

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023

OR

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

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

ARCUTIS BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(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 checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input 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 August 4, 2023 was 61,653,978.

FORWARD-LOOKING STATEMENTS

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

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. Forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed in Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q for the quarter ended June 30, 2023. The forward-looking statements in this Quarterly Report on Form 10-Q are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 105,114	\$ 53,641
Restricted cash	925	1,234
Marketable securities	163,557	355,948
Trade receivables, net	17,207	8,458
Inventories	10,474	7,514
Prepaid expenses and other current assets	11,591	10,611
Total current assets	308,868	437,406
Property, plant, and equipment, net	1,867	1,881
Intangible assets, net	6,812	7,188
Operating lease right-of-use asset	2,546	2,721
Other assets	596	78
Total assets	<u>\$ 320,689</u>	<u>\$ 449,274</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 17,156	\$ 8,827
Accrued liabilities	18,808	28,323
Operating lease liability	695	657
Total current liabilities	36,659	37,807
Operating lease liability, noncurrent	3,755	4,117
Long-term debt, net	199,767	197,769
Total liabilities	240,181	239,693
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at June 30, 2023 and December 31, 2022; no shares issued and outstanding at June 30, 2023 and December 31, 2022;	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized at June 30, 2023 and December 31, 2022; 61,637,428 and 61,052,250 shares issued at June 30, 2023 and December 31, 2022, respectively; 61,630,018 and 61,037,403 shares outstanding at June 30, 2023 and December 31, 2022, respectively	6	6
Additional paid-in capital	951,649	930,425
Accumulated other comprehensive loss	(292)	(1,086)
Accumulated deficit	(870,855)	(719,764)
Total stockholders' equity	80,508	209,581
Total liabilities and stockholders' equity	<u>\$ 320,689</u>	<u>\$ 449,274</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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Product revenue, net	\$ 4,770	\$ —	\$ 7,551	\$ —
Other revenue	420	—	420	—
Total revenues	<u>5,190</u>	<u>—</u>	<u>7,971</u>	<u>—</u>
Operating expenses:				
Cost of sales	776	—	1,559	—
Research and development	25,219	38,205	60,564	78,827
Selling, general, and administrative	45,958	27,622	88,876	49,628
Total operating expenses	<u>71,953</u>	<u>65,827</u>	<u>150,999</u>	<u>128,455</u>
Loss from operations	<u>(66,763)</u>	<u>(65,827)</u>	<u>(143,028)</u>	<u>(128,455)</u>
Other income (expense):				
Other income, net	3,121	421	6,328	563
Interest expense	(7,349)	(2,000)	(14,391)	(3,838)
Total other income (expense)	<u>(4,228)</u>	<u>(1,579)</u>	<u>(8,063)</u>	<u>(3,275)</u>
Net loss	<u>\$ (70,991)</u>	<u>\$ (67,406)</u>	<u>\$ (151,091)</u>	<u>\$ (131,730)</u>
Other comprehensive income (loss):				
Unrealized income (loss) on marketable securities	128	(232)	852	(997)
Foreign currency translation adjustment	(6)	—	(58)	—
Total other comprehensive income (loss)	<u>\$ 122</u>	<u>\$ (232)</u>	<u>\$ 794</u>	<u>\$ (997)</u>
Comprehensive loss	<u>\$ (70,869)</u>	<u>\$ (67,638)</u>	<u>\$ (150,297)</u>	<u>\$ (132,727)</u>
Per share information:				
Net loss per share, basic and diluted	<u>\$ (1.16)</u>	<u>\$ (1.31)</u>	<u>\$ (2.46)</u>	<u>\$ (2.58)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>61,430,620</u>	<u>51,422,386</u>	<u>61,300,577</u>	<u>50,970,465</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, 2021	50,255,614	\$ 5	\$ 706,233	\$ (255)	\$ (408,306)	\$ 297,677
Issuance of shares of common stock for initial public offering, net of issuance costs of \$634	882,353	—	14,366	—	—	14,366
Issuance of common stock upon the exercise of stock options	102,935	—	260	—	—	260
Issuance of common stock upon the vesting of restricted stock units	79,421	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	40,025	—	25	—	—	25
Stock-based compensation expense	—	—	6,533	—	—	6,533
Unrealized loss on marketable securities	—	—	—	(765)	—	(765)
Net loss	—	—	—	—	(64,324)	(64,324)
Balance—March 31, 2022	51,360,348	\$ 5	\$ 727,417	\$ (1,020)	\$ (472,630)	\$ 253,772
Issuance of common stock upon the exercise of stock options	57,113	—	156	—	—	156
Issuance of common stock upon the vesting of restricted stock units	6,625	—	—	—	—	—
Vesting of founder shares subject to repurchase	—	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	27,830	—	20	—	—	20
Shares issued pursuant to the employee stock purchase plan	74,237	—	976	—	—	976
Stock-based compensation expense	—	—	8,096	—	—	8,096
Unrealized loss on marketable securities	—	—	—	(232)	—	(232)
Net loss	—	—	—	—	(67,406)	(67,406)
Balance—June 30, 2022	51,526,153	\$ 5	\$ 736,665	\$ (1,252)	\$ (540,036)	\$ 195,382

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

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

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

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)

	Six Months Ended June 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (151,091)	\$ (131,730)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	373	305
Non-cash lease expense	175	158
Amortization of intangible assets	376	—
Net (accretion) amortization on marketable securities	(3,985)	890
Non-cash interest expense	1,998	788
Stock-based compensation expense	20,057	14,629
Changes in operating assets and liabilities:		
Accounts receivable, net	(8,749)	—
Inventories	(2,960)	—
Prepaid expenses and other current assets	(1,494)	2,059
Accounts payable	8,319	1,166
Accrued liabilities	(9,524)	(7,045)
Operating lease liabilities	(324)	(175)
Net cash used in operating activities	(146,829)	(118,955)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(85,273)	(135,745)
Proceeds from maturities of marketable securities	282,500	203,811
Purchases of property and equipment	(358)	(204)
Net cash provided by investing activities	196,869	67,862
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock upon exercise of stock options	174	416
Proceeds from issuance of common stock, net of issuance costs	—	14,455
Proceeds from issuance of common stock pursuant to employee stock purchase plan	993	976
Net cash provided by financing activities	1,167	15,847
Effect of exchange rate changes on cash	(43)	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	51,164	(35,246)
Cash, cash equivalents, and restricted cash at beginning of period	54,875	97,991
Cash, cash equivalents, and restricted cash at end of period	\$ 106,039	\$ 62,745
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Interest expense paid in cash	\$ 12,313	\$ 2,989

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

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

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

Initial Public Offering and Follow-On Financings

On February 4, 2020, the Company closed an initial public offering (IPO) issuing and selling shares of its common stock receiving aggregate net proceeds of approximately \$167.2 million. The company completed subsequent public sales of its common stock in October 2020, February 2021 and August 2022, receiving aggregate net proceeds of \$93.4 million, \$207.5 million, and \$161.6 million, respectively. In October 2020, the Company also sold shares of common stock in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, receiving net proceeds of \$35.0 million.

At-the-Market (ATM) Offerings

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

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of \$870.9 million and \$719.8 million as of June 30, 2023 and December 31, 2022, respectively. Management expects to continue to incur operating losses. The Company had cash, cash equivalents, restricted cash, and marketable securities of \$269.6 million and \$410.8 million as of June 30, 2023 and December 31, 2022, respectively. The Company has \$200.0 million outstanding under the Loan Agreement as of June 30, 2023, with an additional \$25.0 million in funding that may become available subject to the satisfaction of specified conditions. See Note 8.

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

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

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

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

Segments

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

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated balance sheet as of June 30, 2023, the interim condensed consolidated statements of operations and comprehensive loss, and the condensed consolidated changes in convertible preferred stock and stockholders' equity (deficit) and cash flows for the three and six months ended June 30, 2023 and 2022 are unaudited. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's audited annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair statement of the Company's financial information. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the three month periods are also unaudited. The condensed consolidated results of operations for the three and six months ended June 30, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2022 included herein was derived from the audited financial statements as of that date. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Therefore, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2022.

Cash and Cash Equivalents

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

Restricted Cash

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

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

Marketable Securities

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

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

Trade Receivables, net

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

Inventory

The Company values its inventories at the lower-of-cost or net realizable value. The Company determines the cost of its inventories, which includes costs related to products held for sale in the ordinary course of business, products in process of production for such sale, and items to be currently consumed in the production of goods to be available for sale, on a first-in, first-out (FIFO) basis. Due to the nature of the Company's supply chain process, inventory that is owned by the Company is physically stored at third-party warehouses, logistics providers, and contract manufacturers. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and writes down any excess and obsolete inventories to their net realizable value in the period in which the impairment is first identified. If they occur, such charges are recorded as a component of cost of sales in the condensed consolidated statements of operations. The Company capitalizes inventory costs associated with products following regulatory approval when future commercialization is considered probable and the future economic benefit is expected to be realized. Products that may be used in clinical development programs are excluded from inventory and their costs are charged to research and development expense in the condensed consolidated statement of operations as incurred, as long as they do not have an alternative use. Prior to the initial date regulatory approval is received, costs related to the production of inventory were recorded as research and development expense on the Company's condensed consolidated statements of operations in the period incurred.

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

Intangible Assets, net

The Company paid a milestone payment of \$7.5 million to AstraZeneca in the third quarter of 2022 related to the FDA approval and launch of ZORYVE. This milestone payment was capitalized as an intangible asset and will be amortized to cost of sales over its useful life of 10 years from the date of first commercial sale, as this is the minimum amount of time that the related License Agreement will be in effect. See Note 6. Amortization expense for the three and six months ended June 30, 2023 was \$188,000 and \$376,000, respectively.

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

	Amounts
2023 (July through December)	\$ 374
2024	750
2025	750
2026	750
2027	750
Thereafter	3,438
Total amortization	<u>\$ 6,812</u>

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

Valuation of Other Investments

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

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

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Concentration of Credit Risk and Other Risks and Uncertainties

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

Fair Value Measurement

The Company's financial instruments, in addition to those presented in Note 3, include cash equivalents, accounts receivable, accounts payable, accrued liabilities, and long-term debt. The carrying amount of cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate their fair values due to their short maturities. As the long-term debt is subject to variable interest rates that are based on market rates which regularly reset, the Company believes that the carrying value of the long-term debt approximates its fair value.

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

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

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

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

Property and Equipment

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

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Leases

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

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

Accrued and Prepaid Nonclinical and Clinical Costs

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

Revenues

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

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

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Product Revenue, Net

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

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

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

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

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

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

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

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

Cost of Sales

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

Research and Development

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

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

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Stock-Based Compensation

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

Income Taxes

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

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

Foreign Currency Translation

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

Net Loss Per Share

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

Recently Adopted Accounting Pronouncements

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

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3. Fair Value Measurements

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

	June 30, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds ⁽¹⁾	\$ 105,114	\$ —	\$ —	\$ 105,114
Commercial paper	—	31,227	—	31,227
Corporate debt securities	—	3,960	—	3,960
U.S. Treasury securities	128,370	—	—	128,370
Total assets	<u>\$ 233,484</u>	<u>\$ 35,187</u>	<u>\$ —</u>	<u>\$ 268,671</u>

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

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

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

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

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

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

	June 30, 2023			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
Cash and cash equivalents:				
Money market funds ⁽¹⁾	\$ 105,114	\$ —	\$ —	\$ 105,114
Total cash and cash equivalents	\$ 105,114	\$ —	\$ —	\$ 105,114
Marketable securities:				
Commercial paper	\$ 31,226	\$ —	\$ —	\$ 31,226
Corporate debt securities	3,965	—	(6)	3,959
U.S. Treasury securities	128,598	19	(245)	128,372
Total marketable securities	\$ 163,789	\$ 19	\$ (251)	\$ 163,557

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

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

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

Realized gains or losses on investments for the three and six months ended June 30, 2023 and 2022 were not material. As of June 30, 2023, it was determined that no credit losses exist, because the change in market value of those securities resulted from fluctuations in market interest rates since the time of purchase, rather than a deterioration of the credit worthiness of the issuers. As of June 30, 2023 and December 31, 2022, all securities have a maturity of 18 months or less and all securities with gross unrealized losses have been in a continuous loss position for less than one year. The Company generally holds its marketable securities until maturity and does not intend to sell, and is not required to sell, the investments that are in an unrealized loss position before the recovery of their amortized cost basis.

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4. Balance Sheet Components**Inventories**

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

	June 30, 2023	December 31, 2022
Raw materials	\$ 7,976	\$ 5,659
Work in progress	569	395
Finished goods	1,929	1,460
Total inventories	<u>\$ 10,474</u>	<u>\$ 7,514</u>

Prepaid Expenses and Other Current Assets

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

	June 30, 2023	December 31, 2022
Prepaid co-pay assistance program	\$ 2,164	\$ 3,226
Prepaid insurance	1,549	956
Prepaid clinical trial costs	691	172
Other prepaid expenses and current assets	7,187	6,257
Total prepaid expenses and other current assets	<u>\$ 11,591</u>	<u>\$ 10,611</u>

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2023	December 31, 2022
Accrued compensation	\$ 8,952	\$ 14,000
Accrued sales deductions	4,883	1,567
Clinical trial accruals	2,801	7,896
Accrued expenses and other current liabilities	2,172	4,860
Total accrued liabilities	<u>\$ 18,808</u>	<u>\$ 28,323</u>

5. Property and Equipment, net

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

	June 30, 2023	December 31, 2022
Computer hardware	\$ 1,060	\$ 983
Furniture and fixtures	661	379
Software	104	104
Leasehold improvements	1,568	1,568
Property and equipment, gross	3,393	3,034
Less accumulated depreciation	(1,526)	(1,153)
Property and equipment, net	<u>\$ 1,867</u>	<u>\$ 1,881</u>

Depreciation expense was \$198,000 and \$373,000 for the three and six months ended June 30, 2023, respectively, and \$155,000 and \$305,000 for the three and six months ended June 30, 2022. Leasehold improvements are depreciated over the term of the lease, which is the shorter of the improvements' expected useful lives and the lease term. All other fixed asset depreciation is recorded using the straight-line method over the estimated useful lives of the assets (two to five years).

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6. License Agreements & Acquisition

AstraZeneca License Agreement

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

The Company paid AstraZeneca an upfront non-refundable cash payment of \$1.0 million and issued 484,388 shares of Series B convertible preferred stock, valued at \$3.0 million on the date of the AstraZeneca License Agreement, which were both recorded in research and development expense. The Company subsequently paid AstraZeneca the first milestone cash payment of \$2.0 million upon the completion of a Phase 2b study of roflumilast cream in plaque psoriasis in August 2019 for the achievement of positive Phase 2 data for an AZ-Licensed Product, which was recorded in research and development expense. In the third quarter of 2022, the Company paid \$7.5 million to AstraZeneca as a result of the approval of ZORYVE, which was recorded as an intangible asset. The Company is amortizing the intangible asset to cost of sales over its useful life of 10 years from the date of first commercial sale as this is the minimum amount of time that the related License Agreement will be in effect. Amortization expense during the three and six months ended June 30, 2023 was not material.

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

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

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Hengrui Exclusive Option and License Agreement

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

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

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

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

Iolyx Collaboration Agreement

In June 2019, the Company entered into a collaboration agreement, or Iolyx Agreement, with Iolyx, a related party with common ownership, for the development of clinical compounds, including roflumilast. The Iolyx Agreement grants Iolyx an exclusive license to certain intellectual property developed under the agreement as it relates to the development of new applications of such compounds.

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

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

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

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Ducentis Biotherapeutics LTD Acquisition

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

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

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

7. Commitments and Contingencies

Operating Lease

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

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

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

	Amounts
2023 (July through December)	\$ 482
2024	995
2025	1,024
2026	1,054
2027	1,087
2028	653
Total minimum lease payments	\$ 5,295
Less: Amounts representing interest	(845)
Present value of future minimum lease payments	\$ 4,450
Current portion operating lease liability	695
Operating lease liability, noncurrent	3,755
Total operating lease liability	\$ 4,450

Straight-line rent expense recognized for operating leases was \$177,000 and \$366,000 for the three and six months ended June 30, 2023, respectively, and \$173,000 and \$344,000 for the three and six months ended June 30, 2022. There were no significant variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases for the three and six months ended June 30, 2023 and 2022.

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

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities		
Cash paid for amounts included in the measurement of lease liabilities	\$ 482	\$ 352

The following summarizes additional information related to the operating lease:

	June 30, 2023
Weighted-average remaining lease term (in years)	5.1
Weighted-average discount rate	7.0 %

Manufacturing Agreements

The Company has entered into manufacturing supply agreements for the commercial supply of ZORYVE which include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately \$4.9 million within the next six months, and then approximately \$0.8 million per year for 2024 and 2025. This amount does not represent all of the Company's anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

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Indemnification

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

License Agreements

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

8. Long-term debt

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

The tranche A term loan under the Loan Agreement was funded on December 22, 2021 in the amount of \$75.0 million. With the approval of ZORYVE on July 29, 2022, the tranche B term loans were funded and the Company received \$125.0 million on August 2, 2022. The tranche C term loan is available following the achievement of a net product revenue milestone of \$110.0 million, calculated on a trailing six month basis. The tranche C term loan will remain available for funding until September 30, 2024.

Principal amounts outstanding under the Term Loans will accrue interest at a floating rate equal to the applicable rate in effect from time to time, as determined by SLR on the third business day prior to the funding date of the applicable Term Loan and on the first business day of the month prior to each payment date of each Term Loan. The applicable rate is a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (or on any successor or substitute published rate) for a term of one month, subject to a replacement with an alternate benchmark rate and spread in certain circumstances. On June 30, 2023, the rate was 12.61%. Starting in July 2023, the Secured Overnight Financing Rate (SOFR) for a term of one month was substituted for the benchmark rate. The maturity date for each term loan is January 1, 2027.

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

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

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on the Company's ability to dispose of its business or property, to change its line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on its property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock or to redeem capital stock. The Company has also agreed to a financial covenant whereby, beginning with the month ending December 31, 2023, the Company must generate net product revenue in excess of specified amounts for applicable measuring periods pursuant to the Loan and Security Agreement; provided, however, that such financial covenant shall not apply if the Company's average market capitalization over the trailing five day period prior to the last day of any measurement month is equal to or in excess of \$400.0 million. The Company was in compliance with all financial covenants under the Loan Agreement as of June 30, 2023.

In addition, the Loan Agreement contains customary events of default that entitle the lenders to cause any indebtedness under the Loan Agreement to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the Term Loans. Under the Loan Agreement, an event of default will occur if, among other things, the Company fails to make payments under the Loan Agreement, the Company breaches any of the covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches, the lenders determine that a material adverse change has occurred, or the Company or the Company's assets become subject to certain legal proceedings, such as bankruptcy proceedings. Upon the occurrence and for the duration of an event of default, an additional default interest rate, or the Default Rate, equal to 4.0% per annum will apply to all obligations owed under the Loan Agreement. The prepayment upon default and other potential additional interest provisions under the Loan Agreement were determined to be a compound embedded derivative instrument to be bifurcated from the loan and accounted for as a separate liability for accounting purposes under the guidance in ASC 815, *Derivatives and Hedging*. At the inception of the Loan Agreement and at each balance sheet date through June 30, 2023, the fair value of the embedded derivative was determined to be immaterial and will be remeasured at fair value each reporting period with any future changes in fair value reported in earnings.

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

The debt issuance costs have been recorded as a debt discount which are being accreted to interest expense through the maturity date of the term loan. Interest expense is calculated using the effective interest method, and is inclusive of non-cash amortization of debt issuance costs. The final maturity payment of \$13.7 million is recognized over the life of the term loan through interest expense. At June 30, 2023 and December 31, 2022, the effective interest rate was 14.61% and 13.79%, respectively. Interest expense relating to the term loan for the three and six months ended June 30, 2023 was \$7.4 million and \$14.4 million, respectively, and \$2.0 million and \$3.8 million for the three and six months ended June 30, 2022.

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

	June 30, 2023	December 31, 2022
Principal loan balance	\$ 200,000	\$ 200,000
Accrued final fee	3,360	1,871
Unamortized debt issuance costs	(3,593)	(4,102)
Long-term debt, net	<u>\$ 199,767</u>	<u>\$ 197,769</u>

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

9. Stockholders' Equity

Common Stock

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

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

	June 30, 2023	December 31, 2022
Options issued and outstanding	8,257,763	7,476,223
Common stock awards available for grant under employee incentive plans	4,134,115	3,784,386
Restricted stock units outstanding	2,912,694	1,576,529
Total common stock reserved	<u>15,304,572</u>	<u>12,837,138</u>

Authorized Share Capital

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

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10. Stock-Based Compensation

In January 2020, the Company's board of directors approved the 2020 Equity Incentive Plan (2020 Plan), which became effective January 30, 2020 in connection with the IPO. The 2020 Plan serves as the successor incentive award plan to the Company's 2017 Equity Incentive Plan (2017 Plan) and initially reserved 2,134,000 shares of common stock available for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit (RSU) awards, and other stock-based awards, plus 1,550,150 shares of common stock that were reserved for issuance pursuant to future awards under the 2017 Plan at the time the 2020 Plan became effective, plus shares represented by awards outstanding under the 2017 Plan that are forfeited or lapsed unexercised and which following the effective date of the 2020 Plan are not issued under the 2017 Plan. In addition, the 2020 Plan reserve will increase on January 1 of each year beginning in 2021 through 2030, by an amount equal to the lesser of (a) four percent of the shares of stock outstanding (on an as converted basis) on the day immediately prior to the date of increase and (b) such smaller number of shares of stock as determined by the Company's board of directors; provided, however, that no more than 11,000,000 shares of stock may be issued upon the exercise of incentive stock options. Accordingly, on January 1, 2023, 2022 and 2021, the 2020 Plan reserve increased by 2,442,090, 2,013,830 and 1,747,112 shares, respectively. As of June 30, 2023, the Company had 1,289,068 shares available for future grant under the 2020 Plan.

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

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

In December 2021, the Company's board of directors approved the 2022 Employment Inducement Incentive Plan (2022 Plan). The 2022 Plan initially reserved 1,250,000 shares of common stock available for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, RSU awards, and other stock-based awards. In November 2022, the 2022 Plan reserve was increased by 1,500,000. As of June 30, 2023, the Company had 1,320,260 shares available for future grant under the 2022 Plan.

Stock Option Activity

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

	Number of Options	Weighted- Average Exercise Price	Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance—December 31, 2022	7,476,223	\$ 19.93	7.98	\$ 18,667
Granted	1,185,110	\$ 14.84		
Exercised	(67,197)	\$ 2.59		
Forfeited	(260,006)	\$ 20.25		
Expired	(76,367)	\$ 26.99		
Balance—June 30, 2023	8,257,763	\$ 19.26	7.66	\$ 9,521
Exercisable—June 30, 2023 ⁽¹⁾	4,356,782	\$ 17.72	6.70	\$ 9,250

(1) Options exercisable includes early exercisable options.

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The aggregate intrinsic value is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of June 30, 2023. The intrinsic value of options exercised for the six months ended June 30, 2023 was \$0.7 million.

The total grant-date fair value of the options vested during the six months ended June 30, 2023 was \$14.9 million. The weighted-average grant-date fair value of employee options granted during the six months ended June 30, 2023 was \$10.25.

Restricted Stock Unit Activity

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

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2022	1,576,529	\$ 20.73
Granted	1,816,250	\$ 15.16
Vested	(362,535)	\$ 20.79
Forfeited	(117,550)	\$ 20.16
Unvested Balance—June 30, 2023	2,912,694	\$ 17.27

The grant date fair value of an RSU equals the closing price of the Company's common stock on the grant date. RSUs generally vest equally over four years. There were no RSU grants prior to January 1, 2020.

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	\$ 4,220	\$ 3,255	\$ 7,908	\$ 5,989
Selling, general, and administrative	6,358	4,841	12,149	8,640
Total stock-based compensation expense	\$ 10,578	\$ 8,096	\$ 20,057	\$ 14,629

As of June 30, 2023, there was \$53.6 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 2.5 years. As of June 30, 2023, there was \$44.4 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 3.2 years.

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

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

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

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

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

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

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

	Six Months Ended June 30, 2023	Year Ended December 31, 2022
Expected term (in years)	5.3 – 6.1	5.4 – 6.1
Expected volatility	75.2 – 77.1%	77.9 – 82.1%
Risk-free interest rate	3.5 – 4.3%	1.4 – 4.2%
Dividend yield	—%	—%

2020 Employee Stock Purchase Plan

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

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

Stock-based compensation expense related to the ESPP was \$233,000 and \$547,000 for the three and six months ended June 30, 2023, respectively, and \$212,000 and \$421,000 for the three and six months ended June 30, 2022, respectively.

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11. Net Loss Per Share

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

	As of June 30,	
	2023	2022
Stock options to purchase common stock	8,257,763	7,270,277
Early exercised options subject to future vesting	7,416	22,291
RSUs subject to future vesting	2,912,694	1,424,578
ESPP shares subject to future issuance	17,004	19,136
Total	<u>11,194,877</u>	<u>8,736,282</u>

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

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, and the audited financial statements and notes thereto as of and for the year ended December 31, 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2022, which has been filed with the Securities and Exchange Commission (SEC). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans, objectives, expectations, projections, and strategy for our business, includes forward-looking statements that involve risks and uncertainties. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties, and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. As a result of many factors, including those factors identified below and those set forth in the "Risk Factors" section of our Annual Report on Form 10-K, our actual results and the timing of selected events could differ materially from the forward-looking statements contained in the following discussion and analysis.

Overview

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

We launched our lead product, ZORYVE, in August 2022 after obtaining FDA approval for the treatment of plaque psoriasis, including psoriasis in the intertriginous areas (e.g. groin or axillae), in individuals 12 years of age or older. ZORYVE is approved for once-daily treatment of mild, moderate, and severe plaque psoriasis with no limitations on location or duration of use. In December 2022, we submitted a supplemental New Drug Application (sNDA) for ZORYVE for an expanded indication in plaque psoriasis down to the age of two, with potential FDA approval in the fourth quarter of 2023. In addition, we had our first commercial launch outside of the United States after receiving regulatory approval from Health Canada of ZORYVE in April 2023 for the treatment of plaque psoriasis in individuals 12 years or older. ZORYVE is a once-daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor. PDE4 is an established biological target in dermatology, with multiple PDE4 inhibitors approved by the FDA for the treatment of dermatological conditions.

In addition to the approval of ZORYVE for plaque psoriasis, we are also developing roflumilast cream for the treatment of atopic dermatitis. In atopic dermatitis, we have completed enrollment in three pivotal Phase 3 clinical studies: INTEGUMENT-1 and -2 enrolled subjects 6 years of age or older and INTEGUMENT-PED enrolled subjects between the ages of 2 and 5 years. In the fourth quarter of 2022, we announced positive topline data from both INTEGUMENT-1 and -2 in atopic dermatitis. We intend to submit an sNDA for topical roflumilast cream for the treatment of atopic dermatitis in patients aged, 6 years or older late in the third quarter or early in the fourth quarter of 2023, based on the results of INTEGUMENT-1 and -2. In May 2023, we announced the last subject enrolled in INTEGUMENT-PED, and we expect to provide topline data from this study in the third quarter of 2023. We then expect to submit a subsequent sNDA for the younger age cohort following the potential initial approval of roflumilast cream for treatment of atopic dermatitis in patients aged 6 years or older.

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

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

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

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

We have incurred net losses in each year since inception, including net losses of \$71.0 million and \$67.4 million for the three months ended June 30, 2023 and 2022, respectively, and net losses of \$151.1 million and \$131.7 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of \$870.9 million and cash, cash equivalents, restricted cash, and marketable securities of \$269.6 million. As of June 30, 2023, we had \$200.0 million outstanding under the Loan Agreement, with an additional \$25.0 million in funding that may become available subject to the satisfaction of specified conditions.

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

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

License Agreements & Acquisition

AstraZeneca License Agreement

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

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

Hengrui Exclusive Option and License Agreement

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

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

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

Ducentis Acquisition

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

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

Components of Our Results of Operations

Revenue

Product Revenue, Net

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

Other Revenue

Other revenue relates to the Iolyx Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Cost of Sales

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

Our cost of sales will reflect a lower average per unit cost of materials over the next two years approximately, due to inventory that was previously expensed. As of June 30, 2023 and December 31, 2022, the value of this inventory, mostly at the raw materials stage, was approximately \$11.5 million and \$14.1 million, respectively.

Operating Expenses

Research and Development Expenses

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

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

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

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

Selling, General and Administrative Expenses

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

Other Income, Net

Other income, net primarily consists of interest income earned on our cash, cash equivalents, and marketable securities.

Interest Expense

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

Results of Operations

Comparison of the Three Months Ended June 30, 2023 and 2022

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

	Three Months Ended June 30,		Change	
	2023	2022	\$	%
(in thousands)				
Revenues:				
Product revenue, net	\$ 4,770	\$ —	\$ 4,770	*
Other revenue	420	—	420	*
Total revenues	5,190	—	5,190	*
Operating expenses:				
Cost of sales	776	—	776	*
Research and development	25,219	38,205	(12,986)	(34)%
Selling, general, and administrative	45,958	27,622	18,336	66 %
Total operating expenses	71,953	65,827	6,126	9 %
Loss from operations	(66,763)	(65,827)	(936)	1 %
Other income (expense):				
Other income, net	3,121	421	2,700	641 %
Interest expense	(7,349)	(2,000)	(5,349)	267 %
Total other income (expense)	(4,228)	(1,579)	(2,649)	168 %
Net loss	\$ (70,991)	\$ (67,406)	\$ (3,585)	5 %

*Not applicable

Product revenue, net

We began recording U.S. product revenue in the third quarter of 2022 following the FDA approval and subsequent commercial launch of ZORYVE in August 2022, and Canada product revenue in the second quarter of 2023 following the Health Canada approval and subsequent commercial launch of ZORYVE in June 2023. During the three months ended June 30, 2023, we recognized \$4.8 million of net product revenue related to sales of ZORYVE. Revenue was primarily driven by end customer demand, partially offset by sales discounts, which consisted primarily of co-pay assistance discounts, distribution fees, and managed care rebates.

Other revenue

Other revenue is a result of shares of common stock acquired in connection with the Iolyx Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Cost of Sales

Cost of sales of \$0.8 million for the three months ended June 30, 2023 is related primarily to product costs incurred after FDA approval of ZORYVE, amortization of intangible assets as a result of the milestone payment to AstraZeneca in connection with the FDA approval of ZORYVE, as well as royalties on net sales payable to AstraZeneca under a license agreement. Prior to the date on which the initial regulatory approval was received, costs of raw materials were recorded as research and development expense. Therefore, cost of sales will reflect a lower average per unit cost until the related inventory is sold, which is expected to occur over the next two years. See Note 6 to the condensed consolidated financial statements for additional information.

Research and Development Expenses

	Three Months Ended June 30,		Change	
	2023	2022	\$	%
	(in thousands)			
Direct external costs:				
Topical roflumilast program	\$ 6,770	\$ 21,089	\$ (14,319)	(68)%
Topical JAK inhibitor program	682	430	252	59 %
Other early stage programs	710	197	513	260 %
Indirect costs:				
Compensation and personnel-related	11,659	10,191	1,468	14 %
Other	5,398	6,298	(900)	(14)%
Total research and development expense	<u>\$ 25,219</u>	<u>\$ 38,205</u>	<u>\$ (12,986)</u>	<u>(34)%</u>

Research and development expenses decreased by \$13.0 million, or 34%, for the three months ended June 30, 2023 compared to the three months ended June 30, 2022. The decrease was primarily due to the completion of Phase 3 studies of roflumilast cream in atopic dermatitis and roflumilast foam in seborrheic dermatitis and scalp and body psoriasis. Additionally, manufacturing costs recorded as research and development expenses decreased as we began capitalizing such costs to inventory upon FDA approval of ZORYVE in July 2022.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by \$18.3 million, or 66%, for the three months ended June 30, 2023 compared to the three months ended June 30, 2022. The increase was primarily due to higher compensation and personnel-related expenses of \$10.0 million, higher sales and marketing expenses of \$5.8 million, and higher professional services of \$1.8 million. These increases were primarily due to our commercialization efforts, including the hiring of our sales force.

Other Income, Net

Other income, net increased by \$2.7 million for the three months ended June 30, 2023 compared to the three months ended June 30, 2022, primarily due to the impact of higher interest rates, partially offset by a lower marketable securities balance.

Interest Expense

Interest expense increased by \$5.3 million for the three months ended June 30, 2023 compared to the three months ended June 30, 2022, due to an increase in our long-term debt balance and the impact of higher interest rates. See Note 8 to the condensed consolidated financial statements for additional information.

Comparison of the Six Months Ended June 30, 2023 and 2022

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

	Six Months Ended June 30,		Change	
	2023	2022	\$	%
	(unaudited)			
	(in thousands)			
Revenues:				
Product revenue, net	\$ 7,551	\$ —	\$ 7,551	*
Other revenue	420	—	420	*
Total revenues	<u>7,971</u>	<u>—</u>	<u>7,971</u>	*
Operating expenses:				
Cost of sales	1,559	—	1,559	*
Research and development	60,564	78,827	(18,263)	(23)%
Selling, general, and administrative	88,876	49,628	39,248	79 %
Total operating expenses	<u>150,999</u>	<u>128,455</u>	<u>22,544</u>	18 %
Loss from operations	<u>(143,028)</u>	<u>(128,455)</u>	<u>(14,573)</u>	11 %
Other income (expense):				
Other income, net	6,328	563	5,765	1024 %
Interest expense	<u>(14,391)</u>	<u>(3,838)</u>	<u>(10,553)</u>	275 %
Total other income (expense)	<u>(8,063)</u>	<u>(3,275)</u>	<u>\$ (4,788)</u>	146 %
Net loss	<u>\$ (151,091)</u>	<u>\$ (131,730)</u>	<u>\$ (19,361)</u>	15 %

*Not applicable

Product revenue, net

We began recording product revenue in the third quarter of 2022 following the approval of ZORYVE by the FDA and our subsequent commercial launch in the United States in August 2022, and Canada product revenue in the second quarter of 2023 following the Health Canada approval and subsequent commercial launch of ZORYVE in June 2023. During the six months ended June 30, 2023, we recognized \$7.6 million of net product revenue related to sales of ZORYVE. Revenue was driven by end customer demand. Sales discounts consisted primarily of co-pay card discounts and distribution fees.

Other revenue

Other revenue is a result of shares of common stock acquired in connection with the Iolyx Agreement. See Note 6 to the condensed consolidated financial statements for additional information.

Cost of Sales

Cost of sales of \$1.6 million for the six months ended June 30, 2023 is related primarily to amortization of intangible assets as a result of the milestone payment to AstraZeneca in connection with the FDA approval of ZORYVE and product costs incurred after FDA approval of ZORYVE. Prior to the date on which the initial regulatory approval was received, costs of raw materials were recorded as research and development expense. Therefore, cost of sales will reflect a lower average per unit cost until the related inventory is sold, which is expected to occur over the next two years. See Note 6 to the condensed consolidated financial statements for additional information.

Research and Development Expenses

	Six Months Ended June 30,		Change	
	2023	2022	\$	%
	(unaudited)			
	(in thousands)			
Direct external costs:				
Topical roflumilast program	\$ 22,955	\$ 46,311	\$ (23,356)	(50)%
Topical JAK inhibitor program	1,854	1,393	461	33 %
Other early stage programs	1,843	492	1,351	275 %
Indirect costs:				
Compensation and personnel-related	22,494	19,630	2,864	15 %
Other	11,418	11,001	417	4 %
Total research and development expense	\$ 60,564	\$ 78,827	\$ (18,263)	(23)%

Research and development expenses decreased by \$18.3 million, or 23%, for the six months ended June 30, 2023 compared to the six months ended June 30, 2022. The decrease was primarily due to the completion of Phase 3 studies of roflumilast cream in atopic dermatitis and roflumilast foam in seborrheic dermatitis and scalp and body psoriasis. The decrease was partially offset by an increase in compensation and personnel-related expenses, which includes stock-based compensation, primarily due to an increase in headcount.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by \$39.2 million, or 79%, for the six months ended June 30, 2023 compared to the six months ended June 30, 2022. The increase was primarily due to an increase in compensation and personnel-related expenses of \$21.0 million, an increase in sales and marketing expenses of \$13.4 million, and an increase in professional services of \$3.4 million. These increases were primarily related to commercialization efforts for ZORYVE.

Other Income, Net

Other income, net increased by \$5.8 million for the six months ended June 30, 2023 compared to the six months ended June 30, 2022, primarily due to the impact of higher interest rates, partially offset by a lower marketable securities balance.

Interest Expense

Interest expense increased by \$10.6 million for the six months ended June 30, 2023 compared to the six months ended June 30, 2022, due to an increase in our long-term debt balance and the impact of higher interest rates. See Note 8.

Liquidity, Capital Resources, and Requirements

Sources of Liquidity

To date, our primary sources of capital have been private placements of preferred stock, our IPO completed in January 2020, our follow-on financings in October 2020, February 2021, and August 2022, our Loan Agreement, our ATM, and revenue from the sale of our approved product. We have incurred operating losses since our inception and have an accumulated deficit as a result of ongoing efforts to develop and commercialize our products and product candidates, including conducting nonclinical and clinical trials and providing selling, general and administrative support for these operations. As of June 30, 2023, we had cash, cash equivalents, restricted cash, and marketable securities of \$269.6 million, and an accumulated deficit of \$870.9 million. We maintain cash balances with financial institutions in excess of insured limits. As of June 30, 2023, we had \$200.0 million outstanding under the Loan Agreement, with an additional \$25.0 million in funding that may become available subject to the satisfaction of specified conditions. See Notes 1 and 8 to the condensed consolidated financial statements for additional information.

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

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

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

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

Indebtedness

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

The tranche A term loan was funded on December 22, 2021. Following the approval of ZORYVE, we drew down \$125.0 million on the tranche B term loans, which we received in August 2022. See Notes 1 and 8 to the condensed consolidated financial statements for additional information. The tranche C term loan is available following the achievement of a net product revenue milestone of \$110.0 million, calculated on a trailing six month basis. The tranche C term loan will remain available for funding until September 30, 2024.

Principal amounts outstanding under the Term Loans will accrue interest at a floating rate equal to the applicable rate in effect from time to time, as determined by SLR on the third business day prior to the funding date of the applicable Term Loan and on the first business day of the month prior to each payment date of each Term Loan. The applicable rate is a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (or on any successor or substitute published rate) for a term of one month, subject to a replacement with an alternate benchmark rate and spread in certain circumstances. On June 30, 2023, the rate was 12.61%. Starting in July 2023, the Secured Overnight Financing Rate (SOFR) for a term of one month was substituted for the benchmark rate.

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

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

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, restrictions on our ability to merge or consolidate with any other entity, to incur additional indebtedness, or to pay any dividends or other distributions on capital stock. We have also agreed to a financial covenant whereby, beginning with the month ending December 31, 2023, we must generate net product revenue in excess of specified amounts for applicable measuring periods pursuant to the Loan and Security Agreement; provided, however, that such financial covenant shall not apply if our average market capitalization over the trailing five day period prior to the last day of any measurement month is equal to or in excess of \$400.0 million. We were in compliance with all covenants under the Loan Agreement as of June 30, 2023.

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

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

Cash Flows

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

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
Cash used in operating activities	\$ (146,829)	\$ (118,955)
Cash provided by investing activities	196,869	67,862
Cash provided by financing activities	1,167	15,847
Effect of exchange rate changes on cash	(43)	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	<u>\$ 51,164</u>	<u>\$ (35,246)</u>

Net Cash Used in Operating Activities

During the six months ended June 30, 2023, net cash used in operating activities was \$146.8 million, which consisted of a net loss of \$151.1 million and a change in net operating assets and liabilities of \$14.7 million, partially offset by net non-cash charges of \$19.0 million. The net non-cash charges were primarily related to stock-based compensation expense of \$20.1 million.

During the six months ended June 30, 2022, net cash used in operating activities was \$119.0 million, which consisted of a net loss of \$131.7 million and a change in net operating assets and liabilities of \$4.0 million, partially offset by net non-cash charges of \$16.8 million. The net non-cash charges were primarily related to stock-based compensation expense of \$14.6 million.

Net Cash Provided by Investing Activities

During the six months ended June 30, 2023, net cash provided by investing activities was \$196.9 million, which was comprised primarily of proceeds from the maturities of marketable securities of \$282.5 million, partially offset by purchases of marketable securities of \$85.3 million.

During the six months ended June 30, 2022, net cash provided by investing activities was \$67.9 million, which was comprised primarily of proceeds from the maturities of marketable securities of \$203.8 million, partially offset by purchases of marketable securities of \$135.7 million.

Net Cash Provided by Financing Activities

During the six months ended June 30, 2023, net cash provided by financing activities was \$1.2 million, which was comprised primarily of \$1.0 million in proceeds from the issuance of common stock as part of our ESPP.

During the six months ended June 30, 2022, net cash provided by financing activities was \$15.8 million, which was comprised primarily of the net cash proceeds received from shares sold under our ATM of \$14.5 million.

Contractual Obligations and Contingent Liabilities

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

Facility Operating Lease

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

The lease is subject to fixed rate escalation increases with an initial base rent of \$76,000 per month and includes rent free periods aggregating approximately one year. The amended lease agreement required that we deliver a letter of credit to the landlord of \$1.5 million upon occupying the space, which is allowed to be reduced throughout the lease period as rent obligations are met. Accordingly, as of June 30, 2023, we have a letter of credit and related restricted cash account of \$0.9 million. The total commitment under the operating lease agreement is \$5.3 million, including \$0.5 million for the remaining six months of 2023, \$1.0 million for each of the years 2024 through 2025, \$1.1 million for each of the years 2026 through 2027, and \$0.6 million for the year 2028. See Note 7 to the condensed consolidated financial statements for additional information.

Long-Term Debt Obligations

As of June 30, 2023, we had \$200.0 million outstanding under our Loan Agreement. We have \$25.0 million in additional funding remaining that may become available subject to the satisfaction of specified conditions. See Notes 1 and 8 to the condensed consolidated financial statements for additional information. The total commitment under the Loan Agreement as of June 30, 2023 is \$304.2 million, including \$13.0 million for the remaining six months of 2023, \$25.9 million for the year 2024, \$25.7 million for each of the years 2025 through 2026, and \$213.9 million for the year 2027. These amounts do not represent or include any future draw downs, but instead represent only the contractually obligated minimum payments of interest, principal, and loan fees related to the funding of the \$75.0 million tranche A term loan on December 22, 2021 and the \$125.0 million tranche B term loan on August 2, 2022.

License Agreements & Acquisition

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

Manufacturing Agreements

We have entered into manufacturing supply agreements for the commercial supply of ZORYVE, which include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately \$4.9 million within the next six months, and approximately \$0.8 million per year for 2024 and 2025. This amount does not represent all of our anticipated purchases, but instead represents only the contractually obligated minimum purchases or firm commitments of non-cancelable minimum amounts.

Indemnification

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

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

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Use of Estimates

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

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of June 30, 2023, we had cash and cash equivalents of \$105.1 million, restricted cash of \$0.9 million, and marketable securities of \$163.6 million; which consist of bank deposits, money market funds, commercial paper, government securities, and corporate debt securities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio.

In addition, as of June 30, 2023, we had \$200.0 million outstanding under our Loan Agreement. Amounts outstanding under our Loan Agreement bear interest at a floating rate equal a per annum interest rate equal to 7.45% plus the greater of (a) 0.10% and (b) the per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (or on any successor or substitute published rate) for a term of one month, subject to a replacement with an alternate benchmark rate and spread in certain circumstances. Starting in July 2023, the Secured Overnight Financing Rate (SOFR) for a term of one month was substituted for the benchmark rate. As a result, we are exposed to risks related to our indebtedness from changes in interest rates. Based on the amount outstanding under our Loan Agreement as of June 30, 2023, for every 100 basis point increase in the interest rates, we would incur approximately \$2.0 million of additional annual interest expense. We do not currently engage in hedging transactions to manage our exposure to interest rate risk, but higher interest expense would be offset in part by higher earnings on our cash and marketable securities. We may in the future use swaps, caps, collars, structured collars or other common derivative financial instruments to reduce interest rate risk. It is difficult to predict the effect that future hedging activities would have on our operating results.

We are exposed to foreign currency exchange risk as our Canadian subsidiary operates with the Canadian dollar as its functional currency. The majority of our transactions occur in U.S. dollars. The fluctuation in the value of the U.S. dollar against the Canadian dollar affects the reported amounts of expenses, assets and liabilities. If we expand our international operations our exposure to exchange rate fluctuations will increase. At June 30, 2023 we had cash balances denominated in Canadian dollars of \$1.3 million. We currently do not hedge any foreign currency exposure. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have a material impact on our condensed consolidated financial statements.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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 June 30, 2023, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such required information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Management Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an assessment of the effectiveness of our internal control over financial reporting based on our assessment on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of our assessment, our management concluded that our internal control over financial reporting was effective as of June 30, 2023.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the six months ended June 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

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

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

- (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

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

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

For a discussion of our potential risks and uncertainties, see the information in Part I, "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022. Other than the risk factors set forth below, there have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

We are a "smaller reporting company," and as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

Beginning with this Quarterly Report on Form 10-Q, we have re-qualified as a smaller reporting company. We are therefore entitled to take advantage of many of the same exemptions from disclosure requirements as an emerging growth company, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, as a smaller reporting company with expected annual revenue of less than \$100 million at the end of this fiscal year, we will qualify as a non-accelerated filer and thus be exempt from the requirement to obtain an auditor attestation on the effectiveness of our internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company and/or a non-accelerated filer may make it harder for investors to analyze our results of operations and financial prospects.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could undermine the credibility of our operating results, harm investors' views of us and, as a result, the value of our common stock.

We are subject to Section 404 of the Sarbanes-Oxley Act, which generally requires a company's management to report upon the effectiveness of internal control over financial reporting and an independent registered public accounting firm to attest to the effectiveness of internal control over financial reporting in annual reports on Form 10-K. Pursuant to Section 404(a), we are required to file with the SEC an annual management assessment of the effectiveness of our internal control over financial reporting. However, because we re-qualified as a smaller reporting company and expect to have less than \$100 million in annual revenue at the end of this fiscal year, we will qualify as a non-accelerated filer and thus will no longer be required to comply with the auditor attestation requirements regarding the effectiveness of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act until we become an accelerated filer or large accelerated filer.

Our management's assessment of the effectiveness of our internal control over financial reporting needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis. If we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The effectiveness of our controls and procedures may be limited by a variety of factors, including faulty human judgment and simple errors, omissions or mistakes; fraudulent action of an individual or collusion of two or more people; inappropriate management override of procedures; and the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control.

While we believe our internal control over financial reporting is currently effective, the effectiveness of our internal controls in future periods is subject to the risk that our controls may become inadequate because of changes in conditions. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments and would increase our costs of doing business. We can give no assurance that material weaknesses in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements and cause us to fail to meet our reporting obligations. Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially and adversely affect our business, financial condition, results of operations and prospects.

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

None.

Issuer Purchases of Equity Securities

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Trading Plans

On June 12, 2023, Todd Franklin Watanabe, President, Chief Executive Officer and Director, adopted a Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 109,025 shares of the Company's common stock until September 6, 2024.

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

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

SIGNATURES

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

ARCUTIS BIOTHERAPEUTICS, INC.

Date: August 08, 2023

By: /s/ Todd Franklin Watanabe
Todd Franklin Watanabe
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 08, 2023

By: /s/ Scott L. Burrows
Scott L. Burrows
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

I, Scott L. Burrows, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arcutis Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2023

By: _____ /s/ Scott L. Burrows
Scott L. Burrows
Chief Financial Officer
(Principal Accounting and Financial Officer)

