certain prior year amounts, which are not material, have been reclassified to conform to current year presentation in the condensed consolidated balance sheets, condensed consolidated statement of cash flows and the notes to the condensed consolidated financial statements.

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 condensed consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Restricted Cash

As of June 30, 2025 and December 31, 2024, the Company held $0.3 million and $0.6 million, respectively, of restricted cash as collateral for a letter of credit related to the Company's lease of office space.

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

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 credit losses.

Fair Value Measurement

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

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

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

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

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

Recently Issued Accounting Pronouncements

The Company considers the applicability and impact of any recent Accounting Standards Update (ASU) issued by the Financial Accounting Standards Board (FASB). Other than the ASUs listed below, all other ASUs were assessed and determined to be either not applicable to the Company or are expected to have minimal impact on the Company's condensed consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires qualitative and quantitative updates to the rate reconciliation and income taxes paid disclosures, among others, in order to enhance the transparency of income tax disclosures, including consistent categories and greater disaggregation of information in the rate reconciliation and disaggregation by jurisdiction of income taxes paid. The Company will adopt ASU 2023-09 for its Annual Report on Form 10-K for the year ended December 31, 2025 and does not expect the standard to have a material impact on its disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2024-03.

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

3. Revenues

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
ZORYVE cream 0.3%	$ 27,675	$ 17,258	$ 51,062	$ 32,284
ZORYVE foam	39,212	13,600	69,452	20,143
ZORYVE cream 0.15%	14,617	—	24,836	—
Total product revenue, net	81,504	30,858	145,350	52,427
Other revenue	—	—	2,000	28,000
Total revenues	$ 81,504	$ 30,858	$ 147,350	$ 80,427

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

4. Fair Value Measurements

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

	June 30, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 72,740	$ —	$ —	$ 72,740
Commercial Paper	—	7,774	—	7,774
Certificates of deposit	—	5,222	—	5,222
Corporate debt securities	—	57,172	—	57,172
U.S. Treasury and agency securities	47,915	—	—	47,915
Total assets	$ 120,655	$ 70,168	$ —	$ 190,823

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

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[1]	$ 71,335	$ —	$ —	$ 71,335
Certificates of deposit	—	5,042	—	5,042
Corporate debt securities	—	83,955	—	83,955
U.S. Treasury securities	67,623	—	—	67,623
Total assets	$ 138,958	$ 88,997	$ —	$ 227,955

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

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

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

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

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

	June 30, 2025			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 72,740	$ —	$ —	$ 72,740
Total cash and cash equivalents	$ 72,740	$ —	$ —	$ 72,740
Marketable securities:				
Commercial Paper	$ 7,773	$ 1	$ —	$ 7,774
Certificates of deposit	5,222	—	—	5,222
Corporate debt securities	57,120	54	(2)	57,172
U.S. Treasury and agency securities	47,881	35	(1)	47,915
Total marketable securities	$ 117,996	$ 90	$ (3)	$ 118,083

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

	December 31, 2024			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds[1]	$ 71,335	$ —	$ —	$ 71,335
Total cash and cash equivalents	$ 71,335	$ —	$ —	$ 71,335
Marketable securities:				
Certificates of deposit	$ 5,042	$ —	$ —	$ 5,042
Corporate debt securities	83,855	100	—	83,955
U.S. Treasury securities	67,404	219	—	67,623
Total marketable securities	$ 156,301	$ 319	$ —	$ 156,620

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

As of June 30, 2025 and December 31, 2024, all securities have a maturity of 18 months or less and there were no individual securities that were in a significant unrealized loss position. 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.

The following table summarizes the change in the fair value of the embedded derivative instrument for the six months ended June 30, 2025 and 2024 (in thousands).

	June 30,	
	2025	2024
Beginning balance	$ 570	$ 849
Gain from changes in fair value	(210)	(655)
Ending balance	$ 360	$ 194

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

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5. Balance Sheet Components

Inventories

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

	June 30, 2025	December 31, 2024
Raw materials	$ 6,724	$ 4,300
Work in progress	1,735	584
Finished goods	7,865	9,642
Total inventories	$ 16,324	$ 14,526

Prepaid Expenses and Other Current Assets

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

	June 30, 2025	December 31, 2024
Prepaid co-pay assistance program and rebates	$ 9,958	$ 7,369
Prepaid clinical trial costs	—	3,244
Prepaid insurance	935	844
Other prepaid expenses and current assets	7,742	8,199
Total prepaid expenses and other current assets	$ 18,635	$ 19,656

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2025	December 31, 2024
Accrued sales deductions	$ 63,560	$ 38,430
Accrued compensation	12,321	20,747
Clinical trial accruals	74	—
Accrued expenses and other current liabilities	11,899	7,616
Total accrued liabilities	$ 87,854	$ 66,793

6. License Agreements

Sato License Agreement

On February 27, 2024, the Company entered into a license agreement with Sato Pharmaceutical Co., Ltd. (Sato). Pursuant to the terms of the license agreement with Sato (the Sato Agreement), the Company grants to Sato an exclusive, sublicensable (under certain circumstances) license under certain patent rights and know-how controlled by the Company for Sato to develop, conduct medical affairs activities for, manufacture, commercialize and otherwise exploit roflumilast formulations (the Sato Licensed Products) for all therapeutic uses for certain dermatological indications in humans (the Field) in Japan.

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

Pursuant to the terms of the Sato Agreement, the Company received an upfront payment of $25.0 million and will potentially receive additional payments (i) up to an aggregate amount of $10.0 million upon the achievement of certain regulatory milestones and (ii) up to an aggregate amount of $30.0 million upon the achievement of certain sales milestones. In addition, on a Sato Licensed Product-by-Sato Licensed Product basis, commencing from the first commercial sale of such Sato Licensed Product in Japan until the latest of (i) the

expiration of the last valid claim in the intellectual property rights licensed by the Company to Sato under the Sato Agreement covering such Sato Licensed Product in Japan, (ii) the expiration of regulatory exclusivity for such Sato Licensed Product in Japan, or (iii) ten years after the first commercial sale of such Sato Licensed Product in Japan, the Company will receive low double-digit to mid-teen double-digit percentage royalties on Sato's, its affiliates' and sublicensees' total annual net sales of all Sato Licensed Products, subject to certain royalty reductions.

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

Other revenue under the Sato agreement was zero for the three and six months ended June 30, 2025, respectively, and zero and $25.0 million for the three and six months ended June 30, 2024, respectively.

Huadong License Agreement

In August 2023, the Company entered into a license 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 license agreement with Huadong (the Huadong Agreement), Huadong paid the Company a non-refundable upfront fee pursuant to the terms of the agreement, upon closing in September 2023. The Company received a net payment of $27.0 million, which consisted of a $30.0 million upfront payment less the applicable tax withholding obligation in China of $3.0 million. In addition, the Company received a net payment of $2.7 million in March 2024 related to the achievement of a development and regulatory milestone less the applicable tax withholding. The Company received a net payment of $1.8 million in each of December 2024 and March 2025, related to the achievement of development and regulatory milestones less the applicable tax withholding. The Company may also potentially receive additional payments: (i) up to an aggregate amount of $17.0 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, all of which would be subject to applicable tax withholding obligations.

The term of the Huadong Agreement continues on a Huadong Licensed Product-by-Huadong 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 Huadong Agreement may be terminated by both parties under certain circumstances.

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For the three and six months ended June 30, 2025, the Company recognized zero and $2.0 million, respectively, of Other revenue and zero and $0.2 million, respectively, of income tax expense related to the achievement of a development and regulatory milestone. For the three and six months ended June 30, 2024, the Company recognized zero and $3.0 million, respectively, of Other revenue and zero and $0.3 million, respectively, of income tax expense related to the achievement of a development and regulatory milestone.

AstraZeneca License Agreement

In July 2018, the Company entered into an exclusive 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 (collectively, the AZ-Licensed Products), for all diagnostic, prophylactic and therapeutic uses for human dermatological indications (the Dermatology Field). Under the license agreement with AstraZeneca (the AstraZeneca 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 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 ZORYVE cream 0.3% 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 cream 0.3%, which was recorded as an intangible asset. In the second half of 2024, the Company paid $5.0 million to AstraZeneca upon achievement of $100.0 million in worldwide net sales, which was recorded as a cumulative catch-up adjustment to the carrying value of the intangible asset. In the first half of 2025, the Company paid $10.0 million to AstraZeneca upon achievement of $250.0 million in worldwide net sales and was recorded as a cumulative catch-up adjustment to the carrying value of the 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 AstraZeneca Agreement will be in effect. Amortization expense was $0.6 million and $3.5 million during the three and six months ended June 30, 2025, respectively. Amortization expense was $0.2 million and $0.4 million during the three and six months ended June 30, 2024, respectively.

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. With respect to any AZ-Licensed Products the Company commercializes under the AstraZeneca 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 cream 0.3% in August 2022, the Company began accruing royalties payable to AstraZeneca, which are recorded in cost of sales and accrued liabilities. Royalty expense was $2.5 million and $4.4 million during the three and six months ended June 30, 2025, respectively. Royalty expense was $0.9 million and $1.6 million during the three and six months ended June 30, 2024, respectively.

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7. Long-term debt

On December 22, 2021, the Company entered into a loan and security agreement (the Prior Loan Agreement) with SLR Investment Corp. (SLR) and the lenders party thereto. The Prior Loan Agreement was amended and restated on January 10, 2023 (the AR Loan Agreement) to include Arcutis Canada, Inc. as a borrower and party. On November 1, 2023, the Company entered into an amendment to the AR Loan Agreement to, among others, (i) modify the financial covenant relating to minimum net product revenue, and (ii) include an additional minimum financing covenant. On August 9, 2024, the Company entered into a second amendment to the AR Loan Agreement (the AR Loan Agreement, as amended by the first and second amendments, the Loan Agreement), which it determined to be a modification, to, among others, (i) permit, during the period commencing on October 7, 2024 and ending on December 15, 2024, an optional partial prepayment of term loans outstanding, subject to a 1.0% prepayment penalty (the 2024 Partial Prepayment), (ii) add the tranche C-1 and tranche C-2 term loans, and (iii) facilitate certain other changes, including with respect to the applicable interest rate and maturity date in the event of a 2024 Partial Prepayment. 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 term loan facility is 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, (iv) a tranche C-1 term loan of up to $50.0 million, and (v) a tranche C-2 term loan of up to $50.0 million (collectively, the Term Loans). The tranche A term loan was funded on December 22, 2021. With the approval of ZORYVE cream 0.3% on July 29, 2022, the tranche B term loans were funded on August 2, 2022. As of June 30, 2025 and December 31, 2024, the aggregate principal amount outstanding under the Loan Agreement was $100.0 million.

On October 8, 2024, the Company made a 2024 Partial Prepayment of $100.0 million, which reduced the aggregate principal amount outstanding under the Loan Agreement to $100.0 million. In connection with the 2024 Partial Prepayment, the Company is obligated to pay a prepayment penalty of $1.0 million by June 30, 2026 and a final fee of $6.95 million, representing the final fee applicable to the amount of the 2024 Partial Prepayment, on January 1, 2027.

As a result of such 2024 Partial Prepayment, subject to the Company generating a minimum net product revenue for the trailing six (6) month period ending as of the month prior to the borrowing date equal to 80% of the Company’s projected net product revenue as set forth in its annual plan for the respective period, the Company will be able to draw down the tranche C-1 and tranche C-2 term loans. The tranche C-1 term loan availability will expire on March 31, 2026 and the tranche C-2 term loan availability will expire on June 30, 2026. In addition, as a result of the 2024 Partial Prepayment, (i) the maturity date of the Loan Agreement is August 1, 2029, (ii) the applicable per annum interest rate is equal to 5.95% plus the greater of (a) 2.50% per annum and (b) the one-month Secured Overnight Financing Rate (SOFR), (iii) the Company is no longer subject to certain cost and purchase price restrictions regarding acquisitions, and (iv) the Company may prepay principal amounts outstanding under the Term Loans in minimum increments of $25.0 million, subject to a prepayment premium of (a) 3.0% for any prepayment made prior to the first anniversary of the second amendment, (b) 2.0% for any prepayment made prior after the first anniversary of the second amendment and prior to the second anniversary of the second amendment, or (c) 1.0% for any prepayment made prior after the second anniversary of the second amendment and prior to the maturity date.

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. Prior to the 2024 Partial Prepayment, the applicable rate was a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the one-month SOFR. As a result of such 2024 Partial Prepayment, the applicable interest rate will be a per annum interest rate equal to 5.95% plus the greater of (a) 2.50% and (b) the one-month SOFR. On June 30, 2025, the rate was 10.27%. The benchmark SOFR is subject to change in the event of certain events with respect to the benchmark rate. Interest payments are payable monthly following the funding of any Term Loan.

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

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on the Company's ability to dispose of its business or property, to change its line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on its property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock or to redeem capital stock. The Company also agreed to a financial covenant whereby the Company must generate a minimum net product revenue equal to 75% of its projected net product revenue as set forth in the Company's annual plan for the respective period, tested on a trailing six-month basis, as of the end of each month. 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. The Company was in compliance with all covenants under the Loan Agreement as of June 30, 2025.

In addition, the Loan Agreement contains customary events of default that entitle the lenders to cause any indebtedness under the Loan Agreement to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the Term Loans. Under the Loan Agreement, an event of default will occur if, among other things, the Company fails to make payments under the Loan Agreement, the Company breaches any of the covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches, the lenders determine that a material adverse change has occurred, or the Company or the Company's assets become subject to certain legal proceedings, such as bankruptcy proceedings. Upon the occurrence and for the duration of an event of default, an additional default interest rate, or the Default Rate, equal to 4.0% per annum will apply to all obligations owed under the Loan Agreement. The prepayment upon default and other potential additional interest provisions under the Loan Agreement were determined to be a compound embedded derivative instrument to be bifurcated from the loan and accounted for as a separate liability for accounting purposes under the guidance in ASC 815, *Derivatives and Hedging*. At the inception of the Loan Agreement, the fair value of the embedded derivative was determined to be immaterial. The embedded derivative instrument is remeasured at fair value each reporting period with any future changes in fair value reported in Other income, net in the condensed consolidated statement of operations and comprehensive loss. The amounts recognized in Other income, net related to the change in fair value of the embedded derivative instrument during the three and six months ended June 30, 2025 and 2024 were not material. The fair value of the embedded derivative instrument as of June 30, 2025 and December 31, 2024 was a liability of $0.4 million and $0.6 million, respectively, and is included in Other long-term liabilities in the accompanying condensed consolidated balance sheets. See Note 4.

In connection with the Loan Agreement, the Company is obligated to pay (i) a final fee equal to 6.95% of the aggregate original principal amount of the Term Loans outstanding as of the date of the second amendment (x) with respect to any 2024 Partial Prepayment, upon the earliest to occur of (a) January 1, 2027, (b) the acceleration of all outstanding Term Loans and (c) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, and (y) with respect to the Term Loans outstanding as of the date of the second amendment (other than the 2024 Partial Prepayment), upon the earliest to occur of (a) the maturity date, (b) the acceleration of all outstanding Term Loans and (c) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, (ii) a 2.00% fee with respect to tranche C term loans, due and payable on the earliest to occur of (a) the maturity date, (b) the acceleration of all outstanding Term Loans and (c) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, (iii) a 2.00% extension fee with respect to tranche C term loans which remain unfunded after December 31, 2025, which shall accrue during the period commencing January 1, 2026, and ending on the earliest to occur of (a) the expiration of the tranche C term loan availability, and (b) the date on which tranche C term loan is fully drawn, and (iv) a certain amount of lenders' expenses incurred in connection with the execution of the Loan Agreement. Additionally, in connection with the original Prior Loan Agreement, the Company previously had 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.

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 $13.9 million is recognized over the life of the term loan through interest expense. At June 30, 2025 and December 31, 2024, the effective interest rate was 11.37% and 11.57%, respectively. Interest expense relating to the term loan was $3.0 million and $6.0 million for the three and six months ended June 30, 2025, respectively, and $7.5 million and $15.0 million for the three and six months ended June 30, 2024, respectively.

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

	June 30, 2025	December 31, 2024
Long-term debt, gross	$ 100,000	$ 100,000
Accrued final fee	8,047	7,324
Accrued prepayment penalty	1,000	1,000
Unamortized debt issuance costs	(998)	(1,121)
Total carrying value of debt	108,049	107,203
Less current portion	(1,000)	—
Total long-term debt, net	$ 107,049	$ 107,203

Upon the contractual maturity of the Company's long-term debt, a payment of principal and final fees of $107.0 million is due on August 1, 2029.

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8. Stock-Based Compensation

Stock Option Exchange Program

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

The exchange of stock options was treated as a modification for accounting purposes, which requires an incremental expense of $8.6 million to be recognized for the Replacement RSU Awards over their new service periods (1 - 3 years). In addition, any unamortized expense remaining on the exchanged options as of the modification will be recognized over their original remaining service period.

Stock Option Activity

The following summarizes option activity:

	Number of Options	Weighted-Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($, in thousands)
Balance—December 31, 2024	5,342,909	$ 6.69	8.01	$ 43,120
Granted	2,223,719	13.69		
Exercised	(129,217)	3.59		
Forfeited	(512,105)	9.61		
Expired	(2,865)	26.87		
Balance—June 30, 2025	6,922,441	$ 8.77	7.99	$ 40,747
Exercisable—June 30, 2025	2,805,705	$ 8.26	6.40	$ 20,359

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 June 30, 2025. The intrinsic value of options exercised for the six months ended June 30, 2025 and 2024 was $1.4 million and $0.8 million, respectively.

The total grant-date fair value of the options vested during the six months ended June 30, 2025 and 2024 was $4.6 million and $2.2 million, respectively. The weighted-average grant-date fair value of options granted during the six months ended June 30, 2025 and 2024 was $9.69 and $3.59, respectively.

Restricted Stock Unit Activity

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

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2024	6,055,087	$ 8.04
Granted	2,783,897	13.70
Vested	(1,703,742)	8.64
Forfeited	(552,782)	10.06
Unvested Balance—June 30, 2025	6,582,460	$ 10.11

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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, except for those issued in connection with the Option Exchange as previously described.

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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	$ 3,208	$ 3,799	$ 6,228	$ 7,456
Selling, general and administrative	7,281	8,724	14,039	15,097
Total stock-based compensation expense	$ 10,489	$ 12,523	$ 20,267	$ 22,553

As of June 30, 2025, there was $32.3 million of total unrecognized compensation cost related to unvested options that are expected to vest, which is expected to be recognized over a weighted-average period of 2.8 years. As of June 30, 2025, there was $56.9 million of total unrecognized compensation cost related to RSUs that are expected to vest, which is expected to be recognized over a weighted-average period of 3.0 years.

9. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average common shares outstanding. Pre-funded warrants to purchase 7,500,000 shares of the Company's stock were included in the weighted-average common shares outstanding used in calculating net loss per share for the three and six months ended June 30, 2025 and 2024.

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

	As of June 30,	
	2025	2024
Stock options to purchase common stock	6,922,441	5,872,080
RSUs subject to future vesting	6,582,460	6,679,040
ESPP shares subject to future issuance	22,479	29,722
Total	13,527,380	12,580,842

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10. Segment Reporting

The Company has one reportable segment relating to the development and commercialization of treatments for dermatological diseases. The Company's Chief Operating Decision Maker (the CODM) is its Chief Executive Officer. The CODM evaluates financial information on a consolidated basis for the purposes of allocating resources and assessing performance.

The table below is a summary of the segment profit or loss, including significant segment expenses (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Total revenues	$ 81,504	$ 30,858	$ 147,350	$ 80,427
Less:				
Cost of sales	6,929	3,278	12,780	6,346
Topical roflumilast program costs	2,827	2,931	4,273	6,519
Topical JAK inhibitor program costs	343	595	719	1,262
Other early-stage programs costs	1,695	1,835	3,690	5,968
Research and development compensation and personnel-related expenses	9,779	9,362	19,417	19,740
Selling, general and administrative expenses	69,033	58,049	132,917	112,720
Other segment expenses[(1)]	5,509	4,885	12,694	9,571
Total operating expenses	96,115	80,935	186,490	162,126
Operating loss	(14,611)	(50,077)	(39,140)	(81,699)
Other income, net	2,096	5,229	4,826	9,273
Interest expense	(3,029)	(7,484)	(6,011)	(14,964)
Provision for income taxes	342	—	621	324
Segment and consolidated net loss	$ (15,886)	$ (52,332)	$ (40,946)	$ (87,714)

(1) Other segment expenses include professional services related to research and development, medical affairs, depreciation and amortization expenses.

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, 2024 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, 2024, which has been filed with the Securities and Exchange Commission (SEC). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans, objectives, expectations, projections, and strategy for our business, includes forward-looking statements that involve risks and uncertainties. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties, and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. As a result of many factors, including those factors identified below and those set forth in the "Risk Factors" section of our Annual Report on Form 10-K, our actual results and the timing of selected events could differ materially from the forward-looking statements contained in the following discussion and analysis.*

Overview

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

We launched our lead product, ZORYVE® (roflumilast) cream 0.3% (ZORYVE cream 0.3%), in August 2022 after obtaining our initial U.S. Food and Drug Administration (FDA) approval for the treatment of plaque psoriasis, including psoriasis in the intertriginous areas (e.g. groin or axillae), in individuals 12 years of age or older. ZORYVE cream 0.3% is a once-daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor. ZORYVE cream 0.3% 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 June 2023, we had our first commercial launch outside of the United States following Health Canada approval of ZORYVE cream 0.3% for the treatment of plaque psoriasis in individuals 12 years or age or older.

In December 2023, we received FDA approval for ZORYVE® (roflumilast) topical foam 0.3% (ZORYVE foam) for the treatment of seborrheic dermatitis in individuals aged 9 years and older, with no limitation on severity, location, or duration of use. ZORYVE foam is a once-daily steroid-free foam and, as a PDE4 inhibitor, is the first drug approved for the treatment of seborrheic dermatitis with a new mechanism of action in over two decades. ZORYVE foam became commercially available in the United States in January 2024, and was approved by Health Canada in October 2024 and became commercially available in Canada in December 2024. We also received FDA approval for ZORYVE foam for the treatment of plaque psoriasis of the scalp and body in adults and adolescents ages 12 and older in May 2025, followed by commercial launch in June 2025.

In addition to the approval of ZORYVE cream 0.3% for plaque psoriasis and ZORYVE foam for seborrheic dermatitis and plaque psoriasis of the scalp and body, we also received FDA approval for and commercially launched ZORYVE (roflumilast) cream 0.15% (ZORYVE cream 0.15%) in July 2024 for the treatment of mild to moderate atopic dermatitis in adults and pediatric patients 6 years of age and older, with no limitation on location, body surface area treated, concomitant use, or duration of use specified in the approved labelling. ZORYVE cream 0.15% was also approved by Health Canada in March 2025 and commercially launched in April 2025. ZORYVE cream 0.15% is a once-daily, steroid-free cream that provides rapid disease clearance and significant reduction in itch and has been specifically developed to be a treatment option for long-term disease control. We have also completed a Phase 3 trial of ZORYVE cream 0.05% in pediatric patients 2 to 5 years of age with mild to moderate

atopic dermatitis (INTEGUMENT-PED). Based on the positive results from the INTEGUMENT-PED study, and given our recent approval of ZORYVE cream 0.15% for the treatment of mild to moderate atopic dermatitis in individuals 6 years of age or older, we submitted a supplemental new drug application (sNDA) for topical ZORYVE cream 0.05% for children 2 to 5 years of age in December 2024, which was accepted by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date in October 2025. We conducted INTEGUMENT-OLE, an open label extension study of the long-term safety of ZORYVE cream 0.15% in subjects 6 years of age or older and ZORYVE cream 0.05% in subjects between the ages 2 and 5 years, for which we reported positive results in September 2023 and August 2024, respectively. In June 2025, we initiated INTEGUMENT-INFANT, a Phase 2 study to evaluate the safety and efficacy of investigational ZORYVE cream 0.05% in infants as young as 3 months to less than 2 years with atopic dermatitis, which potentially could serve as the basis for a further expansion of the indication for ZORYVE cream 0.05% to this group of patients.

In July 2024, we entered into a co-promotion agreement with Kowa Pharmaceuticals, Inc. (Kowa) to leverage Kowa's primary care sales force to exclusively market and promote ZORYVE in the United States to primary care practitioners and pediatricians for all FDA-approved indications until at least July 2029. Under the terms of the agreement, Kowa will receive a commission from net sales attributed to Kowa. Promotion of ZORYVE in primary care and pediatrics under the Kowa agreement began in late September 2024.

In addition to ZORYVE, we had been developing ARQ-255, a deep penetrating topical formulation of ivarmacitinib, a potent and highly selective topical Janus kinase type 1 (JAK 1) inhibitor, for the treatment of alopecia areata. Following the completion of a Phase 1b study in the middle of 2025, the Company has elected to halt further development of the program.

In September 2022, we acquired Ducentis BioTherapeutics LTD (Ducentis) and its lead asset, DS-234 (now ARQ-234), a fusion protein that is a potent and highly selective checkpoint agonist of the CD200 Receptor (CD200R). Currently in the preclinical stage, we plan to develop ARQ-234 in atopic dermatitis, where we believe it could be a potentially highly complementary biologic treatment option to ZORYVE cream 0.15% in that indication, if approved. ARQ-234 could potentially be used to treat other inflammatory conditions as well. The Company submitted an Investigational New Drug (IND) application to the FDA in July 2025.

We have incurred net losses in each year since inception, including net losses of $40.9 million and $87.7 million for the six months ended June 30, 2025 and 2024, respectively. As of June 30, 2025, we had an accumulated deficit of $1,162.9 million and cash, cash equivalents, restricted cash, and marketable securities of $191.1 million. As of June 30, 2025, we had $100.0 million outstanding under the Loan Agreement. We paid down $100.0 million of principal related to the Loan Agreement using available cash in October 2024, with the right to re-draw that principal for a defined period.

We expect to continue to incur losses and significant expenses in 2025 as we commercialize ZORYVE, and as we advance our product candidates and label extensions through clinical trials, regulatory submissions and commercialization. We expect to incur commercialization expenses related to the sales, marketing, manufacturing, and distribution of ZORYVE, while we focus our clinical development spend on ARQ-234 and ZORYVE label expansions, if we obtain regulatory approval for them. While we do not anticipate the need to obtain funds through financings or other sources to support our current operations, 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 if or 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 to conduct our nonclinical studies and clinical trials and for manufacturing and supply of our product candidates. We have no internal manufacturing capabilities and we rely on third parties, many of whom are single source suppliers, for our nonclinical and clinical trial materials, as well as the commercial supply of our products.

Components of Our Results of Operations

Revenue

Product Revenue, Net

In August 2022, in conjunction with the launch of our first FDA-approved product, ZORYVE cream 0.3%, we began to recognize revenue from product sales, net of rebates, chargebacks, discounts and other adjustments. We also began recognizing revenue net of deductions for ZORYVE cream 0.3% in Canada in June 2023, ZORYVE foam for seborrheic dermatitis in the United States in January 2024, ZORYVE cream 0.15% for atopic dermatitis in July 2024, ZORYVE foam for seborrheic dermatitis in Canada in December 2024, ZORYVE cream 0.15% in Canada in April 2025, and ZORYVE foam for scalp and body psoriasis in the United States in June 2025. Additionally, if our development efforts for our other product candidates and ZORYVE label expansions are successful and result in regulatory approval, we may generate additional revenue in the future from sales of such other products and label expansions.

Other Revenue

Other revenue relates to our license agreements, primarily the Sato Agreement and the Huadong Agreement**.** See Note 6 to the condensed consolidated financial statements for additional information.

Operating Expenses

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.

Prior to the date on which the initial regulatory approval was received for each product, costs of inventory production were recorded as research and development expense. Subsequent to initial regulatory approval, costs of production are capitalized into inventory, and as that inventory is sold and recognized as revenue, the cost is recognized in cost of sales. During the second half of 2025, the Company expects to have sold its remaining finished goods inventory produced using raw material components for which the cost was previously recognized as research & development expense. As of June 30, 2025 and December 31, 2024, the value of this inventory, mostly at the raw materials stage, was approximately $0.7 million and $5.5 million, respectively.

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, activities related to regulatory filings for our product candidates, and medical affairs activities related to ZORYVE. 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, CD200R program, and early stage programs). Our internal costs are primarily related to personnel or professional services and apply across programs, and thus are not allocable on a program specific basis.

We expect to continue to incur research and development expenses in the future as we develop our product candidates. In particular, we expect to incur research and development expenses for the development of ARQ-234 for atopic dermatitis and for ZORYVE label expansions.

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

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing, or costs required to complete the remaining development of ZORYVE cream and ZORYVE foam, 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. The commission paid to Kowa under our co-promotion agreement is recorded as a selling expense. We expect our selling, general and administrative expenses to continue to increase in the future as we continue to commercialize ZORYVE and potentially other product candidates and support our operations, including increased expenses related to legal, accounting, insurance, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, directors and officers liability insurance premiums, and investor relations activities.

Other Income, Net

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

Interest Expense

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

Provision for Income Taxes

Provision for income taxes is primarily related to foreign income tax expense and foreign withholding taxes incurred in relation to a license agreement.

Results of Operations

Comparison of the Three Months Ended June 30, 2025 and 2024

Product Revenue, Net

We began recording U.S. product revenue in the third quarter of 2022 following the FDA approval and subsequent commercial launch of ZORYVE cream 0.3% in August 2022, and Canada product revenue in the second quarter of 2023 following the Health Canada approval and subsequent commercial launch of ZORYVE cream 0.3% in June 2023. In the first quarter of 2024, we began recording U.S. product revenue following the FDA approval and subsequent commercial launch of ZORYVE foam for seborrheic dermatitis in January 2024. In the third quarter of 2024, we began recording U.S. product revenue following the FDA approval and subsequent commercial launch of ZORYVE cream 0.15% in July 2024. In the fourth quarter of 2024, we began recording Canada product revenue following the Health Canada approval and subsequent commercial launch of ZORYVE foam for seborrheic dermatitis in December 2024. In the second quarter of 2025, we began recording Canada product revenue following the Health Canada approval and subsequent launch of ZORYVE cream 0.15% in April 2025, as well as U.S. product revenue following the FDA approval and subsequent commercial launch of ZORYVE foam for scalp and body psoriasis in June 2025.

	Three Months Ended June 30,		Change	
	2025	2024	$	%
	(in thousands)			
Product revenue, net				
ZORYVE cream 0.3%	$ 27,675	$ 17,258	$ 10,417	60 %
ZORYVE foam	39,212	13,600	25,612	188 %
ZORYVE cream 0.15%	14,617	—	14,617	*
Total product revenue, net	$ 81,504	$ 30,858	$ 50,646	164 %

*Not applicable

Product revenue, net, for ZORYVE cream 0.3% increased by $10.4 million for the three months ended June 30, 2025 compared to the three months ended June 30, 2024, primarily driven by higher end customer demand for ZORYVE cream in the United States and Canada.

Product revenue, net, for ZORYVE foam increased by $25.6 million for the three months ended June 30, 2025 compared to the three months ended June 30, 2024, driven by its commercial launch in the United States in January 2024, higher end customer demand, and its commercial launch in Canada in December 2024.

Product revenue, net, for ZORYVE cream 0.15% increased by $14.6 million for the three months ended June 30, 2025 compared to the three months ended June 30, 2024, driven by its commercial launch in the United States in July 2024.

Cost of Sales

Cost of sales increased by $4.0 million for the three months ended June 30, 2025 compared to the three months ended June 30, 2024. The increase was primarily due to greater ZORYVE cream and foam product sales relative to the comparative period.

Research and Development Expenses

	Three Months Ended June 30,		Change	
	2025	2024	$	%
	(in thousands)			
Direct external costs:				
Topical roflumilast program	$ 2,827	$ 2,931	$ (104)	(4)%
Topical JAK inhibitor program	343	595	(252)	(42)%
Other early stage programs	1,695	1,835	(140)	(8)%
Indirect costs:				
Compensation and personnel-related	9,779	9,362	417	4 %
Other	4,809	4,575	234	5 %
Total research and development expense	$ 19,453	$ 19,298	$ 155	1 %

Research and development expenses increased slightly by $0.2 million, or 1%, for the three months ended June 30, 2025 compared to the three months ended June 30, 2024.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $11.0 million, or 19%, for the three months ended June 30, 2025 compared to the three months ended June 30, 2024. The increase was primarily due to our continued commercialization efforts and growing revenue for ZORYVE and consisted of $7.3 million in sales and marketing expenses and $4.7 million in compensation and personnel-related expenses.

Other Income, Net

Other income, net decreased by $3.1 million for the three months ended June 30, 2025 compared to the three months ended June 30, 2024, primarily due to less interest income resulting from lower cash, cash equivalents, and marketable securities balances.

Interest Expense

Interest expense decreased by $4.5 million for the three months ended June 30, 2025 compared to the three months ended June 30, 2024, due to a lower outstanding principal balance on our long-term debt driven by our $100.0 million principal paydown in October 2024, coupled with the impact of lower interest rates. See Note 7 to the condensed consolidated financial statements for additional information.

Comparison of the Six Months Ended June 30, 2025 and 2024

Product Revenue, Net

We began recording U.S. product revenue in the third quarter of 2022 following the FDA approval and subsequent commercial launch of ZORYVE cream 0.3% in August 2022, Canada product revenue in the second quarter of 2023 following the Health Canada approval and subsequent commercial launch of ZORYVE cream 0.3% in June 2023, and additional U.S. revenue in the first quarter of 2024 following the FDA approval and subsequent commercial launch of ZORYVE foam for seborrheic dermatitis in January 2024. In the third quarter of 2024, we began recording U.S. product revenue following the FDA approval and subsequent commercial launch of ZORYVE cream 0.15% in July 2024. In the fourth quarter of 2024, we began recording Canada product revenue following the Health Canada approval and subsequent commercial launch of ZORYVE foam for seborrheic dermatitis in December 2024. In the second quarter of 2025, we began recording Canada product revenue following the Health Canada approval and subsequent launch of ZORYVE cream 0.15% in April 2025, as well as U.S. product revenue following the FDA approval and subsequent commercial launch of ZORYVE foam for scalp and body psoriasis in June 2025.

	Six Months Ended June 30,		Change	
	2025	2024	$	%
	(in thousands)			
Product revenue, net				
ZORYVE cream 0.3%	$ 51,062	$ 32,284	$ 18,778	58 %
ZORYVE foam	69,452	20,143	49,309	245 %
ZORYVE cream 0.15%	24,836	—	24,836	*
Total product revenue, net	$ 145,350	$ 52,427	$ 92,923	177 %

*Not applicable

Product revenue, net, for ZORYVE cream 0.3% increased by $18.8 million for the six months ended June 30, 2025 compared to the six months ended June 30, 2024, primarily driven by higher end customer demand for ZORYVE cream in the United States and Canada.

Product revenue, net, for ZORYVE foam increased by $49.3 million for the six months ended June 30, 2025 compared to the six months ended June 30, 2024, driven by its commercial launch in the United States in January 2024, higher end customer demand, and its commercial launch in Canada in December 2024.

Product revenue, net, for ZORYVE cream 0.15% increased by $24.8 million for the six months ended June 30, 2025, driven by its commercial launch in the United States in July 2024.

Other Revenue

Other revenue of $2.0 million for the six months ended June 30, 2025 relates to license revenues received in connection with the Huadong Agreement. Other revenue for the six months ended June 30, 2024 includes $25.0 million received as an upfront payment in connection with the Sato Agreement and a $3.0 million milestone payment received in connection with the Huadong Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Cost of Sales

Cost of sales increased by $9.6 million for the six months ended June 30, 2025, compared to the six months ended June 30, 2024, and was primarily due to the increase in ZORYVE cream and foam product sales, amortization expense recorded in connection with the AstraZeneca milestones achieved in the first quarter of 2025 and the second half of 2024, and greater royalties paid to AstraZeneca.

Research and Development Expenses

	Six Months Ended June 30,		Change	
	2025	2024	$	%
	(in thousands)			
Direct external costs:				
Topical roflumilast program	$ 4,273	$ 6,519	$ (2,246)	(34)%
Topical JAK inhibitor program	719	1,262	(543)	(43)%
Other early stage programs	3,690	5,968	(2,278)	(38)%
Indirect costs:				
Compensation and personnel-related	19,417	19,740	(323)	(2)%
Other	8,897	8,950	(53)	(1)%
Total research and development expense	$ 36,996	$ 42,439	$ (5,443)	(13)%

Research and development expenses decreased by $5.4 million, or 13%, for the six months ended June 30, 2025 compared to the six months ended June 30, 2024. The decrease was primarily due to the completion of Phase 3 studies of roflumilast cream in atopic dermatitis, coupled with lower costs related to the development of early stage programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $20.2 million, or 18%, for the six months ended June 30, 2025 compared to the six months ended June 30, 2024. The increase was primarily due to $12.4 million higher compensation and personnel-related expenses and $7.7 million higher sales and marketing expenses. These higher expenses were primarily due to our continued commercialization efforts for ZORYVE.

Other Income, Net

Other income, net decreased by $4.4 million for the six months ended June 30, 2025 compared to the six months ended June 30, 2024, primarily due to less interest income resulting from lower cash, cash equivalents, and marketable securities balances.

Interest Expense

Interest expense decreased by $9.0 million for the six months ended June 30, 2025 compared to the six months ended June 30, 2024, due to a lower outstanding principal balance on our long-term debt driven by our $100.0 million principal paydown in October 2024, coupled with the impact of lower interest rates. See Note 7 to the condensed consolidated financial statements for additional information.

Liquidity, Capital Resources, and Requirements

Sources of Liquidity

Our primary sources of capital to date have been private placements of preferred stock, our IPO completed in January 2020, our follow-on financings in October 2020, February 2021, August 2022, October 2023, and March 2024, our Loan Agreement, our ATM program, and revenue from the sale of ZORYVE cream 0.3% and foam. We have incurred operating losses since our inception and have an accumulated deficit as a result of ongoing efforts to develop and commercialize our products and product candidates, including conducting nonclinical and clinical trials and providing selling, general and administrative support for these operations. As of June 30, 2025, we had cash, cash equivalents, restricted cash, and marketable securities of $191.1 million, and an accumulated deficit of $1,162.9 million. As of June 30, 2025, we had $100.0 million outstanding under the Loan Agreement. We paid down $100.0 million of principal related to the Loan Agreement using available cash on October 8, 2024, with the right to re-draw that principal for a defined period. See Note 7 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 if or 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 product candidates or any future product candidates, and conducting nonclinical studies and clinical trials, in particular our planned or ongoing development activities and our formulation and nonclinical efforts;
- suspensions or delays in the enrollment or changes to the number of subjects we decide to enroll in our ongoing clinical trials;
- the number and scope of clinical programs we decide to pursue, and the number and characteristics of any product candidates we develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing ZORYVE or any future product candidates and any products we successfully commercialize, including costs associated with building out our supply chain;
- the cost of commercialization activities for ZORYVE or any future product candidates that are approved for sale, including marketing, sales and distribution costs, and any discounts or rebates to obtain access;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the costs related to milestone payments to AstraZeneca 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;
- any disputes, lawsuits, or other legal proceedings related to contracts or employment matters;
- 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 (the Prior Loan Agreement) with SLR Investment Corp (SLR) and the lenders party thereto. The Prior Loan Agreement was amended and restated on January 10, 2023 (the AR Loan Agreement) to include Arcutis Canada, Inc., a corporation incorporated under the laws of the Province of Ontario, as a borrower and party. On November 1, 2023, we entered into an amendment to the AR Loan Agreement to, among others, (i) modify the financial covenant relating to minimum net product revenue, and (ii) include an additional minimum financing covenant. On August 9, 2024, we entered into a second amendment to the AR Loan Agreement (the AR Loan Agreement, as amended by the first and second amendments, the Loan Agreement) to, among others, (i) permit, during the period commencing on October 7, 2024 and ending on December 15, 2024, an optional partial prepayment of term loans outstanding, subject to a 1.0% prepayment penalty (the 2024 Partial Prepayment), (ii) add the tranche C-1 and tranche C-2 term loans, and (iii) facilitate certain other changes, including with respect to the applicable interest rate and maturity date in the event of a 2024 Partial Prepayment. The term loan facility is 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, (iv) a tranche C-1 term loan of up to $50.0 million, and (v) a tranche C-2 term loan of up to $50.0 million (collectively, the Term Loans). The tranche A term loan was funded in December 2021. With the approval of ZORYVE cream 0.3% on July 29, 2022, the tranche B term loans were funded in August 2022. As of June 30, 2025 and December 31, 2024, the aggregate principal amount outstanding under the Loan Agreement was $100.0 million.

In October 2024, we made a 2024 Partial Prepayment of $100.0 million, which reduced the aggregate principal amount outstanding under the Loan Agreement to $100.0 million. In connection with the 2024 Partial Prepayment, we are obligated to pay a prepayment penalty of $1.0 million by June 30, 2026 and a final fee of $6.95 million, representing the final fee applicable to the amount of the 2024 Partial Prepayment, on January 1, 2027. As a result of such 2024 Partial Prepayment, subject us generating a minimum net product revenue for the trailing six (6) month period ending as of the month prior to the borrowing date equal to 80% of our projected net product revenue as set forth in its annual plan for the respective period, we will be able to draw down the tranche C-1 and tranche C-2 term loans. The tranche C-1 term loan availability will expire on March 31, 2026 and the tranche C-2 term loan availability will expire on June 30, 2026. In addition, as a result of the 2024 Partial Prepayment, (i) the maturity date of the Loan Agreement is August 1, 2029 (such date, the Maturity Date), (ii) the applicable per annum interest rate is equal to 5.95% plus the greater of (a) 2.50% per annum and (b) the one-month Secured Overnight Financing Rate (SOFR), (iii) we are no longer subject to certain cost and purchase price restrictions regarding acquisitions, and (iv) we may prepay principal amounts outstanding under the Term Loans in minimum increments of $25.0 million, subject to a prepayment premium of (a) 3.0% for any prepayment made prior to the first anniversary of the second amendment, (b) 2.0% for any prepayment made prior after the first anniversary of the second amendment and prior to the second anniversary of the second amendment, or (c) 1.0% for any prepayment made prior after the second anniversary of the second amendment and prior to the Maturity Date.

Principal amounts outstanding under the Term Loans will generally 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. Prior to the 2024 Partial Prepayment, the applicable rate was a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the one-month SOFR. As a result of such 2024 Partial Prepayment, the applicable interest rate will be a per annum interest rate equal to 5.95% plus the greater of (a) 2.50% and (b) the one-month SOFR. On June 30, 2025, the rate was 10.27%. The benchmark SOFR is subject to change in the event of certain events with respect to 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 or prepaid, are due and payable on August 1, 2029.

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.

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 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 our ability to dispose of our business or property, to change our 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 our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock or to redeem capital stock. We also agreed to a financial covenant whereby we must generate a minimum net product revenue equal to 75% of our projected net product revenue as set forth in our annual plan for the respective period, tested on a trailing six-month basis as of the end of each month. 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, 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 (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 outstanding as of the date of the second amendment, (x) with respect to any 2024 Partial Prepayment, upon the earliest to occur of (A) January 1, 2027, (B) the acceleration of all outstanding Term Loans and (C) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, and (y) with respect to the Term Loans outstanding as of the date of the second amendment (other than 2024 Partial Prepayment), upon the earliest to occur of (A) the Maturity Date, (B) the acceleration of all outstanding Term Loans and (C) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, (ii) a 2.00% fee with respect to tranche C term loans, due and payable on the earliest to occur of (A) the Maturity Date, (B) the acceleration of all outstanding Term Loans and (C) the prepayment, or refinancing, substitution or replacement of all outstanding Term Loans, (iii) a 2.00% extension fee with respect to tranche C term loans which remain unfunded after December 31, 2025, which shall accrue during the period commencing January 1, 2026, and ending on the earliest to occur of (A) the expiration of the tranche C term loan availability, and (B) the date on which tranche C term loan is fully drawn, and (iv) a certain amount of lenders' expenses incurred in connection with the execution of the Loan Agreement. Additionally, in connection with the original Prior Loan Agreement, we previously had entered into an Exit Fee Agreement, whereby we agreed to pay an exit fee in the amount of 3.0% of each Term Loan funded upon (i) any change of control transaction or (ii) a revenue milestone, calculated on a trailing six-month basis. Notwithstanding the prepayment or termination of the Term Loan, the exit fee will expire 10 years from the date of the Loan Agreement.

We were in compliance with all covenants under the Loan Agreement as of June 30, 2025.

Cash Flows

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

	Six Months Ended June 30,	
	2025	2024
	(in thousands)	
Cash used in operating activities	$ (30,056)	$ (76,722)
Cash provided by (used in) investing activities	29,173	(90,834)
Cash provided by financing activities	1,775	163,219
Effect of exchange rate changes on cash	204	(99)
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 1,096	$ (4,436)

Net Cash Used in Operating Activities

During the six months ended June 30, 2025, net cash used in operating activities was $30.1 million, which consisted of a net loss of $40.9 million and a change in net operating assets and liabilities of $12.6 million, partially offset by net non-cash charges of $23.4 million. The net non-cash charges were primarily related to stock-based compensation expense of $20.3 million and amortization of intangible assets of $3.5 million.

During the six months ended June 30, 2024, net cash used in operating activities was $76.7 million, which consisted of a net loss of $87.7 million and a change in net operating assets and liabilities of $9.7 million, partially offset by net non-cash charges of $20.7 million. The net non-cash charges were primarily related to stock-based compensation expense of $22.6 million.

Net Cash Provided by (Used in) Investing Activities

During the six months ended June 30, 2025, net cash provided by investing activities was $29.2 million, which was comprised primarily of proceeds from the maturities of marketable securities of $129.1 million, offset by purchases of marketable securities of $89.3 million and a milestone payment made to AstraZeneca of $10.0 million.

During the six months ended June 30, 2024, net cash used in investing activities was $90.8 million, which was comprised primarily of purchases of marketable securities of $231.7 million, offset by proceeds from the maturities of marketable securities of $140.9 million.

Net Cash Provided by Financing Activities

During the six months ended June 30, 2025, net cash provided by financing activities was $1.8 million, which was comprised primarily of $1.3 million of proceeds from the issuance of our common stock pursuant to our employee stock purchase plan.

During the six months ended June 30, 2024, net cash provided by financing activities was $163.2 million, which was comprised primarily of $161.7 million of net proceeds from our February 2024 public stock offering.

Contractual Obligations and Contingent Liabilities

There have been no material changes outside the ordinary course of business to our contractual obligations and commitments as described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2024.

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 June 30, 2025, we had cash and cash equivalents of $72.7 million, restricted cash of $0.3 million, and marketable securities of $118.1 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. Due to the short-term duration and the low risk profile of our investments, an immediate change in interest rates of 100 basis points would not result in a material change to the fair value of our portfolio.

In addition, as of June 30, 2025, we had $100.0 million outstanding under our Loan Agreement. Amounts outstanding under our Loan Agreement bear interest at a floating rate equal to a per annum interest rate equal to 5.95% plus the greater of (a) 2.50% and (b) the one-month Secured Overnight Financing Rate (SOFR). The benchmark SOFR is subject to change in the event of certain events with respect to 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 June 30, 2025, for every 100 basis point increase in the interest rates, we would incur approximately $1.0 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 future investment in marketable securities. We may use swaps, caps, collars, structured collars or other common derivative financial instruments to reduce interest rate risk in the future. 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 June 30, 2025 we had cash balances denominated in Canadian dollars of $6.3 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

Based on an evaluation under the supervision of and with the participation of our management, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of June 30, 2025, to provide reasonable assurance that information required to be disclosed by us 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 principal executive officer and principal 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. Management 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 this assessment, management concluded that our internal control over financial reporting was effective as of June 30, 2025.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the three months ended June 30, 2025, which were identified in connection with management's evaluation required by paragraph (d) of Rules 13a-15 and 15d-15 under the Exchange Act, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

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

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

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

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

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

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

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Arcutis Biotherapeutics, Inc. filed a lawsuit against Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, Padagis) in the U.S. District Court for the District of Delaware on March 27, 2024, based on the submission to the FDA of an Abbreviated New Drug Application (ANDA) seeking approval to market and sell a generic version of Arcutis' ZORYVE® 0.3% cream for the treatment of plaque psoriasis. The Company asserts infringement of the following eleven patents, which are listed in the FDA's Orange Book for Arcutis' ZORYVE® 0.3% cream: 9,884,050; 9,907,788; 10,940,142; 11,129,818; 11,793,796;11,819,496; 11,992,480; 12,005,051; 12,005,052; 12,011,437; and 12,016,848 (collectively, Asserted Patents). Arcutis seeks a judgment that Padagis has infringed or will infringe one or more claims of each of the Asserted Patents and based on that judgment, a permanent injunction prohibiting the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Padagis's proposed generic product before expiration of each of the Asserted Patents found to infringe.

In March 2025, Arcutis agreed to file a joint stipulation to stay the ongoing patent litigation with Padagis at the request of Padagis. On April 3, 2025, the court stayed the case and cancelled all case deadlines, including the trial. The automatic 30-month stay of FDA approval of Padagis's ANDA seeking approval for Arcutis's ZORYVE® 0.3% cream was set to expire on August 14, 2026. The 30-month stay will be extended for each day the stay is in place, starting March 24, 2025 until the stay is lifted.

Teva Pharmaceutical Industries Ltd. filed Oppositions with the European Patent Office against two of our European patents, European Patent Nos. EP 3634380 B1 and EP 3684334 B1, on September 20, 2024 and August 13, 2024, respectively. These patents relate to topical roflumilast compositions. Arcutis filed replies on February 24, 2025, and January 23, 2025, respectively. On February 19, 2025, Arcutis received Teva's reply to Arcutis's January 23, 2025 submission for EP 3684334 to which Arcutis filed an additional reply on April 16, 2025. Oral proceedings concerning the oppositions to European Patent Nos. EP 3634380 B1 and EP 3684334 B1 have been scheduled for January 8, 2026, and December 4, 2025, respectively.

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, 2024. Other than the risk factor 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, 2024.

Changes in tax laws or regulations could have a material adverse effect on our business and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. The Current Administration and Congress may propose various U.S. federal tax law changes, which if enacted could have a material impact on our business, cash flows, financial condition, or results of operations. Furthermore, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense. For example, on July 4, 2025, the One Big Beautiful Bill Act was signed into law, which makes a number of changes to U.S. federal income tax law. The bill includes an estimated $1 trillion in cuts to Medicaid spending, implemented through Medicaid work requirements, patient cost-sharing, and a phasedown of Medicaid provider taxes and state-directed payments. Such reductions in Medicaid spending could result in lower revenue for life science companies. We are continuing to analyze the potential impact of the bill on our operations, business and financial performance.

In October 2021, the Organization for Economic Co-operation and Development (the OECD) announced the OECD/G20 Inclusive Framework on Base Erosion and Profit Shifting (the Framework), which agreed to a two-pillar solution to address tax challenges arising from digitalization of the economy. In December 2021, the OECD released Pillar Two Model Rules defining the global minimum tax rules, which contemplate a minimum tax rate of

15%. To date, various jurisdictions have enacted, or are in the process of enacting, legislation on these rules, and the OECD continues to release additional guidance. While it is uncertain whether the United States will enact legislation to adopt the minimum tax directive, certain countries in which we operate have adopted legislation to implement the minimum tax directive. Further, the OECD issued administrative guidance providing transition and safe harbor rules that could delay the impact of the minimum tax directive. While we continue to monitor the implementation of the Framework and its potential impact, we currently do not expect the Framework to have a material impact on the Company.

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 June 4, 2025, Todd Franklin Watanabe, our Chief Executive Officer, entered into a Rule 10b5-1 trading plan, 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 135,000 shares of common stock held by Mr. Watanabe between October 1, 2025 and September 30, 2026.

On June 6, 2025, Masaru Matsuda, our General Counsel, entered into a Rule 10b5-1 trading plan, 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 83,126 shares of common stock held by Mr. Matsuda between September 4, 2025 and September 4, 2026.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document	Incorporated by Reference Form	Date	Number	Filed/Furnished Herewith
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^	Manufacturing Supply Agreement, dated as of November 8, 2023, by and between the Registrant and Bora Pharmaceuticals Services Inc.				X
10.2^	Amendment No. 1 to the Manufacturing Supply Agreement, dated as of March 22, 2024, by and between the Registrant and Bora Pharmaceuticals Services Inc.				X
10.3^	Amendment No. 2 to the Manufacturing Supply Agreement, dated as of May 14, 2025, by and between the Registrant and Bora Pharmaceuticals Services Inc.				X
10.4	Severance & Change in Control Agreement, dated as of April 10, 2025, by and between the Registrant and Latha Vairavan.	8-K	4/10/25	10.1	
10.5	Amended and Restated Non-Employee Director Compensation Program.	8-K	6/17/25	10.1	
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

^ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10) or certain schedules and attachments to this exhibit have been omitted pursuant to Regulation S-K, Item 601(a)(5). Such omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon 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 Biotherapeutics, 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: August 06, 2025

By: /s/ Todd Franklin Watanabe

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

Date: August 06, 2025

By: /s/ Latha Vairavan

Latha Vairavan
Chief Financial Officer
(Principal Financial and Accounting Officer)

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

MANUFACTURING SUPPLY AGREEMENT

This Manufacturing Supply Agreement (the "**Agreement**"), dated as of November 8, 2023 (the "**Effective Date**"), is entered into by and between Arcutis Biotherapeutics, Inc., a Delaware corporation having its principal place of business at 3027 Townsgate Road, Suite 300, Westlake Village, California 91361 ("**Customer**"), and Bora Pharmaceuticals Services Inc., an Ontario corporation, having its principal place of business at 7333 Mississauga Road, Mississauga, ON L5N 6L4 Canada ("**Manufacturer**", and together with Customer, the "**Parties**", and each, a "**Party**").

WHEREAS, Manufacturer is a manufacturer specializing in complex oral solid dosage, liquid and semi-solid pharmaceutical products for late-phase clinical through commercial manufacturing and packaging;

WHEREAS, Customer wishes to purchase certain Products (as defined below) from Manufacturer; and

WHEREAS, Manufacturer desires to manufacture and sell the Products to Customer.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions. Capitalized terms have the meanings set forth or referred to in this **Section 1**.

"**Acknowledgment**" has the meaning set forth in **Section 3.3**.

"**Action**" means any claim, action, cause of action, demand, lawsuit, arbitration, inquiry, audit, notice of violation, proceeding, litigation, citation, summons, subpoena or investigation of any nature, civil, criminal, administrative, regulatory or other, whether at law, in equity or otherwise.

"**Affiliate**" of a Person means any other Person that directly or indirectly, through one or more intermediaries, Controls, is Controlled by, or is under common Control with, such Person.

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

"**API**" means the active pharmaceutical ingredient or compound identified on and having the chemical composition set forth in Schedule 1 attached hereto, that is contained in the Products.

"**Applicable Law**" means all laws, ordinances, rules, rulings, directives and regulations of any Governmental Authority that apply to the development, manufacture, supply or commercialization of any Products or the other activities contemplated under this Agreement, including (i) all applicable federal, state and local laws, rules and regulations; (ii) the FFDCA, as amended, and regulations promulgated thereunder; (iii) regulations and guidelines of the FDA and other Regulatory Authorities, including cGMPs; and (iv) any applicable non-U.S. equivalents of any of the foregoing, including guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (as amended from time to time).[1]

"**Background Intellectual Property**" means any Intellectual Property Rights either (i) owned or (ii) controlled by a Party prior to the Effective Date.

"**Basic Purchase Order Terms**" means, collectively, any one or more of the following terms specified by Customer in a Purchase Order pursuant to **Section 3.2**: (a) a list of the Products to be purchased; (b) the quantity of each of the Products ordered; (c) the Requested Delivery Date; (d) the unit Price for each of the Products to be purchased; (e) the billing address; and (f) the Delivery Location. For the avoidance of doubt, the term "Basic Purchase Order Terms" does not include any general terms or conditions of any Purchase Order.

"**Batch**" means [***] production lot of a Product as provided in Schedule 2.

"**Breach**" has the meaning set forth in **Section 16.15.**

"**Business Day**" means any day except Saturday, Sunday or any other day on which commercial banks located in the US or Canada are authorized or required by Law to be closed for business.

"**cGMPs**" means the then-current good manufacturing practices applicable to the manufacture of pharmaceutical products for human use as promulgated in U.S. C.F.R. (Title 21, Parts 210-211) and European Community Guide to Good Manufacturing Practices.

"**Change Control Request**" or "**CCR**" means the primary record in which the overall details of a change are captured and monitored.

"**Change of Control**" means, with respect to either Party, (a) a merger (including a reverse triangular merger), consolidation, share exchange or other similar transaction (excluding a financing round) involving a Party and any Third Party which results in the holders of the outstanding voting securities of the relevant Party or any of its Affiliates that controls such Party directly or indirectly, immediately before such merger, consolidation, share exchange or other similar transaction, ceasing to hold more than fifty percent (50%) of the combined voting power of the surviving or continuing entity immediately after such merger, consolidation, share exchange or other similar transaction, or (b) the acquisition by a Third Party, or a group of Third Parties acting in concert, of more than fifty percent (50%) of the outstanding voting equity securities of that Party or any Affiliate that controls such Party directly or indirectly immediately before such acquisition. For the purpose of this definition of Change of Control, the term "group" includes any group acting for the purpose of acquiring, holding, or disposing of securities within the meaning of the relevant laws of the jurisdiction of the relevant Party. The acquiring or combining Third Party in either of (a) or (b), and any of such Third Party's Affiliates (whether in existence as of or at any time following the applicable transaction, but other than the acquired Party and its Affiliates as in existence prior to the applicable transaction or Affiliates the acquired Party controls after the applicable transaction) are referred to collectively herein as the "**Acquirer**".

"**Change Order**" has the meaning set forth in **Section3.4**.

"**Confidential Information**" has the meaning set forth in **Section 13.1**.

"**Control**" (and with correlative meanings, the terms "Controlled by" and "under common Control with") means, with respect to any Person, the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of another Person, whether through the ownership or voting securities, by contract, or otherwise.

"**Customer**" has the meaning set forth in the preamble to this Agreement.

"**Customer Contracts**" means all contracts or agreements to which Customer is a party or to which any of its material assets are bound.

"**Customer Indemnified Party**" has the meaning set forth in **Section 10.2**.

"**Customer Intellectual Property Rights**" means all Intellectual Property Rights owned by or licensed to Customer.

"**Customer Materials**" has the meaning set forth in **Section 3.5(b)**.

"**Customer New IP**" has the meaning set forth in **Section 12.2(d)**.

"**Data Security Program**" has the meaning set forth in **Section 16.15.**

"**Defective**" means not conforming to the Product Warranty under **Section 9.3**.

"**Defective Products**" means Products shipped by Manufacturer to Customer pursuant to this Agreement that are Defective.

"**Delivery Location**" means the street address of Manufacturer's manufacturing facility or designated warehouse for the Product to be delivered Ex Works (EXW Incoterms 2020) as specified in the applicable Purchase Order.

"**Disclosing Party**" has the meaning set forth in **Section 13.1**.

"**Dispute**" has the meaning set forth in **Section 16.17**.

"**Dispute Notice**" has the meaning set forth in **Section 16.17**.

"**Effective Date**" means the date first set forth above.

"**EMA**" means the European Medicines Agency or any successor organization thereto.

"**FDA**" means the US Food and Drug Administration or any successor organization thereto.

"**FFDCA**" means the US Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., as amended.

"**Firm Commitment**" has the meaning set forth in **Section 3.1**.

"**Force Majeure Event**" has the meaning set forth in **Section 16.22**.

"**Forecast**" means, with respect to any specified time period, a good faith projection or estimate of Customer's requirements for Products during each month during the period, which

approximates, as nearly as possible, based on information available at the time to Customer, the quantity of Products that Customer may order for each such month.

"**Governmental Authority**" means any federal, state, local or foreign government or political subdivision thereof, or any agency or instrumentality of such government or political subdivision, or any self-regulated organization or other non-governmental Regulatory Authority or quasi-governmental authority (to the extent that the rules, regulations or orders of such organization or authority have the force of Law), or any arbitrator, court or tribunal of competent jurisdiction.

"**Governmental Order**" means any order, writ, judgment, injunction, decree, stipulation, award or determination entered by or with any Governmental Authority.

"**HPFB**" means the Canadian government's Health Products and Food Branch of Health Canada or any successor organization thereto.

"**Initial Term**" has the meaning set forth in **Section 6.1**.

"**Inspection Period**" has the meaning set forth in **Section 4.5**(c).

"**Intellectual Property Rights**" means all industrial and other intellectual property rights comprising or relating to: (a) Patents; (b) Trademarks; (c) internet domain names, whether or not Trademarks, registered by any authorized private registrar or Governmental Authority, web addresses, web pages, website and URLs; (d) works of authorship, expressions, designs and design registrations, whether or not copyrightable, including copyrights and copyrightable works, software and firmware, application programming interfaces, architecture, files, records, schematics, data, data files, and databases and other specifications and documentation; (e) Trade Secrets; (f) know how and manufacturing processes; and (g) all industrial and other intellectual property rights, and all rights, interests and protections that are associated with, equivalent or similar to, or required for the exercise of, any of the foregoing, however arising, in each case whether registered or unregistered and including all registrations and applications for, and renewals or extensions of, such rights or forms of protection pursuant to the Laws of any jurisdiction throughout in any part of the world.

"**Laboratory**" has the meaning set forth in **Section 4.5(f).**

"**Late Delivery**" has the meaning set forth in **Section 4.3.**

"**Law**" means any statute, law, ordinance, regulation, rule, code, constitution, treaty, common law, Governmental Order, other requirement or rule of law of any Governmental Authority.

"**Losses**" has the meaning set forth in **Section 10.1**.

"**Manufacturer**" has the meaning set forth in the preamble to this Agreement.

"**Manufacturer Contracts**" means all contracts or agreements to which Manufacturer is a party or to which any of its material assets are bound.

"**Manufacturer Indemnified Party**" has the meaning set forth in **Section 10.1**.

"**Manufacturer's Intellectual Property Rights**" means all Intellectual Property Rights owned by or licensed to Manufacturer and existing as of the Effective Date.

"**Manufacturer Materials**" has the meaning set forth in **Section 3.5(b)**.

"**Manufacturer Tooling**" has the meaning set forth in **Section 14**.

"**Nonconforming Products**" means any Products received by Customer from Manufacturer pursuant to a Purchase Order that: (a) do not conform to the listed Products in the applicable Purchase Order; (b) do not fully conform to the Specifications; or (c) exceed the quantity of Products ordered by Customer pursuant to this Agreement or any Purchase Order. Where the context requires, Nonconforming Products are deemed to be Products for purposes of this Agreement.

"**Notice**" has the meaning set forth in **Section 16.4**.

"**Party**" has the meaning set forth in the preamble to this Agreement.

"**Patents**" means all patents (including all reissues, divisionals, provisionals, continuations and continuations-in-part, re-examinations, renewals, substitutions and extensions thereof), patent applications, and other patent rights and any other Governmental Authority-issued indicia of invention ownership (including inventor's certificates, petty patents and patent utility models).

"**Person**" means any individual, partnership, corporation, trust, limited liability entity, unincorporated organization, association, Governmental Authority or any other entity.

"**Personnel**" of a Party means any agents, directors, officers, employees, temporary workers, contractors or subcontractors engaged or appointed by such Party.

"**Pharmacovigilance Agreement**" has the meaning set forth in **Section 2.4.**

"**Prices**" has the meaning set forth in **Section 5.1**.

"**Product**" means the products identified on Schedule 2 and described in the Specifications.

"**Product Warranty**" has the meaning set forth in **Section 9.3**.

"**Scope of Work (SOW)**" means a precise and detailed plan that is mutually agreed and executed by Manufacturer and Customer which carefully describes the nature and scope of additional services to be rendered, additional products to be delivered, and fees to be charged, including the relevant specifications therefor. Project Protocols are generated for activities not included in the manufacturing and material fees, including, but not limited to, the services rendered under Section 3.5 (c).

"**Protected Data**" has the meaning set forth in **Section 16.15**.

"**Purchase Order**" means Customer's firm and written purchase order issued to Manufacturer hereunder, including all terms and conditions attached to, or incorporated into, such purchase order, and any Release issued by Customer to Manufacturer under the Purchase

Order. For the avoidance of doubt, any references to Purchase Orders hereunder also include any applicable Releases.

"**Quality Agreement**" has the meaning set forth in **Section 2.4**.

"**Recall**" means any correction or removal of, field action, or customer notification or communication with respect to, a Product manufactured by Manufacturer, marketed, sold, or distributed by Customer or its Affiliates that is initiated (a) at the direction of the FDA or other Regulatory Authority, or (b) voluntarily by Customer, its Affiliates or Manufacturer to reduce a risk to health posed by such device or to remedy a violation of the FFDCA caused by the Product which may present a risk to health.

"**Receiving Party**" has the meaning set forth in **Section 13.1**.

"**Recipients**" has the meaning set forth in **Section 13.2(c)**.

"**Regulatory Authority**" means any and all supranational, federal, national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other government entity having jurisdiction over either (a) any of the activities contemplated by this Agreement or a Purchase Order; or (b) any of the Parties, including the FDA, EMA and HPFB.

"**Rejected Products**" has the meaning set forth in **Section 4.5(c)**.

"**Release**" means a document issued by Customer to Manufacturer pursuant to a Purchase Order that identifies the quantities of Products constituting Customer's requirements (if such quantities are not specified in the original Purchase Order) and the Delivery Locations and Requested Delivery Dates for such Products.

"**Renewal Term**" has the meaning set forth in **Section 6.2**.

"**Representatives**" means a Party's Affiliates and each of their respective Personnel, partners, shareholders, attorneys, third party advisors, successors and permitted assigns.

"**Requested Delivery Date**" means the requested delivery date for Products ordered hereunder that is set forth in a binding Purchase Order, which must be a Business Day no less than [***] days following delivery of the applicable Purchase Order to Manufacturer. Shorter lead times may be accommodated by Manufacturer if and when possible, as determined in the sole discretion of the Manufacturer.

"**Safety Data Sheet**" or "**SDS**" means written or printed material concerning a hazardous chemical which is prepared in accordance with the regulations promulgated by the Occupational Safety & Health Administration, Department of Labor of the US or any successor entity thereto or any applicable non-US equivalents of any of the foregoing.

"**Second Source Supplier**" has the meaning set forth in **Section 3.5(b).**

"**Specifications**" means the specifications for the Products attached hereto as Schedule 2.

"**Standard Operating Procedures**" or "**SOPs**" means Manufacturer's detailed, written instructions to achieve uniformity of the performance of a specific process; the instructions usually cover more than one task or area covered by cGMP regulations.

"**Taxes**" means any and all present and future sales, income, stamp and other taxes, levies, imposts, duties, deductions, charges, fees or withholdings imposed, levied, withheld or assessed by any Governmental Authority, together with any interest or penalties imposed thereon.

"**Term**" has the meaning set forth in **Section 6.2**.

"**Territory**" means any province or territory where the Product is or is intended to be sold for commercial distribution by Customer.

"**Tooling**" means, collectively, all tooling, dies, test and assembly fixtures, gauges, jigs, patterns, casting patterns, cavities, molds, and documentation (including engineering specifications and test reports) used by Manufacturer in connection with its manufacture and sale of the Products, together with any accessions, attachments, parts, accessories, substitutions, replacements and appurtenances thereto.

"**Trade Secrets**" means all inventions, discoveries, trade secrets, business and technical information and know-how, databases, data collections, patent disclosures and other confidential and proprietary information and all rights therein.

"**Trademarks**" means all rights in and to US and foreign trademarks, service marks, trade dress, trade names, brand names, logos, trade dress, corporate names and domain names and other similar designations of source, sponsorship, association or origin, together with the goodwill symbolized by any of the foregoing, in each case whether registered or unregistered and including all registrations and applications for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection in any part of the world.

"**US**" means the United States of America.

"**Warranty Period**" has the meaning set forth in **Section 9.3(b)**.

2. Purchase and Sale of Products.

2.1 Purchase and Sale. Subject to the terms and conditions of this Agreement, during the Term, Customer shall purchase from Manufacturer, and Manufacturer shall manufacture and sell to Customer, on a non-exclusive basis, the Products to be sold or distributed within the Territory. Schedule 2 contains a description of the Products to be manufactured and sold hereunder; and Schedule 3 contains the purchase Price for each of the Products. The Parties shall, from time to time, subject to Section 5.1, amend Schedule 3 to reflect any agreed revisions to any of the terms described in the foregoing clauses (a) and (b); provided that no such revisions will modify this Agreement or be binding on the Parties unless such revisions have been fully approved in a signed writing by authorized Representatives of both Parties.

2.2 Terms of Agreement Prevail Over Customer's Purchase Order. The Parties intend for the express terms and conditions contained in this Agreement (including any Schedules and Exhibits hereto) and the Basic Purchase Order Terms contained in the applicable Purchase Order to exclusively govern and control each of the Parties' respective rights and obligations with respect to the subject matter of this Agreement, and this Agreement is expressly limited to such terms and conditions. Without limitation of the foregoing, any additional, contrary or different

terms contained in any Purchase Order or other request or communication by Customer pertaining to the sale of Products by Manufacturer, and any attempt to modify, supersede, supplement or otherwise alter this Agreement, will not modify this Agreement or be binding on the Parties unless such terms have been fully approved in a signed writing by authorized Representatives of both Parties in compliance with **Section 3.5** and 16.8.

2.3 Right to Manufacture and Sell Products. This Agreement does not limit Manufacturer's right to manufacture or sell, or preclude Manufacturer from manufacturing or selling, to any Person, or entering into any agreement with any other Person related to the manufacture or sale of, goods or products; provided, however, that Manufacturer, shall not, during the Term, manufacture or sell within the Territory any finished dermatological pharmaceutical products that contain Roflumilast as an active pharmaceutical ingredient. Notwithstanding the foregoing, Manufacturer shall protect Customer's intellectual property and Trade Secrets and Intellectual Property Rights as provided for in this Agreement.

2.4 Quality Agreement and Pharmacovigilance Agreement. Customer and Manufacturer shall enter into a quality agreement, simultaneously with the execution hereof relating to the Products ("**Quality Agreement**"). The Parties shall also enter into a pharmacovigilance agreement which shall include provisions and conditions that are customarily contained in such an agreement ("**Pharmacovigilance Agreement**"). Such Agreements shall define the responsibilities of the Parties with respect to the manufacturing and testing of Product(s) as noted herein and ensure that adverse event and other safety information is exchanged according to a schedule that will permit each Party to comply with Applicable Laws, including any local regulatory requirements. In the event of a conflict between the terms of this Agreement and the terms of the Quality Agreement and/or Pharmacovigilance Agreement, the Quality Agreement will control with respect to quality matters, the Pharmacovigilance Agreement will control with respect to pharmacovigilance matters, and this Agreement will control with respect to all other matters.

2.5 Materials Testing. For each lot of Customer Materials (as defined below) provided to Manufacturer, Manufacturer shall perform the quality control and inspection tests as set forth in the Specifications unless Customer has made arrangements in writing to supply pre-approved material.

2.6 Safety Data Sheets. Prior to Manufacturer's receipt and testing of any materials components or finished Products, and as a condition precedent of any testing or formulation work by Manufacturer pursuant to this Agreement, Customer shall provide Manufacturer with Certificates of Analysis and SDS for any Customer Materials or any materials supplied by Customer, as well as any finished Products and any components to be supplied by Customer which are necessary for the manufacture of Products. Any materials, components or Products requiring disposal shall be presumed hazardous unless otherwise provided in the SDS information provided.

2.7 Regulatory Inspection. Manufacturer shall notify Customer, in accordance with the Quality Agreement, if an authorized agent of the FDA, EMA or other Regulatory Authority or Governmental Authority visits Manufacturer's manufacturing facility and requests or requires information or changes which specifically pertain to Customer Products, and shall provide

Customer with a copy of any written document received from such Regulatory Authority or Governmental Authority as it relates to such Product, appropriately redacted to account for Manufacturer's confidentiality rights and obligations. To the extent legally permissible and practicable, Customer may have not more than two (2) designees to be present at those inspections or document productions, available for questions regarding any such Product, but not take part in directly or communicate directly with the Regulatory Authorities or Governmental Authorities concerning any matters arising in connection with those inspections and/or document productions.

2.8 Regulatory Communications & Filings. Customer agrees to, prior to submitting the following to the applicable Regulatory Authority for approval, provide Manufacturer with copies of any sections of any New Drug Applications, or other regulatory filings and Regulatory Authority correspondence applicable to Products manufactured or tested by Manufacturer, and copies of any changes in or updates to the same as they, from time to time, hereafter occur, so the Manufacturer can confirm information pertaining to its manufacturing facility is accurate.

2.9 Access to Manufacturer's Facilities. During the Term, at its own costs and expenses, Customer shall have access to the portion of Manufacturer's facilities where Manufacturer performs manufacture of the Products at a mutually agreeable date and time during the Manufacturer's regular business hours, in each case for the sole purpose of auditing Manufacturer's compliance with cGMP, the terms of this Agreement or any applicable Purchase Order, and the Applicable Law in the manufacture of Products hereunder, in accordance with the Quality Agreement. Such access shall in no way give Customer the right to any of Manufacturer's confidential or proprietary information and the audits shall be designed to not interfere with the normal operations at the Manufacturer's manufacturing facility. Furthermore, such audits shall normally be limited in frequency to [***] ([***]) each calendar year for [***] ([***]) days and limited to a maximum number of [***] ([***]), or more than [***] ([***]) if deemed necessary by both Parties, duly-authorized employees, agents or representatives of Customer who are subject to written obligations of confidentiality and non-use at least as protective of Manufacturer and Manufacturer's Confidential Information as the terms of this Agreement. Customer has the right to conduct additional audits on a "for cause" basis if (a) any applicable Regulatory Authority asserts that Manufacturer has failed to comply with any applicable regulatory standard in connection with the manufacture of any Product; (b) a Regulatory Authority orders or requires a Recall; or (c) an audit during a certain calendar year reveals a material issue for Manufacturer's non-compliance with its obligation with respect to the Product under this Agreement; provided that: (x) such audit shall be limited to such portions of the manufacturing facility that relate to any non-compliance by the Manufacturer or the manufacturing of such Product that is subject to Recall, (y) such audit shall be conducted within the mutually agreeable date and time during Manufacturer's normal business hours, and (z) the relevant costs and expenses shall be borne by the Customer. Independent and distinct from abovementioned entries in this Section 2.9, Customer shall be allowed to have at least [***] ([***]) Customer employees on site at Manufacturer's manufacturing facility for [***] each calendar year to conduct End of Year inventory count and reconciliation.

2.10 Person in Plant. At all times during the Term, with Manufacturer's prior written consent, not to be unreasonably withheld, delayed or conditioned, Customer shall be allowed to

have Representatives on site at Manufacturer's manufacturing facility (including adequate temporary desk space and other reasonable resources available to these Representatives during the periods they are at the applicable manufacturing facility) and access to all applicable portions of the applicable manufacturing facility, and all associated records, for the purpose of observing, reporting on, and consulting as to any manufacturing activities hereunder, and separate and distinct from objectives set forth in sections 2.7 and 2.9.

3. Ordering Procedure and Inventory Management.

3.1 Forecasts of Customer's Requirements. On or before the Effective Date, Customer shall provide to Manufacturer a Forecast for the [***]-month ([***]) period following the month in which such Forecast is provided. Such Forecast shall be updated by Customer [***] on or before [***] on a rolling [***] ([***]) month basis after the first Forecast submitted to the Manufacturer. It is understood and agreed that with respect to all Forecasts issued to Manufacturer by Customer pursuant to the terms hereof, the Forecast for the first [***] ([***]) months thereof shall constitute a binding and firm order for the quantities of Products specified therein, to the extent not the subject of a previous firm order, regardless of receipt of Customer's actual Purchase Order ("**Firm Commitment**") and the following [***] ([***]) months of the Forecast shall be non-binding, good faith estimates. The Customer agrees that the Manufacturer can purchase raw materials for the non-binding part of the forecast up to [***] ([***]) months in advance or longer if needed to meet the forecast.

3.2 Purchase Orders. On or before [***] and concurrent with the submission of each Forecast, Customer shall issue to Manufacturer a binding and non-cancelable Purchase Order (containing applicable Basic Purchase Order Terms that are consistent with the terms of this Agreement) for the first chronological month of the then applicable Firm Commitment, in written form, via e-mail. The minimum size of any Purchase Order for a Product shall match the Forecast in the Firm Commitment. The maximum quantities ordered will be no more than [***] percent ([***]%) in excess of the forecast for the applicable Firm Commitment for a Product, provided that Bora shall use its commercially reasonable efforts, but shall be under no obligation, to supply Product more than [***] percent ([***]%) in excess of the applicable Firm Commitment. By issuing a Purchase Order to Manufacturer, Customer makes an offer to purchase Products pursuant to the terms and conditions of this Agreement and the Basic Purchase Order Terms contained in such Purchase Order, and on no other terms. Customer shall be obligated to purchase from Manufacturer quantities of Products specified in a Purchase Order (including any related Release).

3.3 Acceptance, Rejection and Cancellation of Purchase Orders. Within [***] ([***]) Business Days following receipt of a Purchase Order, Manufacturer shall issue a written acknowledgment ("**Acknowledgment**") that it accepts or rejects such Purchase Order which may be given via e-mail or by delivering the applicable Products to Customer, whichever occurs first. Each acceptance Acknowledgment shall either confirm the Requested Delivery Date set forth in the Purchase Order or set forth a reasonable alternative delivery date. Manufacturer may reject a Purchase Order or cancel a previously accepted Purchase Order by providing written notice to Customer specifying the applicable date of rejection or cancellation only for reasons: (I) constituting a Force Majeure Event; or (ii) for the failure of such Purchase Order to comply with

the provisions of this Agreement, including if such Purchase Order exceeds the forecast for the applicable Firm Commitment for a Product by more than [***]%. In the event that Manufacturer does not issue an Acknowledgement in writing within [***] ([***]) Business Days after its receipt of the Purchase Order delivered by Customer, the Purchase Order shall be deemed accepted by the Manufacturer.

3.4 Changes in Purchase Order. Purchase Orders may be amended in volume only by mutual agreement of the Parties on a written change order ("**Change Order**") submitted to Manufacturer at least [***] ([***]) calendar days prior to the Requested Delivery Date (or a reasonable alternative delivery date proposed in the Acknowledgement, if applicable) with respect to such Product; provided, however, that Manufacturer shall exercise its commercially reasonable efforts, but shall be under no obligation, to comply with proposed amendments to Purchase Orders that Customer may request after sending a Purchase Order to Manufacturer. In the event that Manufacturer is requested or required to supply Product in addition to that which are specifically set forth in the applicable Purchase Order, any such additional Product and payment must be mutually agreed upon by authorized representatives of the Parties in writing prior to the provision of such services or the incurring of any costs relating thereto; provided, however, that if a specific quantity of Product is to be supplied hereunder, costs incident to any increase in the quantity of Product shall be [***]. Customer's liability to Manufacturer for any modification or cancellation under this Section 3.4 shall be limited to [***]. For clarity, any change to the Specification will be made as set forth in Section 3.6.

3.5 Inventory Management.

(a) Make and Ship. All manufactured Products are considered make and ship. This means Manufacturer will be ready for delivery within [***] ([***]) business days of quality control release. Inventories will be tendered for delivery Ex Works (Incoterms 2020) according to Customer's Requested Delivery Date as specified per their Purchase Orders (or a reasonable alternative delivery date proposed in the Acknowledgement, if applicable). Manufacturer agrees to hold inventory of finished Product on site for up to [***] ([***]) days beyond completion of production ("**Holding Period**") unless otherwise agreed to in writing by the Parties. Holding of finished Products by Manufacturer may be extended on a case by case basis only if agreed by both Parties in writing at a rate of [***] US Dollars ($[***] USD) per pallet per month, however, at no time is Manufacturer obligated to agree to any extended holding of inventory request by Customer.

(b) Raw Materials. Each Statement of Work shall set forth any material to be supplied by Customer to Manufacturer for the manufacture and supply of Products thereunder ("**Customer Materials**"). Such Customer Materials may include API, excipients, investigational drug product, comparators and other materials and information. Customer shall, at Customer's cost and expense, provide Manufacturer with such Customer Materials at a minimum of [***] days prior to Manufacturer's scheduled start date of production of Products, which shall be notified to the Customer in Acknowledgement issued by the Manufacturer, requiring said Customer Materials and in sufficient amounts for Manufacturer's manufacture of Products but not to exceed quantities necessary to support [***] months of the most recently supplied Forecast. The Parties acknowledge and agree that title to the API that Customer supplies shall at

all times belong to and remain with Customer. Manufacturer shall not grant, nor permit any creditor or other Third Party to acquire any security interest, lien, or other encumbrance in the API supplied by Customer. Manufacturer agrees that any API received by Manufacturer shall only be used by Manufacturer to manufacture and test the Products. The risk of loss, delay, or damage in transit shall be with Customer from and after delivery to Manufacturer's designated carrier at Manufacturer's manufacturing facility. Manufacturer will at all times take measures as are required to protect the API, Customer Materials, and any work in process from risk of loss or damage at all stages of the manufacture. In the event that Manufacturer detects a nonconformity with API Specifications, Manufacturer shall give Customer prompt oral and written notice of such nonconformity. Customer Materials shall be shipped to Manufacturer CIP (Incoterms 2020). In the event Customer ships or causes to ship such Customer Materials freight collect, Manufacturer shall invoice Customer for the cost of the freight plus a reasonable administrative fee. The undisputed amounts set forth in each invoice will be due and payable by Customer within [***] ([***]) days of receipt of such invoice. Manufacturer will not be responsible for delays arising from the failure of Customer to provide Customer Materials and co-operation to Manufacturer in a timely manner. Under such event, Manufacturer will use its commercially reasonable efforts, but shall be under no obligation, to meet the agreed upon timeline. Should the occasion arise, Manufacturer will use commercially reasonable efforts to attempt to limit the effect of such delays on services and will inform Customer of the delays and their impact to the timeline. Manufacturer, relying upon the Firm Commitment submitted by the Customer, will maintain the mutually agreed amount of raw materials, including Manufacturer Materials, in stock to ensure that Manufacturer has reasonably sufficient inventory to manufacture the Products. Manufacturer warrants that, during the Term, it will maintain, for the benefit of Customer, complete and accurate records of the inventory of all such Customer Materials. Upon the Customer's request, Manufacturer will provide to Customer a monthly report of the ending monthly inventory balance of all Customer Materials stored by Manufacturer. Except with respect to Customer Materials, Manufacturer shall supply, at its cost, all raw materials to be used in the manufacture of the Products ("**Manufacturer Materials**"). Manufacturer shall comply with all lead times and minimums set forth in the applicable Purchase Order and/or Specifications for all raw materials other than Customer Supplied Materials for production of a Batch of Products. Promptly after each of (i) the Effective Date of this Agreement and (ii) entry into any new Purchase Order where any new Manufacturer Materials not used before such new Purchase Order is required, Manufacturer, where feasible,shall identify, qualify and contract with at least one additional third party supplier of each Manufacturer Material (each, a "**Second Source Supplier**"), subject to the terms of this Section 3.5(b). Manufacturer shall consult with Customer in the identification and engagement of each Second Source Supplier and shall obtain Customer's prior written consent before utilizing any Manufacturer Materials provided by any Second Source Supplier in the Products.

(c) Manufacturer agrees (a) to account for all Customer Materials, (b) not to provide Customer Materials to any third party (including permitted subcontractors) without the express prior written consent of Customer, (c) not to use Customer Materials for any purpose other than conducting the services under the applicable Purchase Order, and (d) to destroy or return to Customer all unused quantities of Customer Materials at Customer's own costs and expenses according to Customer's written directions. Further, Manufacturer agrees not to

analyze, characterize, modify or reverse engineer any Customer Materials or take any action to determine the structure or composition of any Customer Materials unless and to the extent required under the applicable Purchase Order or if required for conducting root cause analysis for Defective Products. The information contained in such Customer Materials shall form part of Customer Intellectual Property and shall be Customer's Confidential Information.

(d) Storage Fees. If Customer fails to take delivery of any Product before the expiration of the Holding Period, Manufacturer shall store such Product as Customer's agent, and storage fees will be charged by Manufacturer, at a rate of [***] US Dollars ($[***] USD) per pallet per month after inventory for Customer has been stored for a period of [***] ([***]) days pursuant to **Section 3.4(a)**. The storage fees shall be invoiced on the [***]. For each such Batch of stored Product, Customer agrees that: (a) Customer has made a fixed commitment to purchase such Product, (b) title and risk of loss for such Product pass to Customer upon the Requested Delivery Date (or a reasonable alternative delivery date proposed in the Acknowledgement, if applicable), (c) such Product shall be on a bill and hold basis for legitimate business purposes, (d) Customer will be responsible for any decrease in market value of such Product that relates to factors and circumstances outside of Manufacturer's control. Within [***] ([***]) Business Days following a written request from the Manufacturer, the Customer shall provide Manufacturer with a letter confirming items (a) through (d) of this Section for each Batch of stored Product.

3.6 Changes to Process or Products.

(a) Changes by Customer. If Customer changes Specifications of the Products at any time after the initial order is placed or the order is started in production based on Firm Commitment, and Manufacturer agrees such change is reasonable with regard to Products manufacture; (i) such change shall be incorporated within the Specifications via a written CCR reviewed and agreed upon in writing by both Manufacturer and Customer; (ii) the Parties shall adjust the total Prices of Products and amend Schedule 3 accordingly, if there are increases or decreases in any Manufacturer Materials or any chemical and component costs greater than [***] percent ([***]%), of which Manufacturer shall give Customer [***] ([***]) days' notice of the effective date of such increase or decrease; and (iii) Customer shall pay Manufacturer for the costs associated with such change including, but not limited to, any additional development or validation studies required, charged at Manufacturer's then-prevailing R&D rates. Customer will be responsible for any reasonable fees resulting from changes to the scope of work outlined in the Purchase Order; however, Customer must approve changes to the budget in writing prior to initiating new work or incurring additional fees. In avoidance of doubt, no change in the CCR shall be implemented by Manufacturer until the Parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change. No revisions to the Specifications that would affect the manufacture of a Product shall be submitted to any Regulatory Authorities unless approved by all Parties in writing.

(b) Changes by Manufacturer. Manufacturer agrees that any changes to the Products developed by Manufacturer, which may be incorporated into the Products shall require the written approval of Customer via a CCR prior to such incorporation. At the time of such

incorporation, such changes shall become part of the Specifications. In avoidance of doubt, no change in the CCR shall be implemented by Manufacturer until the Parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change. It is also agreed that any filings with any Regulatory Authority necessitated by any such change shall be the sole responsibility of the Customer.

(c) Changes or Fees by Regulatory Authorities. The Parties agree that any changes required by a Regulatory Authority, shall be incorporated into the Products as evidenced by the written approval of Customer via a CCR prior to such incorporation. Customer will be responsible for any actual or potential additional Products costs, fees or expenses, such as regulatory user fees, serialization fees or similar such items, and Manufacturer will be responsible for any actual or potential additional costs, fees or expenses for changes to manufacturing process or equipment caused by Manufacturer. At the time of such incorporation, such changes shall become part of the Specifications. If Manufacturer is required by Regulatory Authority to perform validation studies for purposes of validating new manufacturing process or cleaning procedures or new material and finished Products assay procedures with respect to Products in order to continue to engage in the manufacture of said Products for Customer, such studies shall be agreed to by the Parties and set forth in a new Project Protocol. In the event the Parties are unable to reach agreement with respect to such Project Protocol, then Manufacturer shall be under no obligation to perform such studies or otherwise continue the manufacture of the Products affected by said regulation. Any costs to Manufacturer resulting from the operation of this Section 3.6(c) shall be reimbursed by Customer by way of adjustments to the manufacturing fee, materials fee or via an annual charge.

(d) Obsolete Inventory. Any Customer-specific inventory relating to Products, including, but not limited to, materials, expired materials, work-in-process, waste by-products, testing supplies, stability samples, work-in-process, and any Products or finished Product rendered obsolete as a result of formula, artwork, or labeling or packaging changes requested by Customer or by changes required by a Regulatory Authority shall be reimbursed to Manufacturer by Customer at Manufacturer's Materials fee and unless otherwise instructed by Customer and agreed to by Manufacturer, will be shipped to Customer for destruction by Customer. Customer shall bear [***] percent ([***]%) of all shipping and destruction costs related to said obsolete inventory. Manufacturer shall provide written notification to Customer of its intent to dispose of or store obsolete inventory. If Manufacturer does not receive disposition instructions from Customer within [***] ([***]) days from date of notification, obsolete inventory remaining at Manufacturer's facilities shall be subject to a deposit covering the standard cost of the obsolete inventory and storage and or destruction fees at Manufacturer's discretion.

4.1 Shipment, Delivery, Acceptance and Inspection. Shipment. Shipment of Products shall be in accordance with Customer instructions, provided that such instructions comply with Applicable Law. Products will be shipped to Delivery Location to be tendered for delivery promptly following Release. Each shipment will constitute a separate sale and Customer shall pay for the Products shipped, in accordance with the payment terms specified in **Section 5.3**, whether such shipment is in whole or partial fulfillment of a Purchase Order.

4.2 Delivery. Unless otherwise expressly agreed to by the Parties in writing, Manufacturer shall deliver the Products to the Delivery Location, in accordance with Customer instructions. All Products shall be bulk or packaged, and labeled appropriately for the intended use, as specified in the applicable Purchase Order, and each shipment shall be accompanied by an appropriate certificate of analysis pursuant to **Section 4.5(a)**. Each shipment shall also contain a traceable Batch number and date of manufacture. All Prices are Ex Works (EXW Incoterms 2020) Mississauga, Canada. Title to, and all costs and risk of loss for or associated with shipment of the Products, shall transfer from Manufacturer to Customer when Manufacturer makes the Products available to Customer at Delivery Location.

4.3 Late Delivery. In the event that Manufacturer fails to deliver at least [***] ([***]%) of the quantity of Products set forth in any Purchase Order on or before the date that is [***] ([***]) days after the Requested Delivery Date as specified per applicable confirmed Purchase Orders (or a reasonable alternative delivery date proposed in the Acknowledgement, if applicable) ("**Late Delivery**"), Customer will issue letter of potential Late Delivery to Manufacturer. In the event that a Late Delivery issue is not rectified within [***] ([***]) days from the Requested Delivery Date as specified per such confirmed Purchase Orders (or a reasonable alternative delivery date proposed in the Acknowledgement, if applicable), Manufacturer shall be considered to be in "**Supply Failure**" status. Further, in the event of more than [***] ([***]) occasions of Late Delivery occur in [***], Manufacturer shall also be considered to be in Supply Failure. Without limiting its obligations herein, Manufacturer shall, within [***] ([***]) Business Days of becoming aware, inform Customer of any known or anticipated events or conditions that may result in such a Late Delivery or Supply Failure, including but not limited to Force Majeure Events under **Section 16.22**. In the event of a Late Delivery or Supply Failure, and without limiting any other remedy available to the Customer at law or equity: (i) Manufacturer shall fulfill outstanding Purchase Order(s) with such quantities of Products as are immediately available; and (ii) unless and until such Supply Failure is remedied to Customer's satisfaction, Customer shall be entitled to source Product from an alternative manufacturing facility (that Manufacturer shall provide non-financial technology transfer assistance to Customer in qualifying) and shall be relieved from its obligations under this Agreement to (x) purchase any quantities of Product subject to any outstanding Purchase Orders or Forecasts and (y) submit any further Purchase Orders or Forecasts.

4.4 Transfer of Title and Risk of Loss.

(a) Title to Products shipped under any Purchase Order passes to Customer upon Ex Works (Incoterms 2020) Mississauga, Canada.

(b) Risk of loss to Products shipped under any Purchase Order passes to Customer upon Ex Works (Incoterms 2020) Mississauga, Canada.

4.5 Products Testing.

(a) Certificate of Analysis. Manufacturer shall test each Batch of Products purchased pursuant to this Agreement before delivery to Customer to ensure that the Products conform with Specifications, cGMP, and other requirements of Applicable Law. Each certificate of analysis shall set forth the items tested, Specifications and test results for each Batch

delivered. Manufacturer shall send one (1) certificate of analysis to Customer at the time of the Release of Products. Extraordinary reporting or documentation, outside of this Agreement, will be delivered to Customer if requested by Customer and agreed in writing by Manufacturer and shall be subject to an additional charge by Manufacturer. In avoidance of doubt, requests for raw data for Specification testing of Products will not be considered extraordinary.

(b) Stability Testing. Manufacturer shall perform its standard stability test program as defined in Manufacturer's SOPs as separately agreed to for each Products contained herein, with separate charge to Customer if specified as such by applicable Statement of Work. Stability requirements will be defined in a stability protocol with Customer approval. Customer shall receive a copy of the report generated in Manufacturer's annual review for each Product in Manufacturer's standard form as long as Manufacturer is continuing to produce such Products for Customer and for as long as Customer's account is current. If Customer elects to perform its own stability testing on Products, Customer agrees to provide Manufacturer with a copy of the results from such testing on an annual basis.

(c) Rejected Products. Customer shall have the right to reject any Products which fails to meet the Specifications or Applicable Law, in accordance with this **Section 4.5(c)** ("**Rejected Products**"). Customer shall, within [***] ([***]) days after its receipt of any shipment of Products and related certificate of analysis of Products (as described in **Section 4.5(a)** hereof) ("**Inspection Period**"), notify Manufacturer in writing of Customer's rejection of the Products (if any), specifying why the Products failed to meet the Specifications or Applicable Law, and any other claim relating to the Rejected Products accompanied with the sample of the alleged Nonconforming Products, if available, supporting analyses or documentation. Customer will be deemed to have accepted Products unless it provides Manufacturer with written Notice of any Nonconforming Products within the Inspection Period. For the avoidance of doubt, any defect in Products rendering Products nonconforming to the Specifications or Applicable Law, or otherwise Defective, that existed at or prior to delivery and was not reasonably discovered by Customer in accordance with its SOPs during Inspection Period ("**Latent Defect**") is still a cause of rejection if such Latent Defect is attributable to failure of Manufacturer or its Representatives (including such Affiliates) to (i) follow Manufacturer's or such Affiliates' written procedures and SOP applicable to Products and (ii) complete preventative maintenance activities pursuant to Manufacturer's SOP, provided that, Such Latent Defects should be notified by Customer to Manufacturer within [***] ([***]) Business Days after discovery of the defect but no later than [***] ([***]) days after delivery of the Products. Customer shall grant to Manufacturer the right to inspect, or test Rejected Products. All necessary samples of Rejected Products shall be delivered to Manufacturer and submitted for inspection and evaluation by Manufacturer in accordance with Manufacturer's SOPs to determine whether or not said Products meet the Specifications.

(d) Replacement of Rejected Products; Responsibility for Costs. Manufacturer shall, in Customer's sole discretion, either (i) remanufacture such Rejected Products (in an agreed upon Batch order quantity, but in no event less than full Batch increments) with any Customer Materials to be provided by Customer at Customer's cost, except for the cost incurred due to Manufacturer's negligence or willful misconduct which shall be paid by Manufacturer, in the case of Products manufacturing services, repackage Products (including any conforming

Customer Materials recovered from the Rejected Products, or otherwise provided by Customer, at Customer's cost), or (ii) refund Customer for the manufacturing and packaging cost, if applicable, for such Rejected Products. If requested, Manufacturer shall make arrangements with Customer for the return or disposal of Rejected Products; Customer shall ship all Rejected Products to Manufacturer's facility located at 7333 Mississauga Road, Mississauga, ON L5N 6L4 or to such other location as Manufacturer may instruct Customer in writing, and Manufacturer will reimburse Customer for shipping costs incurred. Manufacturer shall ship to Customer, at Manufacturer's expense and risk of loss, the repaired or replaced Products to a location designated by Customer. If after Manufacturer requests in writing from Customer direction on how to dispose of Products, materials, equipment, samples or other items (belonging to the Customer) and is unable to obtain a response from Customer within [***] ([***]) days, Manufacturer may dispose of all such items and bill the Customer for such costs.

(e) Upon the completion of all necessary validation Batches in the event Rejected Products fail to comply with the Specification due to Manufacturer's failure to comply with the applicable written procedures and such failure renders the Products unmarketable, Manufacturer shall bear [***] of the Rejected Products' manufacturing fees, costs of all materials used in manufacturing, including Customer Materials, Supply Failure reimbursement pursuant to **Section 4.3**, and costs of destruction. For clarity, if Products are rejected from use of API or other Customer Materials that, at the time of delivery to Manufacturer, fails to conform to Specifications for such API or other Customer Materials for reason not attributable to Manufacturer, then the cause of the nonconformity shall not be deemed to be attributable to Manufacturer, and this **Section 4.5** shall not apply. In such event, if Customer still requires repair or replacement of Product, the Customer shall be liable to pay for and supply Customer Materials for both the Batch(es) of such Defective Products and the Batch(es) of replaced or repaired Products Destruction of Rejected Products shall be in accordance with all Applicable Laws.

(f) Resolution of Conflict. If Manufacturer does not agree with Customer's determination that Products fails to conform to the Specifications, then Manufacturer shall so notify Customer within [***] ([***]) days of receipt of Customer's Notice of non-conformity with respect to such Products and (if requested) Products sample. In the event of: (i) a conflict between the Parties with respect to the conclusions to be drawn from any test results or, (ii) a difference of opinion between the Parties regarding the rejection of any Batch by Customer with respect to any shipment of Products in such Batch, a sample of such Products Batch shall be submitted by Manufacturer to an independent testing organization, or to a consultant of recognized repute within the US pharmaceutical industry, in either case mutually agreed upon in writing by the Parties (such organization or consultant, the "**Laboratory**"), the appointment of which shall not be unreasonably withheld or delayed by either Party, for testing against the Specifications utilizing the methods set out in the Specifications. The determination of the Laboratory with respect to all or part of any shipment of Products shall be final and binding on the Parties. The fees and expenses of the Laboratory testing shall be borne entirely by: (i) Manufacturer, if the Laboratory determines that Manufacturer is attributable for the nonconformity, (ii) shared equally by the Parties if the Laboratory is unable to make a final determination as to the cause of the nonconformity, and (iii) Customer, in all other circumstances.

4.6 Packaging and Labeling. Manufacturer shall properly pack, mark and tender for delivery and provide Customer with relevant documentation showing the Purchase Order number, Manufacturer's identification number for the subject Products, the quantity of pieces in shipment, the number of cartons or containers in shipment, and the Manufacturer's name.

4.7 Limited Right of Return. Except as provided under **Section 4.5** and **Section 9.4**, Customer has no right to return Products shipped to Customer pursuant to this Agreement.

5. Price; Payment.

5.1 Price. Customer shall purchase the Products from Manufacturer at the prices set forth on Schedule 3 attached hereto ("**Prices**") and as modified below.

(a) During the Term of this Agreement, Manufacturer shall charge Customer those Prices for as set forth in Schedule 3 attached hereto and made a part hereof, subject only to changes, if applicable, pursuant to **Section 3.6** and Section 5.1 (b).

(b) Prices of the Products are subject to review of all Product Specifications, price for Manufacturer Materials, relevant chemical or component, labor cost, feasibility studies and reports, and post regulatory approval process validation on an annual basis. Upon such review and revision, Manufacturer may propose increase or decrease of Manufacturer's Prices to match the actual changes incurred by Manufacturer. In addition, the Parties hereto agree that increases to the Prices shall be negotiated, in good faith, [***]. If the Parties are unable to agree on a re-negotiated price at least [***] ([***]) days prior to the start of a new calendar year, then this Agreement, effective [***], shall continue in full force and effect with prices being adjusted to reflect the percentage change in the most recently published monthly Producer Price Index: Pharmaceutical Preparation Manufacturing (PCU325412) issued by the Bureau of Labor Statistics, US Department of Labor, or comparable successor index, in July of the preceding year as compared to the same month of the year prior thereto until such time as to when price negotiation can be completed.

5.2 Manufacturer may provide the additional services (including, but not limited to, technology transfer service for moving the processing and/or packaging of the Product from Customer's previous manufacturer to Manufacturer's manufacturing site) not specified in this Agreement as requested by the Customer and agreed by executed Project Protocol. The fees for such additional services is otherwise subject to mutual consent of the Parties. For clarity purposes, services related to storage and maintenance/administration of Retain Samples shall be regarded as additional services of which the relevant expenses and costs shall be borne by Customer and charged in accordance with Section 5.3. For used herein, "Retain Samples" shall mean samples retained by Manufacturer for each manufactured Batch of Product released to Customer for further analysis or testing purposes (including, but not limited to, annual inspection and stability test).

5.3 Payment Terms. Manufacturer shall invoice Customer immediately upon release of the Product for the applicable Price for the Product as set forth in the applicable Purchase Order. Manufacturer may also issue an invoice to Customer for the other amount receivable under this Agreement or any Product Protocol. Each such invoice shall state the Purchase Order number, Product name, the quantity of the Product contained in the shipment in question, Price

per unit, and the total amount to be paid by Customer. Manufacturer will send all invoices to Customer via email to [***]. The payment terms are [***] days from the date the invoice is sent to Customer, ex-works Mississauga, Canada. Customer shall pay to Manufacturer all undisputed invoiced amounts within [***] ([***]) days from the date of such invoice without any offset or deduction of any nature whatsoever. Customer will be charged [***]% interest per annum on any payments exceeding [***] days unless in accordance with Section 5.4.

5.4 Invoice Disputes. Customer shall notify Manufacturer in writing of any Dispute with any invoice (along with substantiating documentation and a reasonably detailed description of the Dispute) within [***] ([***]) Business Days from the date of such invoice. In the event the quantity of the Product shipped is greater or less than the quantity reflected in Manufacturer's invoice for such shipment, the amount of such invoice automatically shall be increased or reduced, as the case may be, to reflect the actual quantity of the Product contained in such shipment unless Manufacturer disputes such notice. If the quantity of Product shipped is greater than the amount of Product ordered by Customer , Customer may return such excess amount to Manufacturer in accordance with Section 4.5 (c), at Manufacturer's expense, and pay only for the amount of Product ordered by Customer. The Parties shall seek to resolve any such Disputes expeditiously and in good faith in accordance with the dispute resolution provisions set forth in **Section 16.17**. Notwithstanding anything to the contrary, Customer shall continue performing its obligations under this Agreement during any such Dispute, including Customer's obligation to pay all due and undisputed invoice amounts in accordance with the terms of this Agreement.

5.5 Taxes.

(a) Notwithstanding anything to the contrary herein, each Party shall solely bear and pay all taxes imposed on such Party's net income or gain (in each case, however denominated) arising directly or indirectly from the activities of the Parties under this Agreement. Each Party shall comply with Applicable Laws and regulations regarding filing and reporting for income tax purposes.

(b) It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax ("VAT"), which shall be added thereon as applicable. In the event any payments made by a Party pursuant to this Agreement become subject to withholding taxes under the laws or regulation of any jurisdiction, such Party (and its representatives) shall deduct and withhold the amount of such taxes for the account of the other Party to the extent required by Applicable Law and such amounts payable to the other Party shall be reduced by the amount of taxes deducted and withheld, which shall be treated as paid to the other Party in accordance with this Agreement. To the extent that a Party, subject to Applicable Law, is required to deduct and withhold taxes on any payments made under this Agreement, such Party shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the payee an official tax certificate or other documents evidencing payment of such withholding. Each Party shall provide any tax forms to the other Party that may be reasonably necessary in order for the

other Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with commercially reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

(c) The Parties agree to cooperate and produce on a timely basis any tax forms or reports, including an IRS Form W-9 or an IRS Form W-8BEN-E, reasonably requested by the other Party in connection with any payment made under this Agreement.

6. Term.

6.1 Initial Term. The term of this Agreement commences on the Effective Date and continues for a period of [***] ([***]) years, unless it is earlier terminated pursuant to the terms of this Agreement or Applicable Law, the Agreement is replaced by another agreement, or extended by mutual written agreement (the "**Initial Term**"); provided, however, that as long as any Purchase Order is not completed in accordance with its terms and is not as otherwise terminated or replaced explicitly, the terms of this Agreement shall remain in effect with respect to such Purchase Order.

6.2 Renewal Term. Upon expiration of the Initial Term, the term of this Agreement will automatically renew for additional successive [***] ([***]) year terms unless either Party provides written Notice of non-renewal at least [***] ([***]) months prior to the end of the then-current term (each, a "**Renewal Term**" and together with the Initial Term, the "**Term**"), unless any Renewal Term is earlier terminated with [***] ([***]) months' prior written notice pursuant to the terms of this Agreement or Applicable Law. If the Initial Term or any Renewal Term is renewed for any Renewal Term(s) pursuant to this **Section 6.2**, the terms and conditions of this Agreement during each such Renewal Term will be the same as the terms in effect immediately prior to such renewal. In the event either Party provides timely Notice of its intent not to renew this Agreement, then, unless earlier terminated in accordance with its terms, this Agreement terminates on the expiration of the Initial Term or then-current Renewal Term, as applicable.

6.3 Manufacturer's Right to Terminate. Manufacturer may terminate this Agreement, by providing written Notice to Customer:

(a) if Customer is in material breach of this Agreement, and the breach is not cured by Customer within [***] calendar days after Customer's receipt of written Notice of such breach; or

(b) if Customer (i) becomes insolvent or is generally unable to pay its debts as they become due, (ii) files or has filed against it, a petition for voluntary or involuntary bankruptcy or otherwise becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency Law, (iii) makes or seeks to make a general assignment for the benefit of its creditors, or (iv) applies for or has appointed a receiver, trustee,

custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

Any termination under this **Section 6.3** will be effective on Customer's receipt of Manufacturer's written Notice of termination or such later date (if any) set forth in such Notice.

6.4 Customer's Right to Terminate. Customer may terminate this Agreement, by providing written Notice to Manufacturer:

(a) if Manufacturer is in material breach of this Agreement and the breach is not cured by Manufacturer within [***] ([***]) days after Manufacturer's receipt of written Notice of such breach; provided, however, that if such breach or default, by its nature, cannot be cured within such [***] ([***]) days period, and Manufacturer commences and diligently pursues a plan to cure such material breach or default and provides Customer within such [***] ([***]) days period with a written plan to cure such material breach or default including the date of completion, which plan and completion date are agreed upon in writing by Customer, then Customer shall not terminate this Agreement unless such material breach or default remains uncured following the agreed completion date;

(b) if Manufacturer (i) becomes insolvent or is generally unable to pay its debts as they become due, (ii) files or has filed against it, a petition for voluntary or involuntary bankruptcy or otherwise becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency Law, (iii) makes or seeks to make a general assignment for the benefit of its creditors, or (iv) applies for or has appointed a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business; or

(c) upon [***] ([***]) calendar days written notice in the event that any Governmental Authority takes any action, or raises any objection, in either case that is not attributable to any action or omission by Customer and that prevents Customer from importing, exporting, purchasing or selling such Product for a period of [***]; provided, however, that if such Governmental Authority action or objection specifically relates to Manufacturer's performance hereunder, prior to any such termination, Manufacturer shall have the right to address such action or objection, and in Customer's sole judgement, Customer may terminate this Agreement or consider not terminating;

(d) upon [***] ([***]) days' prior written notice to Manufacturer.

6.5 Effect of Expiration or Termination.

(a) Customer's sole obligation upon termination shall be to pay Manufacturer any payments due and owing hereunder, for Products requested by Customer and manufactured by Manufacturer or service rendered by Manufacturer in accordance with this Agreement up to the date of termination. Manufacturer shall not be entitled to any prospective profits or damages because of Customer's termination of this Agreement. Manufacturer shall make all commercially reasonable efforts to minimize the cost attributable to such termination.

(b) Expiration or termination of the Term will not affect the following rights or obligations of the Parties, nor shall it prejudice any other remedies that the Parties may have under this Agreement:

(i) come into effect upon or prior to termination or expiration of this Agreement.

7. Certain Obligations of the Parties.

7.1 Joint Steering Committee. A Joint Steering Committee shall be formed within [***]. The Joint Steering Committee may meet quarterly to review performance. To the extent that there are any performance issues, escalation will be made to an Executive Steering Committee comprised of, at a minimum, respective Head of Operations and Heads of Quality for both Parties.

7.2 Certain Prohibited Acts. Notwithstanding anything to the contrary in this Agreement, neither Customer or Manufacturer nor any Personnel of either shall:

(a) make any representations, warranties, guarantees, indemnities, similar claims or other commitments:

(i) actually, apparently or ostensibly on behalf of the other Party, or

(ii) to any customer or other Person with respect to the Products, which are additional to or inconsistent with any then-existing representations, warranties, guarantees, indemnities, similar claims or other commitments in this Agreement or any written documentation provided by either Party to the other.

7.3 Credit Risk on Resale of the Products to Customers. Customer shall be solely responsible for all credit risks with respect to, and for collecting payment for, all products (including Products) sold to its customers or other third parties, whether or not Customer has made full payment to Manufacturer for such products. The inability of Customer to collect the purchase price for any product sold to its customers shall not affect Customer's obligation to pay Manufacturer for any Products.

7.4 Non-Solicitation. During the Term of the Agreement and for a period of [***] thereafter, neither Party shall hire any employee, contract employee, or agent of the other Party or its Affiliates without the prior written approval of the other Party. Notwithstanding the foregoing, general employment advertisements and other similar employment solicitations that are not targeted at employees, contract employees or agents of the other Party or any of its Affiliates shall not be deemed as in breach of this Section 7.4.

8. Compliance with Laws. Each Party shall at all times comply with all Laws applicable to this Agreement, each respective Party's performance of their obligations hereunder and each Party's use or sale of the Products. Without limiting the generality of the foregoing, each Party shall (a) at their own expense, maintain all certifications, credentials, licenses and permits necessary to conduct its business relating to the purchase, use or resale of the Products, and (b)

not engage in any activity or transaction involving the Products, by way of resale, lease, shipment, use or otherwise, that violates any Law.

9. Representations and Warranties; Recall.

9.1 Manufacturer's Representations and Warranties. Manufacturer represents and warrants to Customer that:

(a) it is a corporation duly organized, validly existing and in good standing under the Ontario Laws;

(b) it is duly qualified to do business and is in good standing in every jurisdiction in which such qualification is required for purposes of this Agreement;

(c) it has the full right, corporate power and authority to enter into this Agreement and to perform its obligations hereunder;

(d) the execution of this Agreement by its Representative whose signature is set forth at the end of this Agreement, and the delivery of this Agreement by Manufacturer, have been duly authorized by all necessary corporate action on the part of Manufacturer to legally bind Manufacturer to the terms set forth herein;

(e) all of the work it will perform and the Products it will create will be in full compliance with all Applicable Laws, cGMPs, and the Specifications;

(f) work performed hereunder will be performed with the requisite skill, attention, and workmanlike conduct expected of a professional pharmaceutical company currently working in the industry;

(g) neither Manufacturer nor its Representatives or employees involved with service performance have been debarred pursuant to the FFDCA, as amended, or supplemented from time to time;

(h) the execution and delivery by Manufacturer of this Agreement requires no governmental or regulatory approvals to be obtained on the part of Manufacturer, or, if required, Manufacturer has obtained such approvals;

(i) it has no other commitments of its resources that will interfere with its ability to fulfill its obligations under this Agreement, provided however, unforeseen production delays with other Customer programs that precede Customer's production in the same equipment lines may impact timelines, and Manufacturer will use commercially reasonable efforts to mitigate or avoid such delays;

(j) the execution, delivery and performance of this Agreement by Manufacturer will not violate, conflict with, require consent under or result in any breach or default under (i) any of Manufacturer's organizational documents (including its organizational and governing documents) or any other agreement, court order, consent decree or other arrangement, whether written or oral, by which it is bound, (ii) any Applicable Law or (iii) with or without notice or lapse of time or both, the provisions of any material Manufacturer Contract;

(k) it conducts its businesses in compliance in all material respects with the US Foreign Corrupt Practices Act, as amended, the UK Bribery Act, and other similar anti-corruption legislation in other jurisdictions;

(l) it has not made, offered or solicited and will not make, offer or solicit any remuneration, kickbacks, or anything else of value to any person or entity in violation of the federal Anti-Kickback Statute (42 U.S.C. § 1320-a7b(b)) or any applicable state anti-kickback statutes;

(m) to Manufacturer's best knowledge, and as of the Effective Date, the manufacturing process owned by Manufacturer does not infringe or misappropriate any intellectual property owned by any third party, and Manufacturer has not received any notice from a third party in respect of any such claim of infringement or alleged infringement. Manufacturer covenants that should Manufacturer or any person employed by Manufacturer be convicted in the future, of any act for which a person can be debarred as described under the FFDCA, Manufacturer shall immediately notify Customer of such conviction; and it can safely manufacture the Product requested by the Customer in accordance with the agreed Product Specifications, cGMP (if applicable), and Applicable Laws, at its Mississauga, Canada facility, which is a facility inspected and approved by the FDA.

9.2 Customer's Representations and Warranties. Customer represents and warrants to Manufacturer that:

(a) it is a corporation, duly organized, validly existing and in good standing under the laws of Delaware;

(b) it is duly qualified to do business and is in good standing in every jurisdiction in which such qualification is required for purposes of this Agreement;

(c) it has the full right, corporate power and authority to enter into this Agreement and to perform its obligations hereunder;

(d) the execution of this Agreement by its Representative whose signature is set forth at the end of this Agreement, and the delivery of this Agreement by Customer, have been duly authorized by all necessary corporate action on the part of Customer;

(e) the execution, delivery and performance of this Agreement by Customer will not violate, conflict with, require consent under or result in any breach or default under (i) any of Customer's organizational documents (including its organizational and governing documents), (ii) any Applicable Law or (iii) with or without notice or lapse of time or both, the provisions of any material Customer Contract;

(f) this Agreement has been executed and delivered by Customer and (assuming due authorization, execution and delivery by Manufacturer) constitutes the legal, valid and binding obligation of Customer, enforceable against Customer in accordance with its terms;

(g) it is in compliance with all Applicable Laws and Customer Contracts relating to this Agreement, the Products and the operation of its business;

(h) it has obtained all licenses, authorizations, approvals, consents or permits required by Applicable Laws to conduct its business generally and to perform its obligations under this Agreement;

(i) the Specifications for each of the Products are its property and that Customer may lawfully disclose the Specifications to Manufacturer;

(j) any Trademarks utilized in connection with any of the Products are its property and may be lawfully used as directed by Customer;

(k) the Specifications for the Products conform to all Applicable Laws and regulations, and that the Products if labelled and formulated in accordance with the Specifications and manufactured in compliance with applicable CGMPs and the Specifications may be lawfully sold and distributed in every jurisdiction in which Customer markets such Products;

(l) all Customer Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable Specifications, shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement;

(m) the content of all artwork and labeling provided by or on behalf of Customer shall comply with all Applicable Laws;

(n) all Products delivered to Customer by Manufacturer shall be held, used and disposed of by or on behalf of Customer in accordance with Applicable Laws, and Customer will otherwise comply with Applicable Laws relating to Customer's performance under this Agreement;

(o) Customer will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Customer does not hold all necessary regulatory approvals to market and sell the Product; and

(p) to Customer's best knowledge, and as of the Effective Date, there are (i) no Patents or any other rights owned by a third party related to the Customer Intellectual Property Rights (including all applicable copyrights, trademarks, trade secrets, patents, inventions and developments) licensed to Manufacturer used to manufacture Product that would be infringed or misused by performance under this Agreement and (ii) no trade secret or other proprietary right of a third party related to the Customer's Intellectual Property Rights used to manufacture Product that would be infringed or misused by performance under this Agreement.

9.3 Limited Product Warranty. Subject to the provisions of Section 10, Manufacturer warrants to Customer (the "**Product Warranty**") that:

(a) All Products delivered by Manufacturer shall have been manufactured by Manufacturer in compliance with applicable FDA regulations and cGMP as that term is defined under the FFDCA;

(b) for a period of [***] ([***]) years from the Product manufacture date (the "**Warranty Period**"), each Product will materially conform to the Specifications set forth in Schedule 2 and will be free from defects in material and workmanship; and

(c) Customer will receive good and valid title to all Products, free and clear of all encumbrances and liens of any kind.

9.4 DISCLAIMER OF OTHER REPRESENTATIONS AND WARRANTIES; NON-RELIANCE. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH IN **SECTIONS 9.1** AND **9.2** AND THE PRODUCT WARRANTY SET FORTH IN **SECTION 9.3**, (A) NEITHER MANUFACTURER NOR ANY PERSON ON MANUFACTURER'S BEHALF HAS MADE OR MAKES ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY WHATSOEVER, EITHER ORAL OR WRITTEN, INCLUDING ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, OR NON-INFRINGEMENT OR PERFORMANCE OF GOODS OR PRODUCTS TO STANDARDS SPECIFIC TO THE COUNTRY OF IMPORT, WHETHER ARISING BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE, ALL OF WHICH ARE EXPRESSLY DISCLAIMED, AND (B) CUSTOMER ACKNOWLEDGES THAT IT HAS NOT RELIED UPON ANY REPRESENTATION OR WARRANTY MADE BY MANUFACTURER, OR ANY OTHER PERSON ON MANUFACTURER'S BEHALF, EXCEPT AS SPECIFICALLY PROVIDED IN **SECTIONS 9.1, 9.2** AND **9.3** OF THIS AGREEMENT.

9.5 Recall of Products. If either Party, in good faith, determines that a Recall of one or more Products or its labeling may be warranted, such Party shall immediately notify the other Party in writing and shall advise such other Party of the reasons underlying its determination that a Recall may be warranted. The Parties shall consult with each other as to any action to be taken regarding such Recall. Notwithstanding the foregoing, Customer shall have the right to Recall one or more Products or its labeling at any time at its own costs and expenses.

10. Indemnification.

10.1 Indemnification of Manufacturer. Customer shall indemnify, defend and hold Manufacturer, each Affiliate of Manufacturer and the officers, directors and employees thereof (each a "**Manufacturer Indemnified Party**") harmless from and against any and all damages, claims, costs and expenses ("**Losses**") that are incurred by any Manufacturer Indemnified Party as a result of third party claims or Actions brought or made against it arising out of or resulting from:

(a) the breach of this Agreement by Customer;

(b) the negligence or willful misconduct of Customer, its Affiliates, officers, directors and employees thereof;

(c) any bodily injury, property damage or death resulting from any Customer Materials or any Products manufactured and supplied under this Agreement including product liability claims, except to the extent such Losses are attributable to Manufacturer's improper testing, storage or handling of Customer Materials or manufacturing of Products;

(d) the sale or distribution of the Products or their use; or

(e) any claim of infringement or alleged infringement of Intellectual Property Rights of any third party relating to the Customer Intellectual Property Rights licensed hereunder used to any Products manufactured and supplied hereunder or Manufacturer's use of any Customer Intellectual Property Rights licensed hereunder and any Products except, in each case, to the extent such Losses are attributable to the negligence or willful misconduct of any Manufacturer Indemnified Party, or to Manufacturer's breach of this Agreement.

Notwithstanding anything to the contrary in this Agreement, this **Section 10.1** does not apply to any claim (whether direct or indirect) for which a sole or exclusive remedy is provided for under another section of this Agreement, including **Section 4.3**, **Section 4.5**, and **Section 9.4**.

10.2 Indemnification of Customer. Manufacturer shall indemnify, defend and hold Customer, each Affiliate of Customer and the officers, directors and employees thereof (each a "**Customer Indemnified Party**") harmless from and against any and all Losses that are incurred by Customer as a result of a third party claim or Actions brought or made against it arising out of or resulting from:

(a) the breach of this Agreement by Manufacturer;

(b) the negligence or willful misconduct of Manufacturer, its Affiliates, officers, directors and employees thereof except, in each case, to the extent such Losses are attributable to the negligence or willful misconduct of any Customer Indemnified Party, or to Customer's breach of this Agreement; or

(c) any bodily injury, property damage or death resulting from any Manufacturer Materials or any Products manufactured and supplied under this Agreement including product liability claims, except to the extent such Losses are attributable to Customer.

10.3 Exceptions and Limitations on Indemnification. Notwithstanding anything to the contrary in this Agreement, an indemnifying Party is not obligated to indemnify or defend (if applicable) an indemnified Party against any claim if such claim or corresponding Losses arise out of or result from the indemnified Party's or its Personnel's gross negligence or more culpable act or omission (including recklessness or willful misconduct).

10.4 Procedure. To be eligible to be indemnified hereunder, the Party to be indemnified shall (a) provide written notice to the indemnifying Party of any third party claim within [***] ([***]) days after the indemnified Party has knowledge of such claim (except that failure to timely provide such notice will relieve the indemnifying Party of its obligations only to the extent the indemnifying Party is materially prejudiced as a direct result of such delay); (b) give the indemnifying Party sole control over the defense thereof and any related settlement negotiations; and (c) cooperate and, at the indemnifying Party's request and expense, assisting in such defense. Notwithstanding the foregoing, the indemnified Party may participate at its own expense in the defense and any settlement discussions, and will have the right to approve any settlement agreement that involves an admission of fault by the indemnified Party or imposes non-monetary obligations on the indemnified Party; provided, however, that such approval will not be unreasonably conditioned, withheld, or delayed. The indemnified Party shall have the

right to join, but not to control, at its own expense and with counsel of its choice, the defense of any claim that has been assumed by the indemnifying Party.

10.5 For clarity purposes, Manufacturer shall not be responsible for any loss or damage to the Customer Materials except if and to the extent that such loss or damage was due to negligence or willful misconduct by Manufacturer in the storage or handling of the Customer Materials on its premises. Where the Manufacturer is responsible for such loss or damage, its liability is limited to the cost of such lost or damaged Customer Materials.

10.6 Complete Indemnification. As the Parties intend complete indemnification, all costs and expenses incurred by the indemnified Party in connection with enforcement of **Article 10** shall also be reimbursed by the indemnifying Party.

11. Limitation of Liability.

11.1 NO LIABILITY FOR CONSEQUENTIAL OR INDIRECT DAMAGES. EXCEPT WITH RESPECT TO A BREACH OF **ARTICLE 13** (CONFIDENTIALITY), OR EACH PARTY'S INDEMNIFICATION OBLIGATIONS UNDER **ARTICLE 10**, OR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, IN NO EVENT SHALL EITHER PARTY OR ITS/THEIR REPRESENTATIVES BE LIABLE FOR CONSEQUENTIAL, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR ENHANCED DAMAGES, LOST PROFITS OR REVENUES OR DIMINUTION IN VALUE, ARISING OUT OF OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF (A) WHETHER SUCH DAMAGES WERE FORESEEABLE, (B) WHETHER OR NOT THE OTHER PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND (C) THE LEGAL OR EQUITABLE THEORY (CONTRACT, TORT OR OTHERWISE) UPON WHICH THE CLAIM IS BASED, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE.

11.2 MAXIMUM LIABILITY FOR DAMAGES. EXCEPT FOR (I) OBLIGATIONS TO MAKE PAYMENT UNDER THIS AGREEMENT, (II) WITH RESPECT TO A BREACH OF **ARTICLE 13** (CONFIDENTIALITY), (III) WITH RESPECT TO A BREACH OF **ARTICLE 12** (INTELLECTUAL PROPERTY RIGHTS), AND (IV) GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, IN NO EVENT SHALL EITHER PARTY'S AGGREGATE LIABILITY ARISING OUT OF OR RELATED TO THIS AGREEMENT, WHETHER ARISING OUT OF OR RELATED TO BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EXCEED [***] ($[***]) USD.

12. Intellectual Property Rights.

12.1 License. Customer hereby grants to Manufacturer, for the Term of this Agreement, an irrevocable royalty-free, non-assignable, non-exclusive, non-transferable, non-sublicensable right and license under any Customer Intellectual Property Rights (including, but not limited to, Customer's Background Intellectual Property Right and Customer New IP) that would necessarily be infringed by such Manufacturer's manufacture and supply of the applicable Product under the terms set forth in this Agreement, solely to manufacture and supply such Product for Customer under the terms set forth under this Agreement. Manufacturer hereby

grants to Customer an irrevocable, royalty-free, non-assignable except pursuant to Section 16.12, non-exclusive, non-transferable except pursuant to Section 16.12, sublicensable (subject to Manufacturer's prior written approval) right and license under any Manufacturer Intellectual Property Right necessary for Customer or its Affiliates or Regulatory Authorities to access or utilize the Product, including to develop, manufacture and commercialize finished products incorporating, comprising or otherwise exploiting the Product subject to and conditioned upon the terms and conditions of this Agreement.

12.2 Ownership.

(a) Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party.

(b) Manufacturer acknowledges that, as between the Parties, all right, title and interest in and to all Customer's Background Intellectual Property Right and embodiments thereof or any Customer Intellectual Property Rights developed or acquired by Customer after the Effective Date, including any of the rights licensed pursuant to this Section 12.2, are and shall remain Customer Intellectual Property Rights owned by Customer, its Affiliates or by its or their respective third-party licensors. Customer hereby reserves all rights in and to any and all Customer Intellectual Property Rights except to the extent expressly licensed to Manufacturer pursuant to Section 12.1. All goodwill arising from Manufacturer's exercise of the license to Customer's Trademarks set forth in Section 12 shall inure to the benefit of Customer;

(c) Customer acknowledges that, as between the Parties, all right, title and interest in and to all Manufacturer's Background Intellectual Property Right and embodiments thereof or any and all inventions, improvements, and/or Intellectual Property Rights developed, conceived, reduced to practice, made or acquired by Manufacturer or any of its Affiliates, employees or agents (whether solely or jointly or jointly with others) in the course of performance under this Agreement, which relate generally to manufacturing processes and which do not incorporate or rely on any Confidential Information of Customer or Customer Materials (for clarity purposes, excluding Customer New IP) are and shall remain Manufacturer's Intellectual Property Rights owned by Manufacturer, its Affiliates or by its or their respective third-party licensors. To the extent that Customer retains any interest in such Manufacturer's Intellectual Property Right, and subject to the license grant set forth in Section 12.1, Customer hereby assigns to Manufacturer all of Customer's right, title and interest in or to such Manufacturer's Intellectual Property Right.

(d) Subject to **Section 12.2(c)**, Customer shall exclusively own all right, title, and interest in and to any and all inventions, improvements, and/or Intellectual Property Rights that Customer or Manufacturer or any of its Affiliates, employees or agents (whether solely or jointly or jointly with others) develops, conceives, invents, first reduces to practice or otherwise makes in the course of performance under this Agreement, including any that relate to the Product or to any portion of Customer's pipeline of pharmaceutical products, but excluding any Manufacturer's Intellectual Property Rights (collectively, "**Customer New IP**"). Manufacturer shall, and hereby does assign to Customer all of Manufacturer's right, title and interest in and to such Customer New IP without additional compensation to Manufacturer. Manufacturer shall

promptly disclose to Customer in writing all Customer New IP. Manufacturer shall execute, and shall require its Personnel as well as its Affiliates, or other contractors or agents and their Personnel involved in the performance of this Agreement to execute, any documents reasonably required to confirm Customer's ownership of Customer New IP, and any documents required to apply for, maintain and enforce any Patent or other right in the Customer New IP. Manufacturer agrees that such Customer New IP is commercially valuable to Customer and Manufacturer agrees not to disclose such Customer New IP to any third party without Customer's prior written consent.

12.3 Further Assurances. Manufacturer agrees to take all necessary and proper acts, and will cause its employees, Affiliates, contractors, and consultants to take such necessary and proper acts, to effectuate the ownership provisions set forth in this **Section 12**.

13. Confidentiality.

13.1 Scope of Confidential Information. From time to time during the Term, either Party or any of its Affiliates or representatives (as the "**Disclosing Party**") may disclose or make available to the other Party or any of its Affiliates or representatives (as the "**Receiving Party**") information and data, about its business affairs, goods and services, Forecasts, confidential information and materials comprising or relating to Intellectual Property Rights, Trade Secrets, third party confidential information and other sensitive or proprietary information, the Customer Materials, as well as the terms and provisions of this Agreement, whether orally or in written, electronic or other forms including all notes, books, papers, diagrams, documents, reports, e-mail, memoranda, visual observations and all other data or information in whatever form, and whether or not marked, designated or otherwise identified as "confidential", including those made prior to the Effective Date of this Agreement. (collectively, "**Confidential Information**"). Confidential Information does not include information that, to the extent the Receiving Party can demonstrate by competent evidence that such information, at the time of disclosure:

(a) is (at the time of disclosure by the Disclosing Party) or becomes (after the time of such disclosure by the Disclosing Party) generally available to and known by the public other than as a result of, directly or indirectly, any breach of this **Section 13** by the Receiving Party or any of its Representatives, or any Recipient to whom the Receiving Party disclosed such information, of its confidentiality obligations to the Receiving Party;

(b) is or becomes available to the Receiving Party on a non-confidential basis from a third party source, provided that such third party is not and was not, to the actual knowledge of the Receiving Party, prohibited from disclosing such Confidential Information without breaching any confidentiality obligation to the Disclosing Party;

(c) was known by or in the possession of the Receiving Party or its Representatives prior to being disclosed by or on behalf of the Disclosing Party, as evidenced by its written records;

(d) was or is independently developed by or on behalf of the Receiving Party or any of its Affiliates, as evidenced by its written records, without reference to or use of, in whole or in part, any of the Disclosing Party's Confidential Information;

(e) is submitted by the Receiving Party to a Governmental Authority to facilitate the issuance or maintenance of marketing approvals for any Product, provided that reasonable measures shall have been taken to ensure confidential treatment of such Confidential Information;

(f) is of Manufacturer's that is provided to third parties by Customer under appropriate terms and conditions, including confidentiality provisions substantially equivalent to those contained in this Section 13, for consulting, clinical and marketing purposes; or

(g) is required to be disclosed pursuant to Applicable Law or an order of a Governmental Authority; provided that the Receiving Party: (i) provides the Disclosing Party with prompt written notice of such disclosure requirement if legally permitted, (ii) affords the Disclosing Party an opportunity, and cooperates with the Disclosing Party's efforts, to oppose or limit, or secure confidential treatment for such required disclosure (at the Disclosing Party's expense) by at least providing the Disclosing Party with a copy of the proposed disclosure in sufficient time to allow reasonable opportunity to comment thereon, and (iii) if the Disclosing Party is unsuccessful in its efforts pursuant to subsection (ii), discloses only that portion of the Confidential Information that the Receiving Party is legally required to disclose as advised by the Receiving Party's legal counsel.

13.2 Protection of Confidential Information. The Receiving Party shall:

(a) protect and safeguard the confidentiality of the Disclosing Party's Confidential Information against unauthorized use and disclosure to third parties 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;

(b) not use the Disclosing Party's Confidential Information, or permit it to be accessed or used, for any purpose other than to exercise its rights or perform its obligations under this Agreement; and

(c) not disclose any such Confidential Information to any Person, except to the Receiving Party's Representatives, Affiliates, and their respective directors, officers, employees, subcontractors, sublicensees, consultants, and attorneys, accountants, banks and investors (collectively, "**Recipients**") who need to know the Confidential Information to assist the Receiving Party, or act on its behalf, to exercise its rights or perform its obligations under this Agreement and who are bound by the confidentiality obligations set forth in this Agreement or are bound in writing by obligations of confidentiality at least as protective of such Confidential Information as those set forth in this Agreement.

The Receiving Party shall be responsible for any breach of this **Section 13** caused by any of its Recipients. Except as expressly set forth under this Agreement, the Receiving Party shall immediately advise the Disclosing Party of any disclosure, loss, or use of Confidential Information of the Disclosing Party in violation of this Agreement.[3]

13.3 Protection of Nondisclosure of Terms. Each Party agrees not to issue any press releases, reports, or other statements in connection with this Agreement intended for use in the public or private media or otherwise disclose the terms of this Agreement to any third party

without the prior written consent of the other Party hereto, which consent shall not be unreasonably withheld, except to such Party's attorneys, advisors and others on a need to know basis in each case consistent with customary practice under circumstances that protect the confidentiality thereof. Notwithstanding the foregoing, each Party may make announcements concerning the subject matter of this Agreement if required by Applicable Law or any securities exchange or Governmental Authority or any tax authority to which any Party is subject or submits, in which case the Party making such announcement shall provide the other Party with a copy of such announcement at least [***] ([***]) Business Days prior to issuance, to the extent practicable under the circumstances, and shall only disclose information required by Applicable Law or such exchange or authority. Additionally, and notwithstanding anything to the contrary contained herein, Customer may disclose this Agreement as required by and/or in order to comply with the requirements of the US Securities and Exchange Commission or any other agency governing publicly traded companies, including in connection with Customer's public filings; and Manufacturer's Affiliates may disclose this Agreement as required by and/or in order to comply with the requirements of the Taiwan Stock Exchange and/or Taipei Exchange or any other agency governing publicly traded companies, including in connection with the public filings or public announcement of Manufacturer's Affiliates.

13.4 Effect of Termination. Upon the Disclosing Party's request and upon any termination or expiration of this Agreement, the Receiving Party will promptly return to the Disclosing Party or, if so directed by the Disclosing Party, destroy all tangible embodiments of the Disclosing Party Confidential Information (in every form and medium). Notwithstanding the foregoing and subject to a continuing obligation of confidentiality as provided herein, (a) the Receiving Party may retain a single copy of Confidential Information in the files of its legal counsel for the sole purpose of proving what was disclosed, (b) the Receiving Party is not required to return or destroy any Confidential Information if doing so would violate (or result in the violation of) any Law, (a) the Receiving Party shall not be required to expunge any minutes or written consents of its board of directors (or equivalent governance body), and (d) to the extent that the Receiving Party's computer back-up or archiving procedures create copies of Confidential Information, the Receiving Party may retain such copies for the period it normally archives backed-up computer records, so long as such copies are not readily accessible and are not used or consulted for any purpose other than disaster recovery. Confidential Information disclosed by the Disclosing Party under this Agreement shall, in all respects, remain the sole property of the Disclosing Party and nothing contained herein shall be construed as granting or conferring to the Receiving Party any license, interest, ownership rights or Intellectual Property Rights in such Confidential Information.

13.5 Right to Injunctive Relief. Each Party agrees that breaches of this **Article 13** may cause irreparable harm to the other Party and shall entitle such other Party, in addition to any other remedies available to it (subject to the terms of this Agreement), to the right to seek temporary, preliminary and permanent injunctive relief, without the posting of any bond or other security, enjoining such action, and/or specific performance to enforce the terms, or prevent or remedy the violation of this **Section 13**. This provision shall not constitute a waiver by any party of any rights to damages or other remedies which it may have pursuant to this Agreement.

13.6 Ongoing Obligation for Confidentiality. The Parties' obligations of confidentiality, non-use and non-disclosure under this **Section 13** shall survive any expiration or termination of this Agreement for [***].

14. Tooling. All Tooling used to manufacture the Products is owned by Manufacturer ("**Manufacturer Tooling**"). Customer has no right, title, or interest in or to any of the Manufacturer Tooling. Notwithstanding the foregoing, Customer will cover the cost of any other Purchase Order specific equipment, such as Tooling, machinery and or change parts required for the product. Customer retains all right, title and interest in and to the Purchase Order specific equipment, which shall be returned to Customer upon termination or expiration of this Agreement.

15. Insurance. During the Term, each Party shall, at its own expense, maintain or shall cause its Affiliates conducting activities under this Agreement to maintain, and carry in full force and effect comprehensive general liability and umbrella in amounts reasonably sufficient to meet such party's indemnification obligations under this Agreement, of which the combined aggregate limit of general liability and umbrella per year shall in not event be less than [***] US Dollars ($[***] USD) and no less than [***] US Dollars ($[***] USD) per occurrence, and upon the other Party's reasonable request, at the execution of this Agreement, shall provide the other Party with a certificate of insurance evidencing the insurance coverage specified in this Section. The certificate of insurance shall name the other Party as an additional insured. Each Party shall use its reasonable commercial efforts to cause its insurer of such policy to provide the other Party with [***] ([***]) days' advance written notice in the event of a cancellation, non-renewal, or material change in such insurance policy.[4]

16. Miscellaneous.

16.1 Further Assurances. Upon a Party's reasonable request, the other Party shall, at its sole cost and expense, execute and deliver all such further documents and instruments, and take all such further acts, necessary to give full effect to this Agreement.

16.2 Relationship of the Parties. The relationship between Manufacturer and Customer is solely that of vendor and vendee, and are independent contracting parties. Nothing in this Agreement creates any agency, joint venture, partnership or other form of joint enterprise, employment or fiduciary relationship between the Parties. Neither Party has any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any third party.

16.3 Entire Agreement. This Agreement, including and together with the Basic Purchase Order Terms and any related exhibits and schedules, constitutes the sole and entire agreement of the Parties with respect to the subject matter contained herein and therein, and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to such subject matter.

16.4 Notices. Each Party shall deliver all notices, requests, consents, claims, demands, waivers and other communications under this Agreement (each, a "**Notice**") in writing and

addressed to the other Party at its address set forth below (or to such other address that the receiving Party may designate from time to time in accordance with this section). Each Party shall deliver all Notices by personal delivery, nationally recognized overnight courier or certified or registered mail (in each case, return receipt requested, postage prepaid) or notice by facsimile or e-mail (with confirmation of transmission) and such Notice will satisfy the requirements of this **Section 16.4**. Except as otherwise provided in this Agreement, a Notice is effective only (a) on receipt by the receiving Party, and (b) if the Party giving the Notice has complied with the requirements of this Section.

Notice to Manufacturer:	7333 Mississauga Road Mississauga, ON ONL5N 6L4 Canada E-mail: [***] Website: [***] ATTN: [***] Pharmaceutical Services
With a copy to:	Bora Pharmaceuticals Co. Ltd. 6F., No. 2, Aly. 36, Ln. 26, Ruiguang Rd., Neihu District, Taipei City, 114, Taiwan Email: [***] ATTN: [***]
Notice to Customer:	Arcutis Biotherapeutics, Inc. 3027 Townsgate Rd, Suite 300 Westlake Village, CA 91361 Email: [***] ATTN: [***]
With a copy to:	Arcutis Biotherapeutics, Inc. 3027 Townsgate Rd, Suite 300 Westlake Village, CA 91361 Email: [***] ATTN: [***]

16.5 Interpretation. For purposes of this Agreement: (a) the words “include,” “includes” and “including” is deemed to be followed by the words “without limitation”; (B) the word “or” is not exclusive; (c) the words “herein,” “hereof,” “hereby,” “hereto” and “hereunder” refer to this Agreement as a whole; (d) words denoting the singular have a comparable meaning

when used in the plural, and vice-versa; and (e) words denoting any gender include all genders. Unless the context otherwise requires, references in this Agreement: (x) to sections, exhibits, schedules, attachments and appendices mean the sections of, and exhibits, schedules, attachments and appendices attached to, this Agreement; (y) to an agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof; and (z) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. The Parties drafted this Agreement without regard to any presumption or rule requiring construction or interpretation against the Party drafting an instrument or causing any instrument to be drafted. The exhibits, schedules, attachments and appendices referred to herein are an integral part of this Agreement to the same extent as if they were set forth verbatim herein.

16.6 Headings. The headings in this Agreement are for reference only and do not affect the interpretation of this Agreement.

16.7 Severability. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability does not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon a determination that any term or provision is invalid, illegal or unenforceable, the Parties shall negotiate in good faith to modify this Agreement to effect the original intent of the Parties as closely as possible in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

16.8 Amendment and Modification. No amendment to this Agreement is effective unless it is in writing, identified as an amendment to this Agreement and signed by an authorized Representative of each Party.

16.9 Waiver.

(a) No waiver under this Agreement is effective unless it is in writing and signed by an authorized representative of the Party waiving its right.

(b) Any waiver authorized on one occasion is effective only in that instance and only for the purpose stated, and does not operate as a waiver on any future occasion.

(c) None of the following constitutes a waiver or estoppel of any right, remedy, power, privilege or condition arising from this Agreement:

(i) any failure or delay in exercising any right, remedy, power or privilege or in enforcing any condition under this Agreement; or

(ii) any act, omission or course of dealing between the Parties.

16.10 Cumulative Remedies. All rights and remedies provided in this Agreement are cumulative and not exclusive, and the exercise by either Party of any right or remedy does not preclude the exercise of any other rights or remedies that may now or subsequently be available at law, in equity, by statute, in any other agreement between the Parties or otherwise. Notwithstanding the previous sentence, the Parties intend that Customer's rights under **Section**

4.3, **Section 4.5**, **Section 9.4** and each of the Parties' rights under **Section** 10 are such Party's exclusive remedies for the events specified therein.

16.11 Equitable Remedies. Each Party acknowledges and agrees that (a) a breach or threatened breach by such Party of any of its obligations under **Section 13** would give rise to irreparable harm to the other Party for which monetary damages would not be an adequate remedy and (b) in the event of a breach or a threatened breach by such Party of any such obligations, the other Party shall, in addition to any and all other rights and remedies that may be available to such Party at law, at equity or otherwise in respect of such breach, be entitled to equitable relief, including a temporary restraining order, an injunction, specific performance and any other relief that may be available from a court of competent jurisdiction, without any requirement to post a bond or other security, and without any requirement to prove actual damages or that monetary damages will not afford an adequate remedy. Each Party agrees that such Party will not oppose or otherwise challenge the appropriateness of equitable relief or the entry by a court of competent jurisdiction of an order granting equitable relief, in either case, consistent with the terms of this **Section 16.11**.

16.12 Assignment. Neither Party can assign this Agreement, except to Affiliates or any entity acquiring all or substantially all of its business to which this Agreement relates, without the prior written consent of the other Party, which shall not be unreasonably withheld. Any purported assignment or delegation in violation of this Section is null and void. No assignment or delegation relieves the assigning or delegating Party of any of its obligations under this Agreement. Manufacturer may not subcontract any of services to be performed pursuant to this Agreement or any Purchase Order without prior written consent of Customer.

16.13 Successors and Assigns. This Agreement is binding on and inures to the benefit of the Parties and their respective permitted successors and permitted assigns.

16.14 No Third Party Beneficiaries. This Agreement benefits solely the parties to this Agreement and their respective permitted successors and permitted assigns and nothing in this Agreement, express or implied, confers on any other Person any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

16.15 Cyber Security. Manufacturer shall implement, maintain, and comply with comprehensive information and network security programs, practices, and procedures (collectively, "**Data Security Program**") to safeguard any all information in its possession, custody or control that is: (i) related to the manufacturing or packaging the Products; (ii) related to the Products; (iii) Customer's Confidential Information; and/or (iv) subject to any applicable data protection laws (collectively, "**Protected Data**"). Manufacturer shall ensure that the Data Security Program: (i) meets current industry standards; and (ii) complies with all applicable data protection laws. Manufacturer shall document its Data Security Program in written form and shall make appropriate documentation of its Data Security Program available to Customer for review upon Customer's request, upon no less than [***] ([***]) business days' advanced written notice. Manufacturer shall provide to Customer upon request any current audit reports (if any). Manufacturer shall keep its Data Security Program current and up-to-date to improve the security of the Data Security Program, but in no event render the Data Security Program less

comprehensive, secure, or robust. Manufacturer shall notify Customer of any accidental or unlawful destruction, loss, alteration, unauthorized disclosure of or access to Protected Data ("**Breach**") within [***] ([***]) hours of becoming aware of such Breach. Manufacturer shall provide Customer with the name and contact information for an employee of Manufacturer who shall serve as Customer's primary security contact and shall be available to assist Customer twenty-four (24) hours per day, seven (7) days per week as a contact in resolving obligations associated with any Breach. Manufacturer shall make available to Customer all information necessary to demonstrate compliance with its obligations set forth in this Section 16.15 and allow for and contribute to audits, including remote inspections, conducted by Customer or another auditor mandated by Customer. If Manufacturer subcontracts to a third party any services to be performed pursuant to this Agreement or any Purchase Order, Manufacturer shall (i) disclose to such third party only the minimum Protected Data required to provide the services; and (ii) require such third party to execute a written agreement to adhere to obligations no less restrictive than those imposed on Manufacturer in this Section 16.15. Manufacturer acknowledges that it shall remain fully liable to Customer for the performance of such third party's obligations under this Section 16.15.

16.16 Health, Safety, and Environment.

(a) Health, Safety, Hazard, and Security Rules. Manufacturer shall ensure that it and its employees are aware of and comply with appropriate health, safety and security rules at the Manufacturer's site and any relevant Customer site. Manufacturer shall ensure that procedures are in place to assess and manage hazards in the workplace.

(b) Incident Reporting. Manufacturer shall immediately, as soon as it becomes aware, report to Customer in writing any of the following types of incident at the Manufacturer's site where services are being performed under this Agreement:

(i) fatal workplace incidents or other serious occupational health and safety incidents or cases that cause bodily harm;

(ii) fire, flood, explosion, environmental incident or any similar serious event that compromises the facility; or

(iii) an event or occurrence which is reasonably likely to affect the provision of the Product or the performance of this Agreement

(c) Environmental Data. Manufacturer shall provide to Customer good quality environmental footprint data reasonably available to Manufacturer.

(d) Improvement Plan. If Manufacturer fails to meet or maintain the standards required by this section 16.16, Customer may request that the Parties agree on an improvement plan containing measures to be taken by Manufacturer to improve performance.

16.17 Dispute Resolution. Any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity hereof (each, a "**Dispute**"), shall be submitted for negotiation and resolution to the President of Manufacturer (or to such other person of equivalent or superior position designated by Manufacturer in a written Notice to

Customer) and the officer signing this Agreement on behalf of Customer (or to such other person of equivalent or superior position designated by Customer in a written Notice to Manufacturer), by delivery of written Notice (each, a "**Dispute Notice**") from either of the Parties to the other Party. Such persons shall negotiate in good faith to resolve the Dispute. If the Parties are unable to resolve any Dispute within [***] ([***]) days after delivery of the applicable Dispute Notice, either Party may file suit in a court of competent jurisdiction in accordance with the provisions of **Section 16.18** and **Section 16.19** hereunder.

16.18 Choice of Law. This Agreement, including all exhibits, schedules, attachments and appendices attached hereto and thereto, and all matters arising out of or relating to this Agreement, are governed by, and construed in accordance with, the Laws of the State of Delaware, US, without regard to the conflict of laws provisions thereof to the extent such principles or rules would require or permit the application of the Laws of any jurisdiction other than those of the State of Delaware. The Parties agree that the United Nations Convention on Contracts for the International Sale of Products does not apply to this Agreement.

16.19 Choice of Forum. Each Party irrevocably and unconditionally agrees that it shall not commence any action, litigation or proceeding of any kind whatsoever against the other Party in any way arising from or relating to this Agreement, including all exhibits, schedules, attachments and appendices attached hereto and thereto, and all contemplated transactions, including contract, equity, tort, fraud and statutory claims, in any forum other than the state and federal courts in Delaware, US. Each Party irrevocably and unconditionally submits to the exclusive jurisdiction of such courts and agrees to bring any such action, litigation or proceeding only in the state and federal courts in Delaware, US. Each Party agrees that a final judgment in any such action, litigation or proceeding is conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Law.

16.20 Waiver of Jury Trial. Each Party acknowledges and agrees that any controversy that may arise under this Agreement, including any exhibits, schedules, attachments and appendices attached to this Agreement, is likely to involve complicated and difficult issues and, therefore, each such Party irrevocably and unconditionally waives any right it may have to a trial by jury in respect of any legal action arising out of or relating to this Agreement, including any exhibits, schedules, attachments and appendices attached to this Agreement, or the transactions contemplated hereby. Each Party certifies and acknowledges that (a) no Representative of the other Party has represented, expressly or otherwise, that such other Party would not seek to enforce the foregoing waiver in the event of a legal action, (b) such Party has considered the implications of this waiver, (c) such Party makes this waiver voluntarily, and (d) such Party has been induced to enter into this Agreement by, among other things, the mutual waivers and certifications in this Section.

16.21 Counterparts. This Agreement may be executed in counterparts, each of which is deemed an original, but all of which together is deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, e-mail or other means of electronic transmission is deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

16.22 Force Majeure. Manufacturer shall not be liable or responsible to Customer, nor be deemed to have defaulted under or breached this Agreement, for any failure or delay in fulfilling or performing any term of this Agreement, if such failure or delay is caused by or results from acts beyond Manufacturer's control, including: (a) acts of nature; (b) flood, fire, earthquake or explosion; (c) war, invasion, hostilities (whether war is declared or not), terrorist threats or acts, riot or other civil unrest; (d) requirements of Law; (e) actions, embargoes or blockades in effect on or after the date of this Agreement; (f) action by any Governmental Authority (whether or not having the effect of Law); (g) national or regional emergency; (h) strikes, labor stoppages or slowdowns or other industrial disturbances; (i) outbreak of pandemic; (i) shortages of or delays in receiving Manufacturer's Materials; or (j) shortage of adequate power or transportation facilities (each, a "**Force Majeure Event**").

16.23 No Public Announcements or Trademark Use. Unless expressly permitted under this Agreement, neither Party shall either:

(a) make any statement (whether oral or in writing) in any press release, external advertising, marketing or promotion materials regarding the subject matter of this Agreement, the other Party or its business unless:

(i) it has received the express written consent of the other party, or

(ii) it is required to do so by Law.

(b) use the other Party's Trademarks, service marks, trade names, logos, symbols or brand names, in each case, without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed.

[SIGNATURE PAGE TO IMMEDIATELY FOLLOW]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first set forth above.

Bora Pharmaceuticals Services Inc.

By: /s/ Bobby Sheng

Name: Bobby Sheng
Title: CEO

Arcutis Biotherapeutics, Inc.

By: /s/ Frank Watanabe

Name: Frank Watanabe
Title: President & CEO

Schedule 1

API

[***]

Schedule 2

PRODUCT & SPECIFICATIONS

[***]

Schedule 3

FEES

[***]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

AMENDMENT 1

to the

MANUFACTURING SUPPLY AGREEMENT

This Amendment (this "**Amendment**") is entered into as of March 22, 2024 ("**Amendment Effective Date**") between Arcutis Biotherapeutics, Inc. ("**Arcutis**"), and Bora Pharmaceuticals Services Inc. ("**Bora**"). Arcutis and Bora are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, Arcutis and Bora have previously entered into a Manufacturing Supply Agreement with the execution date of November 8, 2023 (the "**Agreement**"); and

WHEREAS, Arcutis and Bora mutually desire to amend the terms and conditions of the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants herein contained, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), and intending to be legally bound, the Parties agree as follows:

1. **Definitions**: Capitalized terms used in this Amendment and not otherwise defined herein shall have the meaning as defined in the Agreement.

2. **Amendments to Schedule 3**: Schedule 3 of the Agreement is repealed and replaced in its entirety with the Attachment 1 of this Amendment.

3. **Continuation of Agreement**: Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Agreement shall remain in full force and effect. To the extent that there is any conflict or inconsistency between the terms of this Amendment and the Agreement, the terms of this Amendment shall supersede and prevail.

4. **Governing Law**: This Amendment shall be binding on the Parties and their respective successors and assigns. This Amendment shall be interpreted, construed and enforced in accordance with the laws of the State of Delaware, USA, without application of any law, rule or judicial precedent thereof that would require application of the laws of any other jurisdiction.

5. **Entire Amendment**: The Agreement (as amended by this Amendment) constitutes the entire agreement of the Parties hereto with respect to the subject matter, and supersedes all prior agreements and understandings, whether written or oral, with respect to the subject matter. This Amendment cannot be amended or modified except in writing, duly executed by all of the Parties.

6. **Execution in Counterparts**: This Amendment may be executed in counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same instrument. A counterpart executed by any Party may be delivered to the other Parties by facsimile or scanned email attachment and such delivery shall have the full force and effect of an original signature.

[Signature page follows]

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

Bora Pharmaceuticals Services Inc.

By: /s/ Bobby Sheng

Name: Bobby Sheng
Title: CEO

Arcutis Biotherapeutics, Inc.

By: /s/ Gregory Sukay

Name: Gregory Sukay
Title: Vice President, Manufacturing & Process Technologies

ATTACHMENT 1

SCHEDULE 3
FEES

[***]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

AMENDMENT 2

to the

MANUFACTURING SUPPLY AGREEMENT

This Amendment (this "**Amendment**") is entered into as of May 14, 2025 ("**Amendment Effective Date**") between Arcutis Biotherapeutics, Inc. ("**Arcutis**"), and Bora Pharmaceuticals Services Inc. ("**Bora**"). Arcutis and Bora are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, Arcutis and Bora have previously entered into a Manufacturing Supply Agreement with the execution date of November 8, 2023 (the "**Agreement**"); and

WHEREAS, Arcutis and Bora mutually desire to amend the terms and conditions of the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants herein contained, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), and intending to be legally bound, the Parties agree as follows:

1. **Definitions**: Capitalized terms used in this Amendment and not otherwise defined herein shall have the meaning as defined in the Agreement.

2. **Amendments to Schedule 3**: Schedule 3 of the Agreement is repealed and replaced in its entirety with the Attachment 1 of this Amendment.

3. **Continuation of Agreement**: Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Agreement shall remain in full force and effect. To the extent that there is any conflict or inconsistency between the terms of this Amendment and the Agreement, the terms of this Amendment shall supersede and prevail.

4. **Governing Law**: This Amendment shall be binding on the Parties and their respective successors and assigns. This Amendment shall be interpreted, construed and enforced in accordance with the laws of the State of Delaware, USA, without application of any law, rule or judicial precedent thereof that would require application of the laws of any other jurisdiction.

5. **Entire Amendment**: The Agreement (as amended by this Amendment) constitutes the entire agreement of the Parties hereto with respect to the subject matter, and supersedes all prior agreements and understandings, whether written or oral, with respect to the subject matter. This Amendment cannot be amended or modified except in writing, duly executed by all of the Parties.

6. **Execution in Counterparts**: This Amendment may be executed in counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same instrument. A counterpart executed by any Party may be delivered to the other Parties by facsimile or scanned email attachment and such delivery shall have the full force and effect of an original signature.

[Signature page follows]

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

Bora Pharmaceuticals Services Inc.

By: /s/ Jeffrey Mowery

Name: Jeffrey Mowery
Title: Division President

Arcutis Biotherapeutics, Inc.

By: /s/ Gregory Sukay

Name: Gregory Sukay
Title: Vice President, Manufacturing & Process Technologies

ATTACHMENT 1

SCHEDULE 3
FEES

[***]

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: August 6, 2025

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, Latha Vairavan, 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: August 6, 2025

By: /s/ Latha Vairavan

Latha Vairavan
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 June 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Todd Franklin Watanabe, Chief Executive Officer of the Company, and Latha Vairavan, 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: August 6, 2025 By: /s/ Todd Franklin Watanabe

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

Date: August 6, 2025 By: /s/ Latha Vairavan

Latha Vairavan
Chief Financial Officer
(Principal Accounting and Financial Officer)