

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

OR

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

For transition period from to
Commission File Number: 001-39186

ARCUTIS BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)
3027 Townsgate Road Suite 300
Westlake Village, California
(Address of Principal Executive Offices)

81-2974255
(I.R.S. Employer Identification Number)
91361
(Zip Code)

(805) 418-5006
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

The number of shares of the registrant's Common Stock outstanding as of November 1, 2024 was 117,044,591.

FORWARD-LOOKING STATEMENTS

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

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. Forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed in Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2024. The forward-looking statements in this Quarterly Report on Form 10-Q are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and par value)

	September 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 134,851	\$ 88,398
Restricted cash	617	925
Marketable securities	195,710	183,463
Trade receivables, net	60,119	25,807
Inventories	14,015	13,134
Prepaid expenses and other current assets	18,408	18,704
Total current assets	423,720	330,431
Property, plant, and equipment, net	1,186	1,539
Intangible assets, net	9,792	6,438
Operating lease right-of-use asset	2,060	2,361
Other assets	596	596
Total assets	<u>\$ 437,354</u>	<u>\$ 341,365</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 19,325	\$ 11,992
Accrued liabilities	52,790	33,941
Current portion of long-term debt, net	99,513	—
Operating lease liability	798	735
Total current liabilities	172,426	46,668
Operating lease liability, noncurrent	2,772	3,382
Long-term debt, net	105,095	201,799
Other long-term liabilities	420	849
Total liabilities	280,713	252,698
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized; 116,998,829 and 96,787,343 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	12	9
Additional paid-in capital	1,267,251	1,070,558
Accumulated other comprehensive income	533	4
Accumulated deficit	(1,111,155)	(981,904)
Total stockholders' equity	156,641	88,667
Total liabilities and stockholders' equity	<u>\$ 437,354</u>	<u>\$ 341,365</u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	\$ 44,755	\$ 8,109	\$ 97,182	\$ 15,660
Other revenue	—	30,000	28,000	30,420
Total revenues	<u>44,755</u>	<u>38,109</u>	<u>125,182</u>	<u>46,080</u>
Operating expenses:				
Cost of sales	5,503	1,182	12,223	2,741
Research and development	19,501	26,236	61,940	86,800
Selling, general, and administrative	58,817	47,595	171,784	136,471
Total operating expenses	<u>83,821</u>	<u>75,013</u>	<u>245,947</u>	<u>226,012</u>
Loss from operations	(39,066)	(36,904)	(120,765)	(179,932)
Other income (expense):				
Other income, net	4,182	2,721	13,455	9,114
Interest expense	(6,653)	(7,559)	(21,617)	(21,950)
Loss before income taxes	(41,537)	(41,742)	(128,927)	(192,768)
Provision for income taxes	—	3,023	324	3,088
Net loss	<u>\$ (41,537)</u>	<u>\$ (44,765)</u>	<u>\$ (129,251)</u>	<u>\$ (195,856)</u>
Other comprehensive income (loss):				
Unrealized gain on marketable securities	771	165	528	1,017
Foreign currency translation adjustment	56	(57)	1	(115)
Total other comprehensive income	<u>827</u>	<u>108</u>	<u>529</u>	<u>902</u>
Comprehensive loss	<u>\$ (40,710)</u>	<u>\$ (44,657)</u>	<u>\$ (128,722)</u>	<u>\$ (194,954)</u>
Per share information:				
Net loss per share, basic and diluted	<u>\$ (0.33)</u>	<u>\$ (0.73)</u>	<u>\$ (1.08)</u>	<u>\$ (3.19)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>124,302,317</u>	<u>61,727,278</u>	<u>119,627,687</u>	<u>61,462,025</u>

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2023	96,787,349	\$ 9	\$ 1,070,558	\$ 4	\$ (981,904)	\$ 88,667
Issuance of shares of common stock net of discount and issuance costs of \$10,820	18,157,895	3	161,679	—	—	161,682
Issuance of common stock upon the exercise of stock options	21,863	—	82	—	—	82
Issuance of common stock upon the vesting of restricted stock units	538,330	—	—	—	—	—
Stock-based compensation expense	—	—	10,030	—	—	10,030
Unrealized loss on marketable securities	—	—	—	(116)	—	(116)
Foreign currency translation adjustment	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	(35,382)	(35,382)
Balance—March 31, 2024	115,505,437	12	1,242,349	(133)	(1,017,286)	224,942
Issuance of common stock upon the exercise of stock options	147,490	—	806	—	—	806
Issuance of common stock upon the vesting of restricted stock units	443,365	—	—	—	—	—
Shares issued pursuant to the employee stock purchase plan	383,975	—	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	116,480,267	12	1,256,327	(294)	(1,069,618)	186,427
Issuance of common stock upon the exercise of stock options	138,566	—	394	—	—	394
Issuance of common stock upon the vesting of restricted stock units	379,996	—	—	—	—	—
Stock-based compensation expense	—	—	10,530	—	—	10,530
Unrealized gain on marketable securities	—	—	—	771	—	771
Foreign currency translation adjustment	—	—	—	56	—	56
Net loss	—	—	—	—	(41,537)	(41,537)
Balance—September 30, 2024	116,998,829	\$ 12	\$ 1,267,251	\$ 533	\$ (1,111,155)	\$ 156,641

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2022	61,037,403	\$ 6	\$ 930,425	\$ (1,086)	\$ (719,764)	\$ 209,581
Issuance of common stock upon the exercise of stock options	31,497	—	100	—	—	100
Issuance of common stock upon the vesting of restricted stock units	285,314	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	3,718	—	—	—	—	—
Stock-based compensation expense	—	—	9,479	—	—	9,479
Unrealized loss on marketable securities	—	—	—	724	—	724
Foreign currency translation adjustment	—	—	—	(52)	—	(52)
Net loss	—	—	—	—	(80,100)	(80,100)
Balance—March 31, 2023	61,357,932	6	940,004	(414)	(799,864)	139,732
Issuance of common stock upon the exercise of stock options	35,700	—	74	—	—	74
Issuance of common stock upon the vesting of restricted stock units	77,221	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	3,719	—	—	—	—	—
Shares issued pursuant to the employee stock purchase plan	155,446	—	993	—	—	993
Stock-based compensation expense	—	—	10,578	—	—	10,578
Unrealized gain on marketable securities	—	—	—	128	—	128
Foreign currency translation adjustment	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	(70,991)	(70,991)
Balance—June 30, 2023	61,630,018	6	951,649	(292)	(870,855)	80,508
Issuance of common stock upon the exercise of stock options	172,320	—	867	—	—	867
Issuance of common stock upon the vesting of restricted stock units	51,988	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	3,718	—	—	—	—	—
Stock-based compensation expense	—	—	9,999	—	—	9,999
Unrealized gain on marketable securities	—	—	—	165	—	165
Foreign currency translation adjustment	—	—	—	(57)	—	(57)
Net loss	—	—	—	—	(44,765)	(44,765)
Balance—September 30, 2023	61,858,044	\$ 6	\$ 962,515	\$ (184)	\$ (915,620)	\$ 46,717

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

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

	Nine Months Ended September 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (129,251)	\$ (195,856)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	495	573
Non-cash lease expense	301	266
Amortization of intangible assets	1,646	563
Net accretion on marketable securities	(5,805)	(5,517)
Non-cash interest expense	2,809	3,014
Stock-based compensation expense	32,337	30,056
Changes in fair value of embedded derivative instrument	(429)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(33,133)	(10,959)
Inventories	(135)	(6,399)
Prepaid expenses and other current assets	(882)	(10,087)
Accounts payable	2,334	4,345
Accrued liabilities	18,850	(323)
Operating lease liabilities	(547)	(489)
Net cash used in operating activities	(111,410)	(190,813)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(237,421)	(107,660)
Proceeds from maturities of marketable securities	231,507	350,500
Purchases of property and equipment	(143)	(422)
Net cash (used in) provided by investing activities	(6,057)	242,418
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon exercise of stock options	1,282	1,041
Proceeds from issuance of common stock pursuant to employee stock purchase plan	649	993
Proceeds from issuance of common stock, net of issuance costs	161,682	—
Net cash provided by financing activities	163,613	2,034
Effect of exchange rate changes on cash	(1)	(118)
Net increase in cash, cash equivalents, and restricted cash	46,145	53,521
Cash, cash equivalents, and restricted cash at beginning of period	89,323	54,875
Cash, cash equivalents, and restricted cash at end of period	\$ 135,468	\$ 108,396
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Milestone for intangible asset not yet paid in cash	\$ 5,000	\$ —
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Interest expense paid in cash	\$ 19,253	\$ 18,862

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

ARCUTIS BIOTHERAPEUTICS, INC.**Notes to Condensed Consolidated Financial Statements****(unaudited)****1. Organization and Description of Business**

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

The Company received U.S. Food and Drug Administration ("FDA") approval of its first product, ZORYVE[®] (roflumilast) cream 0.3% ("ZORYVE cream 0.3%"), on July 29, 2022, for the treatment of plaque psoriasis, including intertriginous psoriasis, in individuals 12 years of age and older (subsequently approved down to 6 years old), and began U.S. commercialization in August 2022. The Company also received Health Canada approval of ZORYVE cream 0.3% in plaque psoriasis on April 28, 2023 and began Canadian commercialization in June 2023. The Company received FDA approval of ZORYVE[®] (roflumilast) topical foam 0.3% ("ZORYVE foam"), on December 15, 2023, for the treatment of seborrheic dermatitis in individuals 9 years of age and older, and began U.S. commercialization in late January 2024. The Company received FDA approval of ZORYVE[®] (roflumilast) cream 0.15%, ("ZORYVE cream 0.15%") on July 9, 2024, for the treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older, and began U.S. commercialization in late July 2024. The Company received Health Canada approval of ZORYVE foam in October 2024.

Initial Public Offering and Follow-On Financings

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

In addition to the sale of common stock, the offering completed in October 2023 consisted of prefunded warrants to purchase 7,500,000 shares of the Company's common stock at \$2.4999 per underlying share of common stock. The exercise price of the warrants is \$0.0001 per underlying share of common stock. The prefunded warrants are exercisable at any time on or after their original issuance, and were not exercised as of September 30, 2024.

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

At-the-Market ("ATM") Offerings

On May 6, 2021, the Company entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC ("Cowen"), under which the Company could from time to time offer and sell shares of its common stock having an aggregate offering price of up to \$100.0 million. Cowen acts 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 ATM program. In March 2022, the Company sold 882,353 shares under the ATM program 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 program 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 to 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 \$1,111.2 million and \$981.9 million as of September 30, 2024 and December 31, 2023, respectively. Management expects to continue to incur operating losses. The Company had cash, cash equivalents, restricted cash, and marketable securities of \$331.2 million and \$272.8 million as of September 30, 2024 and December 31, 2023, respectively. The Company had \$200.0 million outstanding under the Loan Agreement as of September 30, 2024. See Note 7. On October 8, 2024, the Company paid down \$100 million of the principal under Loan Agreement with cash. See Note 10.

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 needed 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

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

Use of Estimates

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

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated balance sheet as of September 30, 2024, the interim condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023, the condensed consolidated statements of changes in stockholders' equity as of September 30, 2024 and 2023, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2024 and 2023 are unaudited. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's audited annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair statement of the Company's financial information. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the three and nine month periods are also unaudited. The condensed consolidated results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2023 included herein was derived from the audited financial statements as of that date. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Therefore, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2023.

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

Restricted Cash

As of September 30, 2024 and December 31, 2023, the Company held \$0.6 million and \$0.9 million, respectively, of restricted cash as collateral for a letter of credit related to the Company's amended office space lease.

Concentration of Credit Risk and Other Risks and Uncertainties

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

Fair Value Measurement

The Company's financial instruments, in addition to those presented in Note 4, include cash equivalents, accounts receivable, accounts payable, accrued liabilities, and long-term debt. The carrying amount of 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.

Co-promotion Agreement

In July 2024, the Company entered into a co-promotion agreement with Kowa Pharmaceuticals America, Inc. ("Kowa") to leverage Kowa's primary care sales force to exclusively market and promote ZORYVE to primary care practitioners and pediatricians for all FDA-approved indications until July 2029. The Company recognizes all revenue and Kowa receives a commission for the net sales attributed to Kowa, which is reflected in selling, general and administrative expense. For the three and nine months ended September 30, 2024, revenue from sales attributed to Kowa were immaterial.

Recently Issued Accounting Pronouncements

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In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in Accounting Standards Codification ("ASC") 280 on an interim and annual basis. ASU 2023-07 will be adopted by the Company in the Form 10-K for the year ended December 31, 2024. The Company is currently evaluating the impact of adopting ASU 2023-07.

3. Revenue

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
ZORYVE cream 0.3%	\$ 22,041	\$ 8,109	\$ 54,325	\$ 15,660
ZORYVE foam	20,262	—	40,405	—
ZORYVE cream 0.15%	2,452	—	2,452	—
Total product revenue, net	44,755	8,109	97,182	15,660
Other revenue	—	30,000	28,000	30,420
Total revenues	\$ 44,755	\$ 38,109	\$ 125,182	\$ 46,080

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

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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):

	September 30, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds ⁽¹⁾	\$ 134,851	\$ —	\$ —	\$ 134,851
Certificates of deposit	—	4,995	—	4,995
Corporate debt securities	—	99,222	—	99,222
U.S. Treasury and agency securities	91,493	—	—	91,493
Total assets	<u>\$ 226,344</u>	<u>\$ 104,217</u>	<u>\$ —</u>	<u>\$ 330,561</u>

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

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

(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.

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.

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

	September 30, 2024			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds ⁽¹⁾	\$ 134,851	\$ —	\$ —	\$ 134,851
Total cash and cash equivalents	\$ 134,851	\$ —	\$ —	\$ 134,851
Marketable securities:				
Certificates of deposit	4,995	—	—	4,995
Corporate debt securities	98,981	241	—	99,222
U.S. Treasury and agency securities	91,106	388	(1)	91,493
Total marketable securities	\$ 195,082	\$ 629	\$ (1)	\$ 195,710

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

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

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

Realized gains or losses on investments for the three and nine months ended September 30, 2024 and 2023 were not material. As of September 30, 2024, it was determined that no credit losses exist, because the change in market value of those securities resulted from fluctuations in market interest rates since the time of purchase, rather than a deterioration of the credit worthiness of the issuers. As of September 30, 2024 and December 31, 2023, all securities have a maturity of 18 months or less and all securities with gross unrealized losses have been in a continuous loss position for less than one year. The Company generally holds its marketable securities until maturity and does not intend to sell, and is not required to sell, the investments that are in an unrealized loss position before the recovery of their amortized cost basis.

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The following table summarizes the change in the fair value of the embedded derivative instrument for the nine months ended September 30, 2024 (in thousands). There was no activity for the nine months ended September 30, 2023.

	September 30, 2024
Beginning balance	\$ 849
Gain from changes in fair value	(429)
Ending balance	\$ 420

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

5. Balance Sheet Components

Inventories

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

	September 30, 2024	December 31, 2023
Raw materials	\$ 4,089	\$ 9,951
Work in progress	1,782	486
Finished goods	8,144	2,697
Total inventories	\$ 14,015	\$ 13,134

Prepaid Expenses and Other Current Assets

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

	September 30, 2024	December 31, 2023
Prepaid co-pay assistance program and rebates	\$ 8,935	\$ 8,608
Prepaid insurance	739	864
Prepaid clinical trial costs	—	1,024
Other prepaid expenses and current assets	8,734	8,208
Total prepaid expenses and other current assets	\$ 18,408	\$ 18,704

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued sales deductions	\$ 30,029	\$ 11,578
Accrued compensation	15,636	14,872
Clinical trial accruals	292	4,192
Accrued expenses and other current liabilities	6,833	3,299
Total accrued liabilities	\$ 52,790	\$ 33,941

6. License, Collaboration and Co-Promotion 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, the Company grants to Sato an exclusive, sublicensable

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

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

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

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

Other revenue under the Sato agreement was zero and \$25.0 million for the three and nine months ended September 30, 2024, respectively.

Huadong License and Collaboration Agreement

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

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

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

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receive additional payments: (i) up to an aggregate amount of \$21.0 million upon the achievement of certain development and regulatory milestones, (ii) up to an aggregate amount of \$40.3 million upon the achievement of certain sales milestones, and (iii) low double-digit to high-teen double-digit tiered percentage royalties on net sales of the Huadong Licensed Products.

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

For the three and nine months ended September 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. For the three and nine months ended September 30, 2023, the Company recognized \$30.0 million of Other revenue and \$3.0 million of income tax expense related to the upfront fee pursuant to the agreement.

AstraZeneca License Agreement

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

The Company paid AstraZeneca an upfront non-refundable cash payment of \$1.0 million and issued 484,388 shares of Series B convertible preferred stock, valued at \$3.0 million on the date of the AstraZeneca License Agreement, which were both recorded in research and development expense. The Company subsequently paid AstraZeneca the first milestone cash payment of \$2.0 million upon the completion of a Phase 2b study of ZORYVE cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product, which was recorded in research and development expense. In the third quarter of 2022, the Company paid \$7.5 million to AstraZeneca as a result of the approval of ZORYVE cream 0.3%, which was recorded as an intangible asset. In the third quarter of 2024, \$5.0 million became payable by the Company to AstraZeneca upon achievement of \$100.0 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 License Agreement will be in effect. Amortization expense was \$1.2 million and \$1.6 million during the three and nine months ended September 30, 2024, respectively, which includes a cumulative catch-up of the amortization expense related to the milestone achieved during the third quarter over its useful life from the date of first commercial sale. Amortization expense was \$0.2 million and \$0.6 million during the three and nine months ended September 30, 2023, respectively.

The Company has agreed to make an additional cash payment to AstraZeneca of \$5.0 million upon the achievement of a specified regulatory approval milestone with respect to the AZ-Licensed Products, and a payment of \$10.0 million when the company achieves \$250.0 million in worldwide net sales. With respect to any AZ-Licensed Products the Company commercializes under the AstraZeneca License Agreement, it will pay AstraZeneca a low to high single-digit percentage royalty rate on the Company's, its affiliates' and its sublicensees' net sales of such AZ-Licensed Products, subject to specified reductions, until, as determined on an AZ-Licensed Product-by-AZ-Licensed Product and country-by-country basis, the later of the date of the expiration of the last-to-expire AstraZeneca-licensed patent right containing a valid claim in such country and 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

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expense was \$1.4 million and \$3.0 million during the three and nine months ended September 30, 2024, respectively. Royalty expense during the three and nine months ended September 30, 2023 were not material.

For the three and nine months ended September 30, 2024, a \$5.0 million milestone payment became payable by the Company to AstraZeneca upon achievement of \$100.0 million in worldwide net sales, which was paid in October 2024. There were no milestone payments made or payable in connection with AZ-Licensed Products for the three and nine months ended September 30, 2023.

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 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 each of December 31, 2023 and September 30, 2024, the aggregate principal amount outstanding under the Loan Agreement was \$200.0 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. See Note 10. Since this payment was reasonably expected to be made as of September 30, 2024 and it would require the use of current assets, the Company reclassified \$99.5 million, the payment net of the short-term portion of debt issuance costs, from long term liabilities to current liabilities as of September 30, 2024. 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.

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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. On September 30, 2024, the rate was 11.12%. 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. 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.

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 September 30, 2024.

In addition, the Loan Agreement contains customary events of default that entitle the lenders to cause any indebtedness under the Loan Agreement to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the Term Loans. Under the Loan Agreement, an event of default will occur if, among other things, the Company fails to make payments under the Loan Agreement, the Company breaches any of the covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches, the lenders determine that a material adverse change has occurred, or the Company or the Company's assets become subject to certain legal proceedings, such as bankruptcy proceedings. Upon the occurrence and for the duration of an event of default, an additional default interest rate, or the Default Rate, equal to 4.0% per annum will apply to all obligations owed under the Loan Agreement. The prepayment upon default and other potential additional interest provisions under the Loan Agreement were determined to be a compound embedded derivative instrument to be bifurcated from the loan and accounted for as a separate liability for accounting purposes under the guidance in ASC 815, *Derivatives and Hedging*. At the inception of the Loan Agreement, the fair value of the embedded derivative was determined to be immaterial. The embedded derivative instrument is remeasured at fair value each reporting period with any future changes in fair value reported in Other income, net in the condensed consolidated statement of operations and comprehensive loss. During the three and nine months ended September 30, 2024, the Company recognized a \$0.2 million loss and \$0.4 million gain in Other income, net, respectively, related to the change in fair value of the embedded derivative instrument. The fair value of the embedded derivative instrument as of September 30, 2024 and December 31, 2023 was a liability of \$0.4 million and \$0.8 million, respectively, and is included in Other long-term liabilities in the accompanying condensed consolidated balance sheets. See Note 4.

In connection with the Loan Agreement, the Company 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

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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 September 30, 2024 and December 31, 2023, the effective interest rate was 12.40% and 14.81%, respectively. Interest expense relating to the term loan for the three and nine months ended September 30, 2024 was \$6.6 million and \$21.6 million, respectively, and \$7.6 million and \$22.0 million for three and nine months ended September 30, 2023.

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

	September 30, 2024	December 31, 2023
Long-term debt, gross	\$ 200,000	\$ 200,000
Accrued final fee	6,970	4,876
Unamortized debt issuance costs	(2,362)	(3,077)
Total carrying value of debt	204,608	201,799
Less current portion	(99,513)	—
Total long-term debt, net	\$ 105,095	\$ 201,799

Based on the Company's long-term debt outstanding at September 30, 2024, a payment of principal and final fees of \$213.9 million would be due on January 1, 2027, the contractual maturity of the long-term debt as of September 30, 2024. This amount decreased and the contractual maturity date was extended following the 2024 Partial Prepayment in October 2024. See Note 10.

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

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

Stock Option Activity

The following summarizes option activity:

	Number of Options	Weighted- Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value (\$, in thousands)
Balance—December 31, 2023	7,919,699	\$ 18.52	7.35	\$ 1,435
Granted	3,677,916	5.18		
Exercised	(307,919)	4.17		
Forfeited ⁽¹⁾	(5,346,477)	22.49		
Expired	(308,725)	24.44		
Balance—September 30, 2024	5,634,494	\$ 6.51	8.04	\$ 23,561
Exercisable—September 30, 2024	2,120,880	\$ 8.16	6.14	\$ 8,715

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

The aggregate intrinsic value is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of September 30, 2024. The intrinsic value of options exercised for the nine months ended September 30, 2024 and 2023 was \$1.7 million and \$1.2 million, respectively.

The total grant-date fair value of the options vested during the nine months ended September 30, 2024 and 2023 was \$3.1 million and \$22.1 million, respectively. The weighted-average grant-date fair value of employee options granted during the nine months ended September 30, 2024 and 2023 was \$3.64 and \$8.76, respectively.

Restricted Stock Unit Activity

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

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2023	2,929,602	\$ 15.24
Granted ⁽¹⁾	5,760,872	5.03
Vested	(1,363,491)	11.40
Forfeited	(839,143)	8.67
Unvested Balance—September 30, 2024	6,487,840	\$ 7.83

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

The grant date fair value of an RSU equals the closing price of the Company's common stock on the grant date. RSUs generally vest equally over four years, except those issued in connection with the Option Exchange as described above.

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Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 3,342	\$ 4,058	\$ 10,341	\$ 11,966
Selling, general, and administrative	6,899	5,941	21,996	18,090
Total stock-based compensation expense	\$ 10,241	\$ 9,999	\$ 32,337	\$ 30,056

As of September 30, 2024, there was \$28.7 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 2.2 years. As of September 30, 2024, there was \$40.4 million of total unrecognized compensation cost related to RSUs that is expected to vest, which is expected to be recognized over a weighted-average period of 2.5 years.

In April 2024, in connection with the retirement of the former Chief Financial Officer, the Company modified the terms of this individual's historical stock awards. As a result of the modifications, the Company recognized \$1.7 million of incremental stock compensation expense during the nine months ended September 30, 2024, which is included in selling, general and administrative expenses.

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

	Nine Months Ended September 30, 2024	Year Ended December 31, 2023
Expected term (in years)	1.8 – 6.1	5.0 – 6.1
Expected volatility	79.1 – 83.2%	75.2 – 78.4%
Risk-free interest rate	3.9 – 5.0%	3.5 – 4.7%
Dividend yield	—%	—%

9. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average common shares outstanding. Pre-funded warrants to purchase 7,500,000 shares of the Company's stock were included in the weighted-average common shares outstanding used in calculating net loss per share for the three and nine months ended September 30, 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 September 30,	
	2024	2023
Stock options to purchase common stock	5,634,494	8,228,270
Early exercised options subject to future vesting	—	3,698
RSUs subject to future vesting	6,487,840	2,924,356
ESPP shares subject to future issuance	115,926	73,252
Total	12,238,260	11,229,576

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10. Subsequent Events

On October 8, 2024, the Company made a 2024 Partial Prepayment of \$100.0 million under the Loan Agreement. After the 2024 Partial Prepayment, based on the Company's long-term debt outstanding immediately following the 2024 Partial Prepayment, a payment of principal and final fees of \$106.95 million would be due on August 1, 2029, the contractual maturity of the long-term debt following the 2024 Partial Prepayment. See Note 7.

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

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

Overview

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

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

In December 2023, we received FDA approval for ZORYVE[®] (roflumilast) topical foam 0.3% ("ZORYVE foam") for the treatment of seborrheic dermatitis in individuals aged 9 years and older, with no limitation on severity, location, or duration of use. ZORYVE foam has been shown to provide rapid disease clearance and significant reduction in itch in clinical trials. In a pivotal Phase 3 study, 80% of individuals treated with ZORYVE foam achieved the primary efficacy endpoint of IGA Success, defined as an IGA score of "clear" or "almost clear" plus a 2-point improvement at Week 8, and just over 50% of individuals achieved an IGA score of clear at Week 8. In addition, individuals treated with ZORYVE foam reported reductions in itch from baseline within 48 hours of first application. ZORYVE foam is a once-daily steroid-free foam and, as a PDE4 inhibitor, is the first drug approved for the treatment of seborrheic dermatitis with a new mechanism of action in over two decades. ZORYVE foam became commercially available in the United States in late January 2024, and announced Health Canada approval on October 18, 2024 and will become commercially available in Canada by the end of 2024. Seborrheic dermatitis is estimated to occur in as many as 10 million people in the United States, and is associated with a substantial psychosocial burden for those suffering from the disease.

In addition to the approval of ZORYVE cream 0.3% for plaque psoriasis and ZORYVE foam for seborrheic dermatitis, we also received FDA approval for and commercially launched ZORYVE (roflumilast) cream 0.15% ("ZORYVE cream 0.15%"), (collectively, "ZORYVE") 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. 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 expect to submit a supplemental new drug application ("sNDA") for topical ZORYVE cream 0.05% for children 2 to 5 years of age in the first quarter of 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 August 2024.

Beyond seborrheic dermatitis, we are also developing ZORYVE foam for scalp and body psoriasis and have successfully completed our Phase 2b and pivotal Phase 3 clinical trials. We announced positive topline data in September 2022, and we submitted an sNDA to the FDA for a label expansion to include scalp and body psoriasis in adults and adolescents ages 12 and over, which was recently accepted by the FDA with a Prescription Drug User Fee Act ("PDUFA") target action date in May 2025.

Based on market research and our internal estimates, we estimate there is an overall patient market of approximately 15.2 million patients in the United States that are treated with topical therapies for plaque psoriasis, seborrheic dermatitis, and atopic dermatitis in dermatology offices (approximately 7.8 million) and outside dermatology (approximately 7.4 million). Of the patients that are treated in dermatology offices, we estimate that approximately 3.3 million of these patients are addressable or accessible with Medicare and Medicaid coverage and that approximately 4.4 million patients across plaque psoriasis, seborrheic dermatitis, and atopic dermatitis are covered by commercial insurance. Patients that are treated outside of dermatology offices are primarily addressable through primary care physicians and pediatricians.

In July 2024, we entered into a co-promotion agreement with Kowa Pharmaceuticals, Inc. 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.

In addition to ZORYVE, we are developing ARQ-255, a deep-penetrating topical formulation of ivarmacitinib, a potent and highly selective topical Janus kinase type 1 ("JAK1") inhibitor, designed to preferentially deliver the drug deep into the hair follicle, the site of inflammation in alopecia areata, in order to potentially develop the first topical treatment for this disease. We recently completed enrollment in a Phase 1b study evaluating ARQ-255 for the treatment of alopecia areata and expect data in the first half of 2025.

In September 2022, we acquired Ducentis BioTherapeutics LTD ("Ducentis") and its lead asset, DS-234 (now ARQ-234), a fusion protein that is a potent and highly selective checkpoint agonist of the CD200 Receptor (CD200R). Currently in the preclinical stage, we plan to develop ARQ-234 in atopic dermatitis, where we believe it could be a potentially highly complementary biologic treatment option to ZORYVE cream in that indication, if approved. ARQ-234 could potentially be used to treat other inflammatory conditions as well. We are working towards submitting an IND during 2025.

We have incurred net losses in each year since inception, including net losses of \$129.3 million and \$195.9 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$1,111.2 million and cash, cash equivalents, restricted cash, and marketable securities of \$331.2 million. As of September 30, 2024, we had \$200.0 million outstanding under the Loan Agreement, of which we paid down \$100.0 million of principal from our available cash on October 8, 2024, with the right to re-draw that principal for a defined period. See Note 10 to the condensed consolidated financial statements for additional information.

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

We rely on third parties 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 will continue to rely on third parties, many of whom are single source suppliers, for our nonclinical and clinical trial materials, as well as the commercial supply of our products.

Components of Our Results of Operations

Revenue

Product Revenue, Net

In August 2022, in conjunction with the launch of our first FDA approved product, ZORYVE cream 0.3%, we began to recognize revenue from product sales, net of rebates, chargebacks, discounts, and other adjustments. Additionally, in June 2023, we began recognizing revenue net of deductions for ZORYVE cream 0.3% in Canada and, in January 2024, for ZORYVE foam. We received FDA approval of ZORYVE cream 0.15% for atopic dermatitis and began recognizing related revenues in July 2024. We will continue to evaluate trends related to revenue for ZORYVE. Additionally, if our development efforts for our other product candidates and ZORYVE label extensions are successful and result in regulatory approval, we may generate additional revenue in the future from product sales.

Other Revenue

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

Cost of Sales

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

Our cost of sales will reflect a lower average per unit cost of materials until inventory that was previously expensed is sold, which is expected to occur over the next seven months. As of September 30, 2024 and December 31, 2023, the value of this inventory, mostly at the raw materials stage, was approximately \$3.4 million and \$8.7 million, respectively.

Operating Expenses

Research and Development Expenses

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

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

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

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing, or costs required to complete the remaining development of ZORYVE cream 0.3%, ZORYVE cream 0.15%, ZORYVE foam, ARQ-255, and ARQ-234 or any other product candidates. This is due

to the numerous risks and uncertainties associated with the development of product candidates. See “Risk Factors” for a discussion of the risks and uncertainties associated with the development of our product candidates.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of salaries and related costs, including payroll taxes, benefits, stock-based compensation, and travel, and costs related to sales and marketing of ZORYVE. 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 will also be 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 related to the Huadong License and Collaboration Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

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

	Three Months Ended September 30,		Change	
	2024	2023	\$	%
(in thousands)				
Revenues:				
Product revenue, net	\$ 44,755	\$ 8,109	\$ 36,646	452 %
Other revenue	—	30,000	(30,000)	(100)%
Total revenues	<u>44,755</u>	<u>38,109</u>	<u>6,646</u>	<u>17 %</u>
Operating expenses:				
Cost of sales	5,503	1,182	4,321	366 %
Research and development	19,501	26,236	(6,735)	(26)%
Selling, general, and administrative	58,817	47,595	11,222	24 %
Total operating expenses	<u>83,821</u>	<u>75,013</u>	<u>8,808</u>	<u>12 %</u>
Loss from operations	(39,066)	(36,904)	(2,162)	6 %
Other income (expense):				
Other income, net	4,182	2,721	1,461	54 %
Interest expense	(6,653)	(7,559)	906	(12)%
Loss before income taxes	(41,537)	(41,742)	205	— %
Provision for income taxes	—	3,023	(3,023)	(100)%
Net loss	<u>\$ (41,537)</u>	<u>\$ (44,765)</u>	<u>\$ 3,228</u>	<u>(7)%</u>

*Not applicable

Product Revenue, Net

We began recording U.S. product revenue in the third quarter of 2022 following the FDA approval and subsequent commercial launch of ZORYVE cream 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. We since recorded U.S. revenue in the first quarter of 2024 following the FDA approval and subsequent commercial launch of ZORYVE foam in January 2024. In the third quarter of 2024, we recorded U.S. product revenue following the FDA approval and subsequent commercial launch of ZORYVE cream 0.15% in July 2024.

	Three Months Ended September 30,		Change	
	2024	2023	\$	%
(in thousands)				
Product revenue, net				
ZORYVE cream 0.3%	\$ 22,041	\$ 8,109	\$ 13,932	172 %
ZORYVE foam	20,262	—	20,262	*
ZORYVE cream 0.15%	2,452	—	2,452	*
Total product revenue, net	<u>\$ 44,755</u>	<u>\$ 8,109</u>	<u>\$ 36,646</u>	<u>452 %</u>

*Not applicable

Product revenue, net, for ZORYVE cream 0.3% increased by \$13.9 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, primarily driven by higher end customer demand and improving gross-to-net discounts for ZORYVE cream 0.3% in the United States.

Product revenue, net, for ZORYVE foam increased by \$20.3 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, driven by its commercial launch in January 2024.

Product revenue, net, for ZORYVE cream 0.15% were \$2.5 million for the three months ended September 30, 2024 compared to no sales in the three months ended September 30, 2023, driven by its commercial launch in July 2024.

Other Revenue

Other revenue for the three months ended September 30, 2023 were the result of license revenues received in connection with the Huadong Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Cost of Sales

Cost of sales increased by \$4.3 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The increase is related primarily to an increase in customer demand for ZORYVE cream 0.3% and foam. Prior to the dates on which the initial regulatory approvals were received for each product, costs of raw materials were recorded as research and development expense. Therefore, cost of sales will reflect a lower average per unit cost until the related inventory is sold, which is expected to occur over the next seven months. See Note 5 to the condensed consolidated financial statements for additional information.

Research and Development Expenses

	Three Months Ended September 30,		Change	
	2024	2023	\$	%
	(in thousands)			
Direct external costs:				
Topical roflumilast program	\$ 1,320	\$ 6,020	\$ (4,700)	(78)%
Topical JAK inhibitor program	1,089	978	111	11 %
Other early-stage programs	2,910	2,026	884	44 %
Indirect costs:				
Compensation and personnel-related	9,834	12,289	(2,455)	(20)%
Other	4,348	4,923	(575)	(12)%
Total research and development expense	<u>\$ 19,501</u>	<u>\$ 26,236</u>	<u>\$ (6,735)</u>	<u>(26)%</u>

Research and development expenses decreased by \$6.7 million, or 26%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The decrease was primarily due to the completion of Phase 3 studies of roflumilast cream in atopic dermatitis, coupled with a decrease in compensation and personnel-related expenses.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by \$11.2 million, or 24%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The increase was primarily due to an increase in compensation and personnel-related expenses of \$7.6 million and an increase in sales and marketing expenses of \$3.2 million. These increases were primarily due to our continued commercialization efforts for ZORYVE.

Other Income, Net

Other income, net increased by \$1.5 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, primarily due to the impact of higher interest rates, coupled with a higher marketable securities balance.

Interest Expense

Interest expense decreased by \$0.9 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, due to the impact of lower interest rates. See Note 7 to the condensed consolidated financial statements for additional information.

Provision for Income Taxes

Income tax expense of \$3.0 million for the three months ended September 30, 2023 was primarily due to income tax expense related to withholding tax on the Huadong License and Collaboration Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Comparison of the Nine Months Ended September 30, 2024 and 2023

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

	Nine Months Ended September 30,		Change	
	2024	2023	\$	%
	(in thousands)			
Revenues:				
Product revenue, net	\$ 97,182	\$ 15,660	\$ 81,522	521 %
Other revenue	28,000	30,420	(2,420)	(8)%
Total revenues	<u>125,182</u>	<u>46,080</u>	<u>79,102</u>	<u>172 %</u>
Operating expenses:				
Cost of sales	12,223	2,741	9,482	346 %
Research and development	61,940	86,800	(24,860)	(29)%
Selling, general, and administrative	171,784	136,471	35,313	26 %
Total operating expenses	<u>245,947</u>	<u>226,012</u>	<u>19,935</u>	<u>9 %</u>
Loss from operations	<u>(120,765)</u>	<u>(179,932)</u>	<u>59,167</u>	<u>(33)%</u>
Other income (expense):				
Other income, net	13,455	9,114	4,341	48 %
Interest expense	<u>(21,617)</u>	<u>(21,950)</u>	<u>333</u>	<u>(2)%</u>
Loss before income taxes	<u>(128,927)</u>	<u>(192,768)</u>	<u>63,841</u>	<u>(33)%</u>
Provision for income taxes	324	3,088	(2,764)	(90)%
Net loss	<u>\$ (129,251)</u>	<u>\$ (195,856)</u>	<u>\$ 66,605</u>	<u>(34)%</u>

*Not applicable

Product Revenue, Net

We began recording U.S. product revenue in the third quarter of 2022 following the FDA approval and subsequent commercial launch of ZORYVE cream 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. We since recorded U.S. revenue in the first quarter of 2024 following the FDA approval and subsequent commercial launch of ZORYVE foam in January 2024. In the third quarter of 2024, we recorded U.S. product revenue following the FDA approval and subsequent commercial launch of ZORYVE cream 0.15% in July 2024.

	Nine Months Ended September 30,		Change	
	2024	2023	\$	%
	(in thousands)			
Product revenue, net				
ZORYVE cream 0.3%	\$ 54,325	\$ 15,660	\$ 38,665	247 %
ZORYVE foam	40,405	—	40,405	*
ZORYVE cream 0.15%	2,452	—	2,452	*
Total product revenue, net	\$ 97,182	\$ 15,660	\$ 81,522	521 %

*Not applicable

Product revenue, net, for ZORYVE cream 0.3% increased by \$38.7 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023, primarily driven by higher end customer demand and improvements in gross-to-net discounts for ZORYVE cream 0.3% in the United States and the commercial launch of ZORYVE cream 0.3% in Canada in June 2023.

Product revenue, net, for ZORYVE foam increased by \$40.4 million for the nine months ended September 30, 2024 compared to no sales in the nine months ended September 30, 2023, driven by its commercial launch in January 2024.

Product revenue, net, for ZORYVE cream 0.15% were \$2.5 million for the nine months ended September 30, 2024 compared to no sales in the nine months ended September 30, 2023, driven by its commercial launch in July 2024.

Other Revenue

Other revenue in the nine months ended September 30, 2024 includes \$25.0 million received as an upfront payment in connection with the Sato Agreement and a \$3.0 milestone payment received in connection with the Huadong Agreement. Other revenue in the nine months ended September 30, 2023 primarily includes license revenues received in connection with the Huadong Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Cost of Sales

Cost of sales increased by \$9.5 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The increase is related primarily to an increase in customer demand for ZORYVE cream 0.3% and foam. Prior to the dates on which the initial regulatory approvals were received for each product, costs of raw materials were recorded as research and development expense. Therefore, cost of sales will reflect a lower average per unit cost until the related inventory is sold, which is expected to occur over the next seven months. See Note 5 to the condensed consolidated financial statements for additional information.

Research and Development Expenses

	Nine Months Ended September 30,		Change	
	2024	2023	\$	%
	(in thousands)			
Direct external costs:				
Topical roflumilast program	\$ 7,839	\$ 28,974	\$ (21,135)	(73)%
Topical JAK inhibitor program	2,351	2,832	(481)	(17)%
Other early-stage programs	8,878	3,869	5,009	129 %
Indirect costs:				
Compensation and personnel-related	29,574	34,784	(5,210)	(15)%
Other	13,298	16,341	(3,043)	(19)%
Total research and development expense	\$ 61,940	\$ 86,800	\$ (24,860)	(29)%

Research and development expenses decreased by \$24.9 million, or 29%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The decrease was primarily due to the completion of Phase 3 studies of roflumilast cream in atopic dermatitis, coupled with decreases in compensation and personnel-related expenses and consulting costs, partially offset by manufacturing and preclinical costs incurred related to the development of early-stage programs.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by \$35.3 million, or 26%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The increase was primarily due to an increase in compensation and personnel-related expenses of \$19.1 million and an increase in sales and marketing expenses of \$14.7 million. These increases were primarily due to our continued commercialization efforts for ZORYVE.

Other Income, Net

Other income, net increased by \$4.3 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023, primarily due to the impact of higher interest rates and higher marketable securities balance.

Interest Expense

Interest expense decreased by \$0.3 million for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023, due to the impact of lower interest rates. See Note 7 to the condensed consolidated financial statements for additional information.

Provision for Income Taxes

Income tax expense of \$0.3 million and \$3.0 million for the nine months ended September 30, 2024 and 2023, respectively, were primarily due to withholding tax on the Huadong License and Collaboration Agreement. See Note 6 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. We have incurred operating losses since our inception and have an accumulated deficit as a result of ongoing efforts to develop and commercialize our products and product candidates, including conducting nonclinical and clinical trials and providing selling, general and administrative support for these operations. As of September 30, 2024, we had cash, cash equivalents, restricted cash, and marketable securities of \$331.2 million, and an accumulated deficit of \$1,111.2 million. We maintain cash balances with financial institutions in excess of insured limits. As of September 30, 2024, we had \$200.0 million outstanding under the Loan Agreement, of which we paid down \$100.0 million of principal from available cash on October 8, 2024, with the right to re-draw that principal for a defined period. See Note 10 to the condensed consolidated financial statements for additional information.

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

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

- the timing, receipt, and amount of sales of any current and future products;
- the scope, progress, results, and costs of researching and developing our lead product candidates or any future product candidates, and conducting nonclinical studies and clinical trials, in particular our planned or ongoing development activities 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, Hengrui or any future collaborator or licensing partner, upon the achievement of predetermined milestones;
- any product liability or other lawsuits related to our products;

- the expenses needed to attract and retain skilled personnel;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio; and
- costs associated with any adverse market conditions or other macroeconomic factors.

Indebtedness

On December 22, 2021, we entered into a loan and security agreement (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 each of December 31, 2023 and September 30, 2024, the aggregate principal amount outstanding under the Loan Agreement was \$200.0 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. On September 30, 2024, the rate was 11.12%. 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. 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 September 30, 2024.

Cash Flows

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

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Cash used in operating activities	\$ (111,410)	\$ (190,813)
Cash (used in) provided by investing activities	(6,057)	242,418
Cash provided by financing activities	163,613	2,034
Effect of exchange rate changes on cash	(1)	(118)
Net increase in cash, cash equivalents, and restricted cash	<u>\$ 46,145</u>	<u>\$ 53,521</u>

Net Cash Used in Operating Activities

During the nine months ended September 30, 2024, net cash used in operating activities was \$111.4 million, which consisted of a net loss of \$129.3 million and a change in net operating assets and liabilities of \$13.5 million, partially offset by net non-cash charges of \$31.4 million. The net non-cash charges were primarily related to stock-based compensation expense of \$32.3 million.

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

Net Cash (Used in) Provided by Investing Activities

During the nine months ended September 30, 2024, net cash used in investing activities was \$6.1 million, which was comprised primarily of purchases of marketable securities of \$237.4 million, offset by proceeds from the maturities of marketable securities of \$231.5 million.

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

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2024, net cash provided by financing activities was \$163.6 million, which was comprised primarily of \$161.7 million of net proceeds from our February 2024 public stock offering.

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

Contractual Obligations and Contingent Liabilities

Except as set forth in Note 7, Long-term Debt, and Note 10, Subsequent Events, of the notes to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, there have been no material changes outside the ordinary course of business to our contractual obligations and commitments as described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2023.

Smaller Reporting Company Status

As of June 30, 2024, the market value of our ordinary shares held by non-affiliates exceeded \$700.0 million. As a result, we will be a large accelerated filer. Additionally, we will no longer qualify as a smaller reporting company beginning with our first Quarterly Report on Form 10-Q for the quarterly period ending March 31, 2025. As a result of this transition, we will be subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us and we will also not be able to take advantage of certain scaled disclosures available to smaller reporting companies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of September 30, 2024, we had cash and cash equivalents of \$134.9 million, restricted cash of \$0.6 million, and marketable securities of \$195.7 million; which from time to time consist of bank deposits, money market funds, commercial paper, government securities, and corporate debt securities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

In addition, as of September 30, 2024, we had \$200.0 million outstanding under our Loan Agreement. On October 8, 2024, the Company made a 2024 Partial Prepayment of \$100.0 million, which reduced the principal amount outstanding to \$100.0 million. Amounts outstanding under our Loan Agreement bear interest at a floating rate equal 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") as the current 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 after the prepayment, 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 marketable securities. We may in the future use swaps, caps, collars, structured collars or other common derivative financial instruments to reduce interest rate risk. It is difficult to predict the effect that future hedging activities would have on our operating results.

We are exposed to foreign currency exchange risk as our Canadian subsidiary operates with the Canadian dollar as its functional currency. The majority of our transactions occur in U.S. dollars. The fluctuation in the value of the U.S. dollar against the Canadian dollar affects the reported amounts of expenses, assets and liabilities. If we expand our international operations our exposure to exchange rate fluctuations will increase. At September 30, 2024 we had cash balances denominated in Canadian dollars of \$4.5 million. We currently do not hedge any foreign currency exposure. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have a material impact on our condensed consolidated financial statements.

Item 4. CONTROLS AND PROCEDURES***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2024, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such required information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

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

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

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

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

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

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

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Arcutis Biotherapeutics, Inc. filed a lawsuit against Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, Padagis) in the U.S. District Court for the District of Delaware on March 27, 2024, based on the submission to the FDA of an ANDA seeking approval to market and sell a generic version of Arcutis's ZORYVE® 0.3% cream for the treatment of plaque psoriasis. The 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.

On July 19, 2024, Arcutis filed its first amended complaint that added the last five of the above listed patents to its infringement allegations. These patents were issued by the U.S. Patent and Trademark Office and listed in FDA's Orange Book for Arcutis's ZORYVE® 0.3% cream after the filing of the original complaint. On August 2, 2024, Padagis responded to the first amended complaint, denying infringement and asserting counterclaims seeking a declaratory judgment that the asserted patents are not infringed, invalid and/or unenforceable. The court issued a scheduling order on June 10, 2024, which sets trial at the court's convenience, or around April 13-17, 2026. The automatic 30-month stay of FDA approval of Padagis's ANDA seeking approval for Arcutis's ZORYVE® 0.3% cream is set to expire on August 14, 2026.

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, 2023 and Part II, Item 1A, "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024. Other than the risk factors set forth below, there have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023.

We expect to be a large accelerated filer and will no longer qualify as a "smaller reporting company" which will require additional compliance initiatives and heightened disclosure and reporting requirements.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our senior management on our internal control over financial reporting. However, during any period in which we qualify as a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. As of June 30, 2024, the market value of our ordinary shares held by non-affiliates exceeded \$700.0 million. As a result, we will be a large accelerated filer effective December 31, 2024. Additionally, we will no longer qualify as a "smaller reporting company," as defined in the Exchange Act, beginning with our first Quarterly Report on Form 10-Q for the quarterly period ending March 31, 2025. As a result of this transition, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm with our Annual Report on Form 10-K for the fiscal year ending December 31, 2024. To prepare for compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have dedicated internal resources, engaged outside consultants and adopted a detailed work plan to assess and document the adequacy of internal control over financial reporting. We have continued steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts to date and continued efforts, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal control over financial reporting is effective as required by Section 404. As a result of this transition, we will be subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us during the period in which we qualified as a smaller reporting company, and we will also not be able to take advantage of certain scaled disclosures available to smaller reporting companies. Any failure to comply with the increased disclosure and reporting requirements could have an adverse effect on our business, financial condition and results of operations.

Our current and future collaboration arrangements may not be successful, which could adversely affect our ability to develop and commercialize future product candidates.

We have entered into a strategic collaboration and licensing agreement for topical roflumilast in Greater China and Southeast Asia with Hangzhou Zhongmei Huadong Pharmaceutical Co., a wholly owned subsidiary of Huadong Medicine Co., Ltd., a strategic collaboration and licensing agreement for topical roflumilast in Japan with Sato Pharmaceutical Co., Ltd., and a co-promotion agreement with Kowa Pharmaceuticals America, Inc. to exclusively market and promote ZORYVE to primary care practitioners and pediatricians for all FDA approved indications in the United States. In the future, we may seek additional collaboration arrangements for the commercialization, or potentially for the development, of certain of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. We will face, to the extent that we decide to enter into future collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement, and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us. Our current and future collaborations may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates; a collaborator with sales, marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities, including with respect to accessing primary care and pediatric practices; collaborators are or may in the future be entitled to fees, royalties, profit sharing, and other consideration, which may limit or otherwise negatively impact our profit and financial performance;
- we have and could in the future grant exclusive rights to our collaborators that prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development, or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering products that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Furthermore, we cannot assure you that any collaboration, or other strategic transaction, will achieve the expected synergies. For example, such transactions may require us to incur non-recurring or other charges, increase our near- and long-term expenditures, and pose significant integration or implementation challenges or disrupt our management or business. These transactions entail numerous operational and financial risks, including exposure to unknown liabilities, dependence upon the performance and discretion of counterparties that we do not control and that may underperform or fail, disruption of our business, and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.

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

As of September 30, 2024, we had \$200.0 million outstanding under our Loan Agreement. On August 9, we entered into a second amendment to the Loan Agreement, pursuant to which the terms were revised to, among others, permit an optional partial prepayment of term loans outstanding during the period commencing on October 7, 2024 and ending on December 15, 2024, subject to a 1.0% prepayment penalty (the "2024 Partial Prepayment"). On October 8, 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 our annual plan for the respective period, we will be able to draw down a tranche C-1 term loan of up to \$50.0 million and a tranche C-2 term loan of up to \$50.0 million. 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. As security for the obligations under the Loan Agreement, we granted SLR, for the benefit of the lenders, a continuing security interest in substantially all of our assets, including our intellectual property, subject to certain exceptions.

The Loan Agreement contains a number of representations and warranties and affirmative and restrictive covenants, including financial covenants, and the terms may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry, or take future actions. The Loan Agreement includes a financial covenant whereby we must generate 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.

If the debt under the Loan Agreement were accelerated due to an event of default or otherwise, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition. If we do not have or are unable to generate sufficient cash to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern. Moreover, regardless of a potential event of default, the debt under the Loan Agreement matures and is due on August 1, 2029. As a result, we may need to refinance or secure separate financing in order to repay amounts outstanding when due, however, no assurance can be given that an extension will be granted, that we will be able to renegotiate the terms of the agreement with the lender, or that we will be able to secure separate debt or equity financing on favorable terms, if at all.

In order to service our indebtedness, we need to generate cash from our operating activities or additional equity or debt financings. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the

proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry, and in the economy generally. This may place us at a competitive disadvantage compared to our competitors that have less indebtedness.

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

None.

Issuer Purchases of Equity Securities

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Trading Plans

During the three months ended September 30, 2024, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Chair of the Board

The Company’s board of directors (the “Board”) elected Keith Leonard to serve as Chair of the Board, effective 4 November 2024. Mr. Leonard has served as a member of the Board since September 2021. Over his more than 30 years in the biopharmaceutical industry, he has had a wide variety of roles and brings deep expertise in pharmaceutical commercialization. He currently chairs the board of Unity Biotechnology, serves on the board of Intuitive Surgical, and was previously chair of the boards of Kythera Biopharmaceuticals and Sienna Biopharmaceuticals, and served on the boards of Sanifit SA, Anacor Pharmaceuticals, Affymax, and ARYx Therapeutics. He was also previously chief executive officer of Unity Biotherapeutics and Kythera Biopharmaceuticals. Mr. Leonard succeeds Patrick Heron. Mr. Heron, who has served as a member of the Board since its formation and as Chair of the Board since 2019, will continue to serve as an independent director.

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	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				X

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

* 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: November 06, 2024

By: /s/ Todd Franklin Watanabe

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

Date: November 06, 2024

By: /s/ David Topper

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

