

**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, 2022

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 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 July 29, 2022 was 51,562,525.

## 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, 2022. 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 Balance Sheets  
(In thousands, except share and par value)

	June 30, 2022 (unaudited)	December 31, 2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 61,512	\$ 96,449
Restricted cash	1,233	1,542
Marketable securities	220,657	290,610
Prepaid expenses and other current assets	12,024	14,172
Total current assets	295,426	402,773
Property, plant, and equipment, net	2,078	2,261
Operating lease right-of-use asset	2,882	3,040
Other assets	78	78
Total assets	<u>\$ 300,464</u>	<u>\$ 408,152</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 8,437	\$ 7,353
Accrued liabilities	18,463	25,540
Operating lease liability	582	433
Total current liabilities	27,482	33,326
Operating lease liability, noncurrent	4,450	4,774
Long-term debt, net	73,138	72,350
Other long-term liabilities	12	25
Total liabilities	105,082	110,475
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at June 30, 2022 and December 31, 2021; no shares issued and outstanding at June 30, 2022 and December 31, 2021;	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized at June 30, 2022 and December 31, 2021; 51,548,438 and 50,345,755 shares issued at June 30, 2022 and December 31, 2021, respectively; 51,526,153 and 50,255,614 shares outstanding at June 30, 2022 and December 31, 2021, respectively	5	5
Additional paid-in capital	736,665	706,233
Accumulated other comprehensive loss	(1,252)	(255)
Accumulated deficit	(540,036)	(408,306)
Total stockholders' equity	195,382	297,677
Total liabilities and stockholders' equity	<u>\$ 300,464</u>	<u>\$ 408,152</u>

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

**ARCUTIS BIOTHERAPEUTICS, INC.**  
**Condensed 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,	
	2022	2021	2022	2021
<b>Operating expenses:</b>				
Research and development	\$ 38,205	\$ 30,765	\$ 78,827	\$ 52,396
General and administrative	27,622	11,315	49,628	25,769
Total operating expenses	65,827	42,080	128,455	78,165
Loss from operations	(65,827)	(42,080)	(128,455)	(78,165)
<b>Other income (expense):</b>				
Other income, net	421	72	563	115
Interest expense	(2,000)	—	(3,838)	—
Total other income (expense)	(1,579)	72	(3,275)	115
Net loss	\$ (67,406)	\$ (42,008)	\$ (131,730)	\$ (78,050)
<b>Other comprehensive loss:</b>				
Unrealized loss on marketable securities	(232)	(78)	(997)	(34)
Comprehensive loss	\$ (67,638)	\$ (42,086)	\$ (132,727)	\$ (78,084)
<b>Per share information:</b>				
Net loss per share, basic and diluted	\$ (1.31)	\$ (0.84)	\$ (2.58)	\$ (1.60)
Weighted-average shares used in computing net loss per share, basic and diluted	51,422,386	50,000,716	50,970,465	48,648,262

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

**ARCUTIS BIOTHERAPEUTICS, INC.**  
**Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
(In thousands, except share data)  
(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance—December 31, 2020	—	\$ —	43,338,438	\$ 4	\$ 472,569	\$ (2)	\$ (201,950)	\$ 270,621
Issuance of shares of common stock for initial public offering, net of issuance costs of \$603	—	—	6,325,000	1	207,489	—	—	207,490
Issuance of common stock upon the exercise of stock options	—	—	111,282	—	325	—	—	325
Issuance of common stock upon the vesting of restricted stock units	—	—	32,362	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	79,925	—	53	—	—	53
Stock-based compensation expense	—	—	—	—	8,503	—	—	8,503
Unrealized gain on marketable securities	—	—	—	—	—	44	—	44
Net loss	—	—	—	—	—	—	(36,042)	(36,042)
Balance—March 31, 2021	—	\$ —	49,887,007	\$ 5	\$ 688,939	\$ 42	\$ (237,992)	\$ 450,994
Issuance of common stock upon the exercise of stock options	—	—	62,314	—	710	—	—	710
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	73,623	—	52	—	—	52
Shares issued pursuant to the employee stock purchase plan	—	—	22,658	—	478	—	—	478
Stock-based compensation expense	—	—	—	—	4,340	—	—	4,340
Unrealized loss on marketable securities	—	—	—	—	—	(78)	—	(78)
Net loss	—	—	—	—	—	—	(42,008)	(42,008)
Balance—June 30, 2021	—	\$ —	50,045,602	\$ 5	\$ 694,519	\$ (36)	\$ (280,000)	\$ 414,488

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

**ARCUTIS BIOTHERAPEUTICS, INC.**  
**Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
(In thousands, except share data)  
(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance—December 31, 2021	—	\$ —	50,255,614	\$ 5	\$ 706,233	\$ (255)	\$ (408,306)	\$ 297,677
Issuance of shares of common stock under ATM, net of issuance costs of \$634	—	—	882,353	—	14,366	—	—	14,366
Issuance of common stock upon the exercise of stock options	—	—	102,935	—	260	—	—	260
Issuance of common stock upon the vesting of restricted stock units	—	—	79,421	—	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	40,025	—	25	—	—	25
Stock-based compensation expense	—	—	—	—	6,533	—	—	6,533
Unrealized loss on marketable securities	—	—	—	—	—	(765)	—	(765)
Net loss	—	—	—	—	—	—	(64,324)	(64,324)
Balance—March 31, 2022	—	\$ —	51,360,348	\$ 5	\$ 727,417	\$ (1,020)	\$ (472,630)	\$ 253,772
Issuance of common stock upon the exercise of stock options	—	—	57,113	—	156	—	—	156
Issuance of common stock upon the vesting of restricted stock units	—	—	6,625	—	—	—	—	—
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 financial statements.*

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

	Six Months Ended June 30,	
	2022	2021
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (131,730)	\$ (78,050)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	305	202
Non-cash lease expense	158	158
Net amortization/accretion on marketable securities	890	1,415
Non-cash interest expense	788	—
Stock-based compensation expense	14,629	12,843
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,059	(9,805)
Accounts payable	1,166	(4,386)
Accrued liabilities	(7,045)	(4,585)
Operating lease liabilities	(175)	174
Net cash used in operating activities	(118,955)	(82,034)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of marketable securities	(135,745)	(211,876)
Proceeds from maturities of marketable securities	203,811	109,550
Purchases of property and equipment	(204)	(597)
Net cash provided by (used in) investing activities	67,862	(102,923)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock upon exercise of stock options	416	1,035
Proceeds from issuance of shares under ATM, net of issuance costs	14,455	—
Proceeds from issuance of common stock, net of issuance costs	—	207,490
Proceeds from issuance of common stock pursuant to employee stock purchase plan	976	478
Net cash provided by financing activities	15,847	209,003
Net increase (decrease) in cash, cash equivalents, and restricted cash	(35,246)	24,046
Cash, cash equivalents, and restricted cash at beginning of period	97,991	66,624
Cash, cash equivalents, and restricted cash at end of period	\$ 62,745	\$ 90,670
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:</b>		
Interest expense paid in cash	\$ 2,989	\$ —

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



**ARCUTIS BIOTHERAPEUTICS, INC.**  
**Notes to Condensed 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 individuals with plaque psoriasis, including intertriginous psoriasis, in individuals 12 years of age and older. See Note 12. The Company's current portfolio is comprised of highly differentiated topical 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 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 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 IPO issuing and selling 10,781,250 shares of common stock at a public offering price of \$17.00 per share, including 1,406,250 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares. The aggregate net proceeds received by the Company from the offering were approximately \$167.2 million, after deducting underwriting discounts, commissions, and offering related transaction costs. Upon the closing of the IPO, all of the outstanding shares of convertible preferred stock automatically converted into shares of common stock. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

On October 6, 2020, the Company completed a public offering of 4,000,000 shares of common stock at an offering price of \$25.00 per share, receiving aggregate net proceeds of approximately \$93.4 million after deducting the underwriting discounts, commissions, and offering related transaction costs. In addition, the Company concurrently sold 1,400,000 shares of common stock in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at a price per share equal to the public offering price, receiving net proceeds of \$35.0 million.

On February 5, 2021, the Company completed a public offering of 6,325,000 shares of common stock at an offering price of \$35.00 per share, including 825,000 shares sold pursuant to the underwriters full exercise of their option to purchase additional shares. The aggregate net proceeds received by the Company were approximately \$207.5 million, after deducting underwriting discounts, commissions, and offering related transaction costs.

On August 2, 2022, the Company priced a public offering of 8,625,000 shares of common stock at an offering price of \$20.00 per share, including the underwriters full exercise of their option to purchase an additional 1,125,000 shares. The aggregate net proceeds to the Company from the offering, including the exercise of the underwriters' option to purchase additional shares, are expected to be \$161.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. The offering is expected to close on August 5, 2022. See Note 12.

***At-the-Market 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 at-the-market (ATM) offerings for an aggregate offering price of up to \$100.0 million. Cowen will act as the Company's sales agent for the ATM program and is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold under the Sales Agreement. In March 2022, the Company sold 882,353 shares under the ATM for \$17.00 per share and received \$14.5 million in net proceeds.

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

### ***Liquidity***

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of \$540.0 million and \$408.3 million as of June 30, 2022 and December 31, 2021, respectively. The Company had cash, cash equivalents, restricted cash, and marketable securities of \$283.4 million and \$388.6 million as of June 30, 2022 and December 31, 2021, respectively. As of June 30, 2022, the Company had \$75.0 million outstanding under the Loan Agreement. Upon FDA approval of ZORYVE in July 2022, \$125.0 million of additional funding became available under the Loan Agreement which the Company drew down and received on August 2, 2022. After this draw down, the Company will have \$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. On August 2, 2022, the Company priced a public offering of its common stock, from which it expects to receive net proceeds of approximately \$161.7 million. The offering is expected to close on August 5, 2022. See Notes 8 and 12.

Prior to selling common stock in its IPO, the Company had historically financed its operations primarily through the sale of its convertible preferred stock. Management expects operating losses to continue for the foreseeable future.

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 balances, 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.

### ***Coronavirus Outbreak***

In March 2020, the World Health Organization declared a pandemic related to the global novel coronavirus disease 2019 (COVID-19) outbreak. The Company is monitoring the impact COVID-19 may have on the clinical development of its product candidates, including potential delays or modifications to its ongoing and planned trials, as well as its planned commercial activities. The Company believes that the rapid spread of the Omicron variant in late 2021 and early 2022 likely had a minor impact on the enrollment of our clinical trials. Because of this likely impact along with the inherent challenges of enrolling young children in clinical trials, the Company has updated its expected timeline for providing topline data for the INTEGUMENT-PED trial, in atopic dermatitis subjects between two and five years of age, to 2023. The Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its financial condition and operations, including ongoing and planned clinical trials and commercial activities.

## ***2. Summary of Significant Accounting Policies***

### ***Basis of Presentation***

The Company's condensed financial statements have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP).

### ***Use of Estimates***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed 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 accruals for research and development activities, fair value of common stock and convertible preferred stock (prior to the IPO completed in January 2020), 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.

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

**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 Financial Statements**

The interim condensed balance sheet as of June 30, 2022, the interim condensed statements of operations and comprehensive loss, and the condensed changes in convertible preferred stock and stockholders' equity (deficit) and cash flows for the three and six months ended June 30, 2022 and 2021 are unaudited. These unaudited interim condensed 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 financial statements related to the three month periods are also unaudited. The condensed results of operations for the three and six months ended June 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 or for any other future annual or interim period. The condensed balance sheet as of December 31, 2021 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 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, 2021.

**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, 2022 and December 31, 2021, the Company held \$1.2 million and \$1.5 million, respectively, of restricted cash as collateral for a letter of credit related to our amended office space lease. See Note 7.

**Marketable Securities**

Marketable securities consist of investment grade short to intermediate-term fixed income investments that have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in fixed income securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase, including those that have maturity dates beyond one year from the balance sheet date, are classified as current assets on the condensed 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). Realized gains and losses as well as credit losses, if any, on marketable securities are 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. Unrealized gains and losses on marketable securities are reported as a component of accumulated other comprehensive income (loss) on the condensed balance sheets. Interest on marketable securities is included in other income, net.

**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, and marketable securities. 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 the financial institutions holding its cash to the extent recorded on the condensed balance sheets.

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

Management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

***Fair Value Measurement***

The Company's financial instruments, in addition to those presented in Note 3, include cash equivalents, accounts payable, accrued liabilities, and long-term debt. The carrying amount of cash equivalents, 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 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, 2022 and 2021.

***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.

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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.

***Nonclinical and Clinical Accruals and Costs***

The Company records accrued liabilities for estimated costs of 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 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, 2022 and 2021, the Company has not experienced any material differences between accrued costs and actual costs incurred.

***Convertible Preferred Stock***

Prior to its IPO, the Company classified its outstanding convertible preferred stock outside of stockholders' equity (deficit) on its condensed balance sheets as the requirements of triggering a deemed liquidation event, as defined within its amended and restated certificate of incorporation, were not entirely within the Company's control. In the event of such a deemed liquidation event, the proceeds from the event were to be distributed in accordance with the liquidation preferences, provided that the holders of convertible preferred stock had not converted their shares into common stock. The Company recorded the issuance of convertible preferred stock at the issuance price less related issuance costs. The Company did not adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty as to whether or when a deemed liquidation event may have occurred. In connection with the IPO in February 2020, the Company's outstanding shares of convertible preferred stock were automatically converted into 24,385,388 shares of common stock.

***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.

***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.

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**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 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.

The U.S. Congress enacted the American Rescue Plan Act on March 10, 2021, Families First Coronavirus Response Act (FFCR Act) on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) on March 27, 2020. The American Rescue Plan Act is a follow-up to the CARES Act, which continue the emergency economic stimulus package and includes spending and tax breaks to strengthen the U.S. economy and fund a nationwide effort to curtail the effect of COVID-19. The American Rescue Plan Act, FFCR Act, and CARES Act include numerous tax-related provisions, including modifications to the limitations on business interest expense and net operating losses (NOLs), certain refundable employee retention credits, as well as a payment delay of employer payroll taxes in 2020 after the date of enactment. The Company does not expect the American Rescue Plan Act, FFCR Act, or CARES Act to have a material impact on the Company's financial statements.

**Variable Interest Entities**

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 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.

**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 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, 2022			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds <sup>(1)</sup>	\$ 61,512	\$ —	\$ —	\$ 61,512
Commercial paper	—	50,932	—	50,932
Corporate debt securities	—	55,198	—	55,198
U.S. Treasury securities	114,527	—	—	114,527
Total assets	<u>\$ 176,039</u>	<u>\$ 106,130</u>	<u>\$ —</u>	<u>\$ 282,169</u>

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

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds <sup>(1)</sup>	\$ 95,145	\$ —	\$ —	\$ 95,145
Commercial paper	—	119,413	—	119,413
Corporate debt securities	—	114,324	—	114,324
U.S. Treasury securities	58,177	—	—	58,177
Total assets	<u>\$ 153,322</u>	<u>\$ 233,737</u>	<u>\$ —</u>	<u>\$ 387,059</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, 2022			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
<b>Cash and cash equivalents:</b>				
Money market funds <sup>(1)</sup>	\$ 61,512	\$ —	\$ —	\$ 61,512
Total cash and cash equivalents	<u>\$ 61,512</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 61,512</u>
<b>Marketable securities:</b>				
Commercial paper	\$ 50,932	\$ —	\$ —	\$ 50,932
Corporate debt securities	55,448	—	(250)	55,198
U.S. Treasury securities	115,529	—	(1,002)	114,527
Total marketable securities	<u>\$ 221,909</u>	<u>\$ —</u>	<u>\$ (1,252)</u>	<u>\$ 220,657</u>

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

	December 31, 2021			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated fair value
<b>Cash and cash equivalents:</b>				
Money market funds <sup>(1)</sup>	\$ 95,145	\$ —	\$ —	\$ 95,145
Corporate debt securities	1,304	—	—	1,304
Total cash and cash equivalents	<u>\$ 96,449</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 96,449</u>
<b>Marketable securities:</b>				
Commercial paper	\$ 119,413	\$ —	\$ —	\$ 119,413
Corporate debt securities	113,145	—	(125)	113,020
U.S. Treasury securities	58,307	—	(130)	58,177
Total marketable securities	<u>\$ 290,865</u>	<u>\$ —</u>	<u>\$ (255)</u>	<u>\$ 290,610</u>

(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, 2022 and 2021 were not material. As of June 30, 2022 and December 31, 2021, unrealized credit losses on marketable securities were not material, and accordingly, no allowance for credit losses were recorded. As of June 30, 2022 and December 31, 2021, 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.



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**4. Balance Sheet Components****Prepaid Expenses and Other Current Assets**

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

	June 30, 2022	December 31, 2021
Prepaid clinical trial costs	\$ 2,416	\$ 5,629
Prepaid insurance	1,986	518
Other prepaid expenses and current assets	7,622	8,025
Total prepaid expenses and other current assets	<u>\$ 12,024</u>	<u>\$ 14,172</u>

**Accrued Liabilities**

Accrued liabilities consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Clinical trial accruals	\$ 8,782	\$ 13,217
Accrued compensation	5,907	9,130
Accrued expenses and other current liabilities	3,774	3,193
Total accrued liabilities	<u>\$ 18,463</u>	<u>\$ 25,540</u>

**5. Property and Equipment, net**

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

	June 30, 2022	December 31, 2021
Computer hardware	\$ 841	\$ 775
Furniture and fixtures	379	346
Software	104	104
Construction in process	22	—
Leasehold improvements	1,568	1,568
Property and equipment, gross	2,914	2,793
Less accumulated depreciation	(836)	(532)
Property and equipment, net	<u>\$ 2,078</u>	<u>\$ 2,261</u>

Depreciation expense was \$155,000 and \$305,000 for the three and six months ended June 30, 2022, respectively, and \$104,000 and \$202,000 for the three and six months ended June 30, 2021, respectively. 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**

### ***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. Upon the approval of ZORYVE in July 2022, \$7.5 million became payable to AstraZeneca. 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. Royalties paid to AstraZeneca by the Company will be recorded in cost of goods sold.

There were no payments made or payable in connection with AZ-Licensed Products for the three and six months ended June 30, 2022 and 2021.

### ***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 SHR0302, a Janus kinase type 1 inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Japan, Canada, 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.

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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, 2022 and 2021.

***Hawkeye (Iolix Therapeutics) Collaboration Agreement***

In June 2019, the Company entered into a collaboration agreement, or Hawkeye Agreement, with Hawkeye Therapeutics, Inc. (Hawkeye), a related party with common ownership, for the development of one or more new applications of roflumilast. The Hawkeye Agreement grants Hawkeye an exclusive license to certain intellectual property developed under the agreement as it relates to the applications.

Contemporaneously with the execution of the Hawkeye Agreement, the Company entered into a stock purchase agreement, purchasing 995,000 shares of Hawkeye's common stock at \$0.0001 per share, representing 19.9% of the outstanding common stock of Hawkeye at the time of the purchase. In the event that Hawkeye issues shares of Series A convertible preferred stock with proceeds over \$5.0 million, Hawkeye is required to issue to the Company a number of fully-paid fully-vested shares of common stock determined by dividing (i) \$2,000,000 by (ii) an amount equal to the cash price per share for Series A convertible preferred stock. Other than the potential issuance of this common stock, there are no upfront payments, milestones, or royalties pursuant to the Hawkeye Agreement. The Company determined that Hawkeye is a VIE for which consolidation is not required as it is not the primary beneficiary.

**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.

The Company recognized the ROU asset and lease liability for the new space on May 1, 2020. The lease payment term for the new space began on December 30, 2020. The lease payments terminate 91 months thereafter, 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 renewal and one-time cancellation options have not been considered in the determination of the ROU asset or lease liability as the Company did not consider it reasonably certain it would exercise these options.

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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. As a result, the Company recognizes rent expense on a straight-line basis for the full amount of the commitment including the minimum rent increases over the life of the lease and the free rent period. The amended lease agreement provided for a leasehold improvement allowance up to \$1.25 million, which the Company fully utilized by incurring related costs. This amount, along with \$320,000 of additional costs incurred for leasehold improvements beyond the allowance, were capitalized and included in property and equipment as of December 31, 2020.

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, the Company reduced the line of credit and related restricted cash account to \$1.2 million.

All leasehold improvements will be depreciated over the remaining term of the lease.

The minimum annual rental payments of the Company's operating lease liability as of June 30, 2022 are as follows (in thousands):

	Amounts
2022 (July through December)	\$ 430
2023	964
2024	994
2025	1,025
2026	1,054
Thereafter	1,740
<b>Total minimum lease payments</b>	<b>\$ 6,207</b>
Less: Amounts representing interest	(1,175)
<b>Present value of future minimum lease payments</b>	<b>\$ 5,032</b>
Current portion operating lease liability	582
Operating lease liability, noncurrent	4,450
<b>Total operating lease liability</b>	<b>\$ 5,032</b>

Straight-line rent expense recognized for operating leases was \$173,000 and \$344,000 for the three and six months ended June 30, 2022, respectively, and \$170,000 and \$345,000 for the three and six months ended June 30, 2021, respectively. There were no significant variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases for the three and six months ended June 30, 2022 and 2021.

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

	Six Months Ended June 30,	
	2022	2021
<b>Cash flows from operating activities</b>		
Cash paid for amounts included in the measurement of lease liabilities	\$ 352	\$ —

The following summarizes additional information related to the operating lease:

	June 30, 2022
Weighted-average remaining lease term (in years)	6.1
Weighted-average discount rate	7.0 %

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### ***Manufacturing Agreements***

The Company has entered into manufacturing supply agreements for the commercial supply of topical roflumilast cream which include certain minimum purchase commitments. Firm future purchase commitments under these agreements are approximately \$8.1 million within the next six months and then approximately \$0.6 million per year for 2023, 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.

### ***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. The terms of certain of our 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.

### ***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. Each tranche B term loan is available following delivery to SLR of satisfactory evidence that the Company has received FDA approval of roflumilast cream for an indication relating to the treatment of patients with plaque psoriasis (FDA Approval). 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. See Note 12. 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, 2022, the rate was 8.57%. The maturity date for each term loan is January 1, 2027.

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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.

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; 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 covenants under the Loan Agreement as of June 30, 2022.

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. 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 our 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 through June 30, 2022, 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.

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The debt issuance costs have been recorded as a debt discount which are being accreted to interest expense through the maturity date of the term loan. Interest expense is calculated using the effective interest method, and is inclusive of non-cash amortization of debt issuance costs. The final maturity payment of \$5.2 million is recognized over the life of the term loan through interest expense. At June 30, 2022, the effective interest rate was 10.64%. Interest expense relating to the term loan for the three and six months ended June 30, 2022 was \$2.0 million and \$3.8 million, respectively.

The carrying value of the Term Loans consists of the following (in thousands):

	June 30, 2022	December 31, 2021
Principal loan balance	\$ 75,000	\$ 75,000
Accrued final fee	525	—
Unamortized debt issuance costs	(2,387)	(2,650)
Long-term debt, net	<u>\$ 73,138</u>	<u>\$ 72,350</u>

## 9. Convertible Preferred Stock and Stockholders' Equity

### Convertible Preferred Stock

In connection with the Company's IPO in February 2020, all of the Company's outstanding shares of convertible preferred stock were automatically converted into 24,385,388 shares of common stock.

### 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, 2022, 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, 2022	December 31, 2021
Options issued and outstanding	7,270,277	5,757,957
Common stock awards available for grant under employee incentive plans	2,913,258	2,068,004
Restricted stock units outstanding	1,424,578	335,196
Total common stock reserved	<u>11,608,113</u>	<u>8,161,157</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, 2022 and December 31, 2021.



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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 has 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 our 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, 2022 and 2021, the plan reserve increased by 2,013,830 and 1,747,112 shares, respectively. As of June 30, 2022, the Company had 1,129,763 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 has 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. The Company began granting out of the 2022 Plan in the first quarter of 2022 and has 649,200 shares available for future grant under the plan as of June 30, 2022.

**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, 2021	5,757,957	\$ 19.06	8.37	\$ 34,887
Granted	1,772,668	\$ 19.20		
Exercised	(160,048)	\$ 2.60		
Forfeited	(96,106)	\$ 25.40		
Expired	(4,194)	\$ 27.42		
Balance—June 30, 2022	<u>7,270,277</u>	\$ 19.35	8.35	\$ 37,448
Exercisable—June 30, 2022 <sup>(1)</sup>	<u>3,035,411</u>	\$ 14.46	7.37	\$ 29,966

(1) Options exercisable includes early exercisable options.

The aggregate intrinsic value is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of June 30, 2022. The intrinsic value of options exercised for the six months ended June 30, 2022 was \$2.5 million.



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The total grant-date fair value of the options vested during the six months ended June 30, 2022 was \$13.4 million. The weighted-average grant-date fair value of employee options granted during the six months ended June 30, 2022 was \$13.41.

**Restricted Stock Unit Activity**

The following table summarizes information regarding our RSUs:

	Number of Units	Weighted-Average Grant Date Fair Value
Balance—December 31, 2021	335,196	\$ 29.26
Granted	1,208,128	\$ 18.54
Vested	(86,046)	\$ 29.52
Forfeited	(32,700)	\$ 18.23
Unvested Balance—June 30, 2022	<u>1,424,578</u>	<u>\$ 20.41</u>

The grant date fair value of an RSU equals the closing price of our 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 statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	\$ 3,255	\$ 2,112	\$ 5,989	\$ 3,632
General and administrative	4,841	2,228	8,640	9,211
Total stock-based compensation expense	<u>\$ 8,096</u>	<u>\$ 4,340</u>	<u>\$ 14,629</u>	<u>\$ 12,843</u>

As of June 30, 2022, there was \$64.9 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 2.9 years. As of June 30, 2022, there was \$25.8 million of total unrecognized compensation cost related to RSUs that is expected to vest, which is expected to be recognized over a weighted-average period of 3.4 years.

In March 2021, in connection with the retirement of the former Chief Financial Officer, the Company modified the terms of this individual's historical stock awards. As a result of the modifications, the Company recognized approximately \$5.3 million of incremental stock-based compensation expense during the period, which is included in general and administrative expenses.

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.

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**Expected Volatility** — Prior to 2022, the Company did not have sufficient trading history for its common stock to solely use its own historical volatility. Therefore, the expected volatility was estimated based on a combination of its own historical common stock volatility as well as the average historical volatilities for comparable publicly traded pharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle, and area of specialty. The Company applied that process until a sufficient amount of historical information regarding the volatility of its own stock price became available. 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, 2022	Year Ended December 31, 2021
Expected term (in years)	5.5 – 6.1	5.5 – 6.2
Expected volatility	79.7 – 82.1%	80.6 – 85.2%
Risk-free interest rate	1.4 – 3.0%	0.6 – 1.3%
Dividend yield	—%	—%

### **Early Exercise of Employee Options**

The terms of the 2017 and 2020 Plans permit certain option holders to exercise options before their options are vested, subject to certain limitations. Upon early exercise, the awards become subject to a restricted stock agreement. The shares of restricted stock granted upon early exercise of the options are subject to the same vesting provisions in the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment, at the price paid by the purchaser. While such shares have been issued, they are not considered outstanding for accounting purposes until they vest and are therefore excluded from shares used in determining loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. The liability is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. Accordingly, the Company has recorded the unvested portion of the exercise proceeds of \$37,000 and \$82,000 as a liability from the early exercise in the accompanying condensed balance sheets as of June 30, 2022 and December 31, 2021, respectively. As of June 30, 2022 and December 31, 2021, there were \$25,000 and \$57,000 recorded in accrued liabilities, respectively, and \$12,000 and \$25,000 recorded in other long-term liabilities, respectively related to shares that were subject to repurchase.

### **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.

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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, 2022 and 2021, the ESPP reserve increased by 503,457 and 436,778 shares, respectively. As of June 30, 2022, the Company had 1,134,295 shares available for future grant under the ESPP.

Stock-based compensation expense related to the ESPP was \$212,000 and \$421,000 for the three and six months ended June 30, 2022, respectively, and \$99,000 and \$216,000 for the three and six months ended June 30, 2021, respectively.

#### **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,	
	2022	2021
Stock options to purchase common stock	7,270,277	5,073,312
Early exercised options subject to future vesting	22,291	185,834
RSUs subject to future vesting	1,424,578	314,468
ESPP shares subject to future issuance	19,136	8,074
Total	8,736,282	5,581,688

#### **12. Subsequent Event**

On July 29, 2022, the Company received FDA approval of its lead product, ZORYVE, or roflumilast cream, for the treatment of individuals with plaque psoriasis, including intertriginous psoriasis, in individuals 12 years of age and older.

With the approval of ZORYVE, the tranche B term loans became available and were funded on August 2, 2022 in the amount of \$125.0 million. See Note 8. Also upon approval, a milestone payment of \$7.5 million became payable, and a low to high single-digit percentage royalty rate based upon net sales will begin to be paid to AstraZeneca in accordance with our license agreement. See Note 6.

On August 2, 2022, the Company priced a public offering of 8,625,000 shares of its stock at an offering price of \$20.00 per share, including the underwriters full exercise of their option to purchase an additional 1,125,000 shares. The aggregate net proceeds to the Company from the offering are expected to be \$161.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. The offering is expected to close on August 5, 2022.

## 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 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, 2021 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, 2021, 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 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. 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 progress towards our goal of bridging the treatment innovation gap in dermatology, while maximizing our probability of technical success and financial resources.

Our lead product, ZORYVE™ (roflumilast) cream 0.3%, recently obtained FDA approval on July 29, 2022 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 the duration of use. In addition, we submitted and Health Canada has accepted a New Drug Submission (NDS) for roflumilast cream for plaque psoriasis in Canada with a target action date of April 30, 2023. 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 systematic treatment of dermatological conditions. In addition to the recent approval of ZORYVE for plaque psoriasis, we are also developing roflumilast cream for the treatment of atopic dermatitis. In atopic dermatitis, we completed enrollment in INTEGUMENT-1, the first of two pivotal Phase 3 clinical trials in subjects six years of age or older. We continue to enroll subjects in our other two pivotal Phase 3 atopic dermatitis trials: INTEGUMENT-2 in subjects six years of age or older and INTEGUMENT-PED in subjects between the ages of two and five years. We expect to provide topline data from each of INTEGUMENT-1 and -2 by the end of 2022. We intend to submit a supplemental New Drug Application (sNDA) for topical roflumilast cream for the treatment of atopic dermatitis patients aged six years or older in 2023 based on the results of INTEGUMENT-1 and -2. We expect to provide topline data from INTEGUMENT-PED in 2023 and submit a subsequent sNDA for the younger age cohort following the potential initial atopic dermatitis approval in patients aged six years or older.

We are also developing a topical foam formulation of roflumilast, and have successfully completed a Phase 3 clinical trial in seborrheic dermatitis and completed enrollment in a single pivotal Phase 3 clinical trial in scalp and body psoriasis. In seborrheic dermatitis, we announced positive topline data in June 2022 and we expect the data to be a sufficient basis for an NDA submission in the first quarter of 2023. In our Phase 3 scalp and body psoriasis trial, we anticipate topline data late in the third quarter or early in the fourth quarter of 2022. If positive, we expect the data to be a sufficient basis for a sNDA submission.

Beyond topical roflumilast, we are developing ARQ-252, a potent and highly selective topical JAK1 inhibitor. In May 2021, we announced that the Phase 2 study of ARQ-252 in chronic hand eczema did not meet its primary endpoint with further analyses of the study pointing to inadequate local drug delivery to the skin. Given these analyses, we also elected to terminate the Phase 2a clinical trial evaluating ARQ-252 as a potential treatment in vitiligo, as we began reformulation efforts to develop an enhanced formulation of ARQ-252 that delivers more active drug to targets in the skin. Additionally, we have Investigational New Drug application (IND)-enabling efforts continuing for ARQ-255, an alternative deep-penetrating topical formulation of ARQ-252 designed to reach deeper into the skin and hair follicle in order to potentially treat alopecia areata. The ARQ-255 formulation is separate and distinct from ARQ-252, and thus there are no implications to ARQ-255 from ARQ-252. We expect to initiate a clinical trial of ARQ-255 in alopecia areata in 2022.

Since our inception in 2016, we have invested a significant portion of our efforts and financial resources in clinical development activities. We have not generated any revenue from product sales and have funded our operations primarily with the net proceeds from equity and debt offerings. Prior to our IPO, we received \$162.5 million in net cash proceeds from private placements of convertible preferred stock which was converted into shares of common stock in connection with our IPO. On February 4, 2020, we received \$167.2 million in net proceeds in connection with our IPO. On October 6, 2020, we closed a public offering and a concurrent private placement of our common stock and received an aggregate of \$128.4 million in net proceeds. On February 5, 2021, we closed a public offering of our common stock and received an aggregate of \$207.5 million in net proceeds. In December 2021, we received \$72.4 million in net proceeds under the Loan Agreement. In March 2022, we received \$14.5 million in net proceeds related to shares issued under our ATM. On August 2, 2022, we received \$125.0 million in proceeds under the Loan Agreement. On August 2, 2022, we priced a public offering of 8,625,000 shares of common stock at an offering price of \$20.00 per share, including the underwriters full exercise of their option to purchase an additional 1,125,000 shares. The aggregate net proceeds to us from the offering, including the exercise of the underwriters' option to purchase additional shares, are expected to be \$161.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The offering is expected to close on August 5, 2022.

We have incurred net losses in each year since inception, including net losses of \$67.4 million and \$131.7 million for the three and six months ended June 30, 2022, respectively, and \$42.0 million and \$78.1 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2022, we had an accumulated deficit of \$540.0 million and cash, cash equivalents, restricted cash, and marketable securities of \$283.4 million. As of June 30, 2022, we had \$75.0 million outstanding under the Loan Agreement. Upon FDA approval of ZORYVE for the treatment of psoriasis, we drew down an additional \$125.0 million under the Loan agreement, which was received on August 2, 2022. After this draw down, we have \$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 receive \$161.7 million from the closing of the public offering of our common stock on August 5, 2022.

We expect to continue to incur losses for the foreseeable future and expect to incur increased expenses as we begin to commercialize ZORYVE in psoriasis and as we advance ZORYVE and our product candidates through clinical trials, regulatory submissions, and commercialization. We expect to incur significant commercialization expenses related to sales, marketing, manufacturing, and distribution of ZORYVE, and our other product candidates if we obtain regulatory approval for them. If our available cash 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.

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. In addition, we are in the process of completing the build out of our sales organization. Accordingly, we expect to incur significant expenses related to our sales organization and our commercial infrastructure to support ZORYVE commercialization.

## **COVID-19 Update**

In March 2020, the World Health Organization declared a pandemic related to the COVID-19 outbreak. COVID-19 has placed strains on the providers of healthcare services, including the sites where we conduct our clinical trials. These strains have resulted in some clinical sites slowing or halting enrollment in clinical trials and restricting the on-site monitoring of clinical trials. We follow FDA guidance on clinical trial conduct during the COVID-19 pandemic, including the remote monitoring of clinical data. We are monitoring the impact COVID-19 may have on the clinical development of our product candidates, including potential delays or modifications to ongoing and planned trials. We believe that the rapid spread of the Omicron variant in late 2021 and early 2022 has likely had a minor impact on the enrollment of our clinical trials. Because of this likely impact, along with the inherent challenges of enrolling young children in clinical trials, we have updated our expectation for providing topline data for the INTEGUMENT-PED trial, in atopic dermatitis subjects between two and five years of age, to 2023. We cannot, at this time, predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on our ongoing and planned clinical trials and other business operations, including our commercialization activities.

There have been no disruptions in our supply chain of drug manufacturers necessary to conduct our clinical trials and, given our drug inventories, we believe that we will be able to supply the drug needs of our ongoing clinical studies and commercialization efforts.

In alignment with public health guidance designed to slow the spread of COVID-19, we implemented a remote work plan for all employees as of mid-March 2020. With COVID-19 moving to an endemic phase, we have formally returned to our previously existing hybrid work environment consisting of both local and remote employees. We may need to undertake additional actions that could impact our operations as required by applicable laws or regulations, or which we determine to be in the best interests of our employees.

## **License Agreements**

### ***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. Upon the approval of ZORYVE in July 2022, \$7.5 million became payable to AstraZeneca. 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. See Note 6 to the unaudited condensed 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 SHR0302, a Janus Kinase (JAK) 1 inhibitor, in topical formulations for the treatment of skin diseases, disorders, and conditions in the United States, Canada, 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 unaudited condensed financial statements for additional information.

### **Components of Our Results of Operations**

#### ***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 Phase 3 trials of roflumilast cream for atopic dermatitis, ARQ-252 for chronic hand eczema and vitiligo, and ARQ-255 for alopecia areata.

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 to acquire such licenses, 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-252, and ARQ-255, or any future 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.

#### ***General and Administrative Expenses***

Our general and administrative expenses consist primarily of salaries and related costs, including payroll taxes, benefits, stock-based compensation, and travel. Other general and administrative expenses include costs related to sales and marketing as we begin commercialization of ZORYVE, legal costs of pursuing patent protection of our intellectual property, insurance, and professional services fees for marketing, auditing, tax, and general legal services. We expect our general and administrative expenses to continue to increase in the future as we expand our operating activities and begin commercialization of ZORYVE, increase our headcount, and support our operations as a public company; 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 our long term debt.



## Results of Operations

### Comparison of the Three Months Ended June 30, 2022 and 2021

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

	Three Months Ended June 30,		Change	
	2022	2021	\$	%
(unaudited) (in thousands)				
<b>Operating expenses:</b>				
Research and development	\$ 38,205	\$ 30,765	\$ 7,440	24 %
General and administrative	27,622	11,315	16,307	144 %
Total operating expenses	65,827	42,080	23,747	56 %
Loss from operations	(65,827)	(42,080)	(23,747)	56 %
<b>Other income (expense):</b>				
Other income, net	421	72	349	485 %
Interest expense	(2,000)	—	(2,000)	*
Total other income (expense)	(1,579)	72	(1,651)	(2293)%
Net loss	\$ (67,406)	\$ (42,008)	\$ (25,398)	60 %

\*Not applicable

### Research and Development Expenses

	Three Months Ended June 30,		Change	
	2022	2021	\$	%
(unaudited) (in thousands)				
<b>Direct external costs:</b>				
Topical roflumilast program	\$ 21,089	\$ 16,886	\$ 4,203	25 %
Topical JAK inhibitor program	430	3,864	(3,434)	(89)%
Other early stage programs	197	79	118	149 %
<b>Indirect costs:</b>				
Compensation and personnel-related	10,191	6,329	3,862	61 %
Other	6,298	3,607	2,691	75 %
Total research and development expense	\$ 38,205	\$ 30,765	\$ 7,440	24 %

Research and development expenses increased by \$7.4 million, or 24%, for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. The increase was primarily due to an increase in direct costs related to the topical roflumilast program of \$4.2 million, an increase in compensation and personnel-related costs of \$3.9 million, and an increase in other costs of \$2.7 million. These increases were partially offset by a decrease in direct costs related to the topical JAK inhibitor program (ARQ-252 and ARQ-255) of \$3.4 million. The increase in topical roflumilast program costs was primarily due to increased manufacturing costs and, to a lesser extent, clinical trial costs. Manufacturing costs increased due to the timing of purchases of roflumilast active pharmaceutical ingredient (API) and manufacturing of commercial supply ahead of launch. Clinical trial costs increased due to the ongoing Phase 3 studies of roflumilast cream in atopic dermatitis partially offset by the completion of Phase 3 studies of roflumilast cream in plaque psoriasis and Phase 3 studies of roflumilast foam in seborrheic dermatitis. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was primarily due to an increase in headcount. The increase in other costs was primarily due to an

increase in medical affairs spending and consulting activity. The decrease in topical JAK inhibitor program costs was primarily due to the completion of our Phase 2 studies of ARQ-252 in chronic hand eczema and vitiligo.

***General and Administrative Expenses***

General and administrative expenses increased by \$16.3 million, or 144%, for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. The increase was primarily due higher compensation and personnel-related expenses of \$9.5 million, higher sales and marketing expenses of \$4.1 million, and higher professional services of \$1.9 million. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was primarily due to an increase in headcount related to commercialization efforts. The increase in sales and marketing expenses was primarily related to commercialization efforts for ZORYVE. The increase in professional services was due to an increase in consulting activity.

***Other Income, Net***

Other income, net increased by \$0.3 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021, primarily due to a larger marketable securities balance for the three months ended June 30, 2022.

***Interest Expense***

Interest expense increased by \$2.0 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021, due to interest expense related to our long-term debt. See Note 8.

**Comparison of the Six Months Ended June 30, 2022 and 2021**

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

	Six Months Ended June 30,		Change	
	2022	2021	\$	%
	(unaudited)			
	(in thousands)			
<b>Operating expenses:</b>				
Research and development	\$ 78,827	\$ 52,396	\$ 26,431	50 %
General and administrative	49,628	25,769	23,859	93 %
Total operating expenses	<u>\$ 128,455</u>	<u>\$ 78,165</u>	<u>\$ 50,290</u>	64 %
Loss from operations	(128,455)	(78,165)	(50,290)	64 %
<b>Other income (expense):</b>				
Other income, net	563	115	448	390 %
Interest expense	(3,838)	—	(3,838)	*
Total other income (expense)	(3,275)	115	\$ (3,390)	(2948)%
Net loss	<u>\$ (131,730)</u>	<u>\$ (78,050)</u>	<u>\$ (53,680)</u>	69 %

\*Not applicable

**Research and Development Expenses**

	Six Months Ended June 30,		Change	
	2022	2021	\$	%
	(unaudited)			
	(in thousands)			
<b>Direct external costs:</b>				
Topical roflumilast program	\$ 46,311	\$ 26,673	\$ 19,638	74 %
Topical JAK inhibitor program	1,393	7,515	(6,122)	(81)%
Other early stage programs	492	256	236	92 %
<b>Indirect costs:</b>				
Compensation and personnel-related	19,630	11,438	8,192	72 %
Other	11,001	6,514	4,487	69 %
Total research and development expense	<u>\$ 78,827</u>	<u>\$ 52,396</u>	<u>\$ 26,431</u>	50 %

Research and development expenses increased by \$26.4 million, or 50%, for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. The increase was primarily due to an increase in direct costs related to the topical roflumilast program of \$19.6 million, compensation and personnel-related costs of \$8.2 million, and an increase in other costs of \$4.5 million. These increases were partially offset by a decrease in direct costs related to the topical JAK inhibitor program of \$6.1 million. The increase in topical roflumilast program costs relate primarily to increased clinical trial costs and increased manufacturing. Clinical trial costs increased due to the ongoing Phase 3 studies of roflumilast cream in atopic dermatitis and Phase 3 studies of roflumilast foam in scalp psoriasis partially offset by the completion of Phase 3 studies of roflumilast cream in plaque psoriasis. Manufacturing costs increased due to the timing of purchases of roflumilast API and manufacturing of commercial supply ahead of launch. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was primarily due to an increase in headcount. The increase in other costs were primarily due to an increase in medical affairs spending and consulting activity. The decrease in topical JAK inhibitor program costs were primarily due to the completion of our Phase 2 studies of ARQ-252 in chronic hand eczema and vitiligo.

#### ***General and Administrative Expenses***

General and administrative expenses increased by \$23.9 million, or 93%, for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. The increase was primarily due to an increase in compensation and personnel-related expenses of \$11.2 million, an increase in sales and marketing expenses of \$7.7 million, and an increase in professional services of \$3.6 million. The increase in compensation and personnel-related expenses, which includes stock-based compensation, was due to an increase in headcount related to commercialization efforts. The increase in sales and marketing expenses was primarily related to commercialization efforts for ZORYVE. The increase in professional services was mainly due to an increase in consulting activity.

#### ***Other Income, Net***

Other income, net increased by \$0.4 million for the six months ended June 30, 2022 compared to the six months ended June 30, 2021, primarily due to a larger marketable securities balance for the six months ended June 30, 2022.

#### ***Interest Expense***

Interest expense increased by 3.8 million for the six months ended June 30, 2022 compared to the six months ended June 30, 2021, due to interest expense related to our long-term debt. See Note 8.

### **Liquidity, Capital Resources, and Requirements**

#### ***Sources of Liquidity***

We have incurred operating losses since our inception and have an accumulated deficit as a result of ongoing efforts to develop our product candidates, including conducting nonclinical and clinical trials and providing general and administrative support for these operations. As of June 30, 2022, we had cash, cash equivalents, restricted cash, and marketable securities of \$283.4 million, and an accumulated deficit of \$540.0 million. As of June 30, 2022, we had \$75.0 million outstanding under our Loan Agreement. Upon FDA approval of ZORYVE, we drew down an additional \$125 million under the Loan Agreement, which we received on August 2, 2022. After this draw down, we have \$200 million outstanding under the Loan Agreement and \$25.0 million in additional funding remaining that may become available subject to the satisfaction of specified conditions. We expect to receive \$161.7 million from the closing of the public offering of our common stock on August 5, 2022. See Notes 8 and 12 to the unaudited condensed financial statements for additional information.

We have historically financed our operations primarily through 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, and our ATM.

**Cash Flows**

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

	Six Months Ended June 30,	
	2022	2021
	(unaudited)	
	(in thousands)	
Cash used in operating activities	\$ (118,955)	\$ (82,034)
Cash provided by (used in) investing activities	67,862	(102,923)
Cash provided by financing activities	15,847	209,003
Net increase (decrease) in cash, cash equivalents, and restricted cash	<u>\$ (35,246)</u>	<u>\$ 24,046</u>

**Net Cash Used in Operating Activities**

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.

During the six months ended June 30, 2021, net cash used in operating activities was \$82.0 million, which consisted of a net loss of \$78.1 million and a change in net operating assets and liabilities of \$18.6 million offset by net non-cash charges of \$14.6 million. The change in net operating assets and liabilities was primarily due to an increase of \$9.8 million in prepaid expenses and other current assets due to an increase in prepaid clinical trials and a decrease of \$9.0 million in accounts payable and accrued liabilities due to the timing of payments to contract research organizations and payment of employee bonuses accrued for at December 31, 2020. The net non-cash charges were primarily related to stock-based compensation expense of \$12.8 million.

**Net Cash Provided by (Used in) Investing Activities**

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.

During the six months ended June 30, 2021, net cash used in investing activities was \$102.9 million, which was comprised primarily of purchases of marketable securities of \$211.9 million, partially offset by the proceeds from the maturities of marketable securities of \$109.6 million.

**Net Cash Provided by Financing Activities**

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.

During the six months ended June 30, 2021, net cash provided by financing activities was \$209.0 million, which was comprised primarily of the net cash proceeds received from the follow-on financing in February 2021 of \$207.5 million.

**Funding Requirements**

We have historically incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of \$540.0 million as of June 30, 2022. We had cash, cash equivalents, and marketable securities of \$282.2 million as of June 30, 2022. As of June 30, 2022, we had \$75.0 million outstanding under the Loan Agreement. Upon FDA approval of ZORYVE, we drew down an additional \$125.0 million under the Loan Agreement which we received on August 2, 2022. Following this draw down, we have \$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 receive \$161.7 million from the closing of the public offering of our common stock on August 5, 2022. See Notes 8 and 12 to the unaudited condensed financial statements for additional information.

If our available cash balances, amounts available under the Loan Agreement and anticipated future cash flows from operations are insufficient to satisfy our liquidity 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 reductions in staff and delaying, scaling back, or stopping certain research and development programs. 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.

We have based our projections of operating capital 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. Our 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 clinical studies of roflumilast cream in plaque psoriasis and atopic dermatitis, roflumilast foam in scalp and body psoriasis, ARQ-252 in chronic hand eczema and vitiligo, and ARQ-255 in alopecia areata;
- suspensions or delays in the enrollment, issues with data collection, or changes to the number of subjects we decide to enroll in our ongoing clinical trials as a result of the COVID-19 pandemic, competing trials or otherwise;
- 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 reviews and approvals for our product candidates;
- the cost of manufacturing any current and future products and product candidates, including any products we successfully commercialize, including costs associated with building out our supply chain;
- the cost of commercialization activities for any current and future products that are approved for sale, including marketing, sales, and distribution costs, and any discounts or rebates to channel 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 due to AstraZeneca, Hengrui, or any future collaboration or licensing partners upon the achievement of negotiated milestones;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio.

### ***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. Each tranche B term loan is available following delivery to SLR of satisfactory evidence that we have received FDA Approval of roflumilast cream for an indication relating to the treatment of patients with plaque psoriasis, which we refer to as the FDA Approval. With the approval of ZORYVE on July 29, 2022, we drew down \$125.0 million on the tranche B term loans, which we received on August 2, 2022. See Notes 8 and 12 to the unaudited condensed 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, 2022, the rate was 8.57%.

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; 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, 2022.

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.

## **Contractual Obligations and Contingent Liabilities**

The following summarizes our significant contractual obligations as of June 30, 2022.

### ***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, 2022, we have a letter of credit and related restricted cash account of \$1.2 million. The total commitment under the operating lease agreement is \$6.2 million, including \$0.4 million for the remaining six months of 2022, \$1.0 million for each of the years 2023 through 2027, and \$0.6 million for the year 2028. See Note 7 to the unaudited condensed financial statements for additional information.

### ***Long-Term Debt Obligations***

As of June 30, 2022, we had \$75.0 million outstanding under our Loan Agreement. Upon FDA approval of ZORYVE, we drew down an additional \$125.0 million under the Loan Agreement which we received on August 2, 2022. After this draw down, we have \$200.0 million outstanding under the Loan Agreement and \$25.0 million in additional funding remaining that may become available subject to the satisfaction of specified conditions. See Notes 8 and 12 to the unaudited condensed financial statements for additional information. The total commitment under the Loan Agreement as of June 30, 2022 is \$109.5 million, including \$3.3 million for the remaining six months of 2022, \$6.5 million for each of the years 2023 through 2026, and \$80.2 million for 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.

### ***License Agreements***

The terms of certain of our license agreements 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. Upon FDA approval of ZORYVE on [July 29, 2022], a \$7.5 million milestone payment became payable to AstraZeneca. These potential obligations are further described in Note 6 to the unaudited condensed 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 \$8.1 million within the next six months and then approximately \$0.6 million per year for the following three years. 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 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, 2021. There were no material changes to our critical accounting policies during the six months ended June 30, 2022.

### **Recent Accounting Pronouncements**

See Note 2 to our unaudited condensed 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, 2022, we had cash and cash equivalents of \$61.5 million, restricted cash of \$1.2 million, and marketable securities of \$220.7 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, 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. As a result, we are exposed to risks related to our indebtedness from changes in interest rates. We do not believe that a hypothetical 100 basis point increase or decrease in the applicable interest rate would have had a significant impact on our interest expense for the three months ended June 30, 2022. On June 30, 2022, the interest rate was 8.57%.

## **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, 2022, 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, 2022.

### ***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, 2022 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, 2021. 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, 2021.

***We have limited experience as a commercial company and the sales, marketing, and distribution of ZORYVE or any future approved products may be unsuccessful or less successful than anticipated.***

We recently received approval of our NDA of ZORYVE and we have initiated a commercial launch of ZORYVE in the United States. As a company, we have no prior experience commercializing a drug. The success of our commercialization efforts is difficult to predict and subject to the effective execution of our business plan, including, among others, the continued development of our internal sales, marketing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the development and management of such capabilities. For example, our commercial launch may not develop as planned or anticipated, which may require us to, among others, adjust or amend our business plan and incur significant expenses. Further, given our lack of experience commercializing products, we do not have a track record of successfully executing a commercial launch. If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if our commercialization efforts do not develop as planned, we may not be able to successfully commercialize ZORYVE and any future approved products, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry.

***As we have not yet commenced commercial sales of ZORYVE and we continue to develop a pipeline of drug products through clinical trials, our capital requirements are difficult to predict and may change. We may need additional financing in the future and may be unable to obtain additional financing on terms favorable to us or at all.***

We expect to expend substantial resources for the foreseeable future in connection with our commercialization efforts, the development of our current product candidates, the maintenance and expansion of our business operations and capabilities and the development or acquisition of additional product candidates. These expenditures will include costs associated with marketing and selling any products approved for sale, including ZORYVE, conducting non-clinical studies and clinical trials, obtaining regulatory approvals, and securing manufacturing and supply of product candidates. Our operating expenses and capital requirements are difficult to predict and are affected by, and are subject to assumptions regarding, among others, the success of our commercialization efforts involving ZORYVE, market acceptance of ZORYVE, competing products, our ability to successfully execute on our business plan, and our internal projections and estimates of costs and execution timing. Our plans and capital requirements may change as a result of many factors, including factors currently unknown to us. 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. Such financing may result in dilution to stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. 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. 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.

### 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**

None.

**ITEM 6. EXHIBITS**

Exhibit Number	Description of Document	Incorporated by Reference Form	Date	Number	Filed/Furnished Herewith
3.1	<a href="#">Restated Certificate of Incorporation.</a>	10-Q	5/12/20	3.1	
3.2	<a href="#">Restated Bylaws.</a>	10-Q	5/12/20	3.2	
4.1	<a href="#">Form of Common Stock Certificate.</a>	S-1/A	1/21/20	4.1	
4.2†	<a href="#">Amended and Restated Investors' Rights Agreement, dated October 8, 2019, by and among the Registrant and certain of its stockholders.</a>	S-1/A	1/21/20	4.2	
31.1	<a href="#">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.</a>				X
31.2	<a href="#">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.</a>				X
32.1*	<a href="#">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.</a>				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.

\* 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 04, 2022

By: /s/ Todd Franklin Watanabe

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

Date: August 04, 2022

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, Todd Franklin Watanabe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arcutis Biotherapeutics, Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 4, 2022

By: \_\_\_\_\_ /s/ Todd Franklin Watanabe

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





