

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38130

Aileron Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

13-4196017

(I.R.S. Employer
Identification No.)

738 Main Street #398

Waltham, MA

(Address of principal executive offices)

02451

(Zip Code)

Registrant's telephone number, including area code: (617) 995-0900

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	ALRN	The Nasdaq Capital 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

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

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

As of October 11, 2023, the registrant had 4,541,167 shares of common stock, \$0.001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our assessment of strategic options and our ability to identify and implement any strategic transaction;
- anticipated cost savings in connection with our discontinuation of ALRN-6924 and our workforce reduction announced in February 2023;
- success in retaining, or changes required in, our remaining current officers, key employees or directors;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash, and cash equivalents;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our intellectual property position and strategy;
- developments relating to our competitors and our industry;
- the impact of government laws and regulations;
- the impact the coronavirus pandemic may have on our operations; and
- our ability to maintain our listing on the Nasdaq Capital Market.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements in our Annual Report on Form 10-K and in this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein and have filed or incorporated by reference hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AILERON THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS (UNAUDITED)

(In thousands, except share and per share data)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,069	\$ 5,194
Investments	—	16,048
Prepaid expenses and other current assets	699	606
Restricted cash	25	25
Total current assets	12,793	21,873
Operating lease, right-of-use asset	—	40
Other non-current assets	—	24
Property and equipment, net	29	70
Total assets	\$ 12,822	\$ 22,007
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 484	\$ 1,720
Accrued expenses and other current liabilities	1,140	1,631
Operating lease liability, current portion	—	33
Total current liabilities	1,624	3,384
Total liabilities	1,624	3,384
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and no shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Common stock, \$0.001 par value; 45,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; 4,541,167 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	91	91
Additional paid-in capital	292,285	291,365
Accumulated other comprehensive loss	—	(48)
Accumulated deficit	(281,178)	(272,785)
Total stockholders' equity	11,198	18,623
Total liabilities and stockholders' equity	\$ 12,822	\$ 22,007

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

AILERON THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	22	4,239	2,019	15,565
General and administrative	1,955	2,243	6,027	7,379
Restructuring and Other	6	—	940	—
Total operating expenses	<u>1,983</u>	<u>6,482</u>	<u>8,986</u>	<u>22,944</u>
Loss from operations	(1,983)	(6,482)	(8,986)	(22,944)
Interest income	155	110	322	180
Other income (expense), net	1	4	271	(18)
Net loss	(1,827)	(6,368)	(8,393)	(22,782)
Net loss per share — basic and diluted	<u>\$ (0.40)</u>	<u>\$ (1.40)</u>	<u>\$ (1.85)</u>	<u>\$ (5.02)</u>
Weighted average common shares outstanding—basic and diluted	<u>4,541,167</u>	<u>4,541,179</u>	<u>4,541,167</u>	<u>4,538,707</u>
Comprehensive loss:				
Net loss	\$ (1,827)	\$ (6,368)	\$ (8,393)	\$ (22,782)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net of tax of \$0	2	3	48	(85)
Total other comprehensive gain (loss)	<u>2</u>	<u>3</u>	<u>48</u>	<u>(85)</u>
Total comprehensive loss	<u>\$ (1,825)</u>	<u>\$ (6,365)</u>	<u>\$ (8,345)</u>	<u>\$ (22,867)</u>

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

AILERON THERAPEUTICS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (UNAUDITED)

(In thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensiv e Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balances at December 31, 2022	<u>4,541,167</u>	<u>\$ 91</u>	<u>\$ 291,365</u>	<u>\$ (48)</u>	<u>\$ (272,785)</u>	<u>\$ 18,623</u>
Stock-based compensation expense	—	—	391	—	—	391
Unrealized gain on investments	—	—	—	38	—	38
Net loss	—	—	—	—	(4,779)	(4,779)
Balances at March 31, 2023	<u>4,541,167</u>	<u>\$ 91</u>	<u>\$ 291,756</u>	<u>\$ (10)</u>	<u>\$ (277,564)</u>	<u>\$ 14,273</u>
Stock-based compensation expense	—	—	300	—	—	300
Unrealized gain on investments	—	—	—	8	—	8
Net loss	—	—	—	—	(1,787)	(1,787)
Balances at June 30, 2023	<u>4,541,167</u>	<u>\$ 91</u>	<u>\$ 292,056</u>	<u>\$ (2)</u>	<u>\$ (279,351)</u>	<u>\$ 12,794</u>
Stock-based compensation expense	—	—	229	—	—	229
Unrealized gain on investments	—	—	—	2	—	2
Net loss	—	—	—	—	(1,827)	(1,827)
Balances at September 30, 2023	<u>4,541,167</u>	<u>\$ 91</u>	<u>\$ 292,285</u>	<u>\$ —</u>	<u>\$ (281,178)</u>	<u>\$ 11,198</u>
Balances at December 31, 2021	<u>4,528,667</u>	<u>\$ 91</u>	<u>\$ 289,282</u>	<u>\$ (13)</u>	<u>\$ (245,456)</u>	<u>\$ 43,904</u>
Issuance of common stock	12,500	—	—	—	—	—
Stock-based compensation expense	—	—	689	—	—	689
Unrealized loss on investments	—	—	—	(62)	—	(62)
Net loss	—	—	—	—	(8,422)	(8,422)
Balances at March 31, 2022	<u>4,541,167</u>	<u>\$ 91</u>	<u>\$ 289,971</u>	<u>\$ (75)</u>	<u>\$ (253,878)</u>	<u>\$ 36,109</u>
Stock-based compensation expense	—	—	528	—	—	528
Unrealized loss on investments	—	—	—	(26)	—	(26)
Net loss	—	—	—	—	(7,992)	(7,992)
Balances at June 30, 2022	<u>4,541,167</u>	<u>\$ 91</u>	<u>\$ 290,499</u>	<u>\$ (101)</u>	<u>\$ (261,870)</u>	<u>\$ 28,619</u>
Stock-based compensation expense	—	—	442	—	—	442
Unrealized gain on investments	—	—	—	3	—	3
Net loss	—	—	—	—	(6,368)	(6,368)
Balances at September 30, 2022	<u>4,541,167</u>	<u>\$ 91</u>	<u>\$ 290,941</u>	<u>\$ (98)</u>	<u>\$ (268,238)</u>	<u>\$ 22,696</u>

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

AILERON THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED)

(In thousands)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (8,393)	\$ (22,782)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	67	126
Net amortization of premiums and discounts on investments	(156)	(85)
Stock-based compensation expense	920	1,659
Gain on sale of property and equipment	(42)	—
Loss on disposal of fixed assets	16	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(93)	667
Other assets	24	—
Accounts payable	(1,236)	(265)
Operating lease liabilities	(33)	(95)
Accrued expenses and other current liabilities	(491)	319
Net cash used in operating activities	<u>(9,417)</u>	<u>(20,456)</u>
Cash flows from investing activities:		
Proceeds from sale of property and equipment	42	—
Purchases of investments	—	(19,912)
Proceeds from sales or maturities of investments	16,250	41,607
Net cash provided by investing activities	<u>16,292</u>	<u>21,695</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	—	—
Net cash provided by financing activities	<u>—</u>	<u>—</u>
Net increase in cash, cash equivalents and restricted cash	6,875	1,239
Cash, cash equivalents and restricted cash at beginning of period	5,219	3,625
Cash, cash equivalents and restricted cash at end of period	<u>\$ 12,094</u>	<u>\$ 4,864</u>

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

AILERON THERAPEUTICS, INC.
NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

(Amounts in thousands, except share and per share data)

1. Nature of the Business and Basis of Presentation

Aileron Therapeutics, Inc. (“Aileron” or the “Company”) is a clinical stage chemoprotection oncology company. The Company's product candidate, ALRN-6924, is a MDM2/MDMX dual inhibitor that leverages its proprietary peptide drug technology.

On February 21, 2023, the Company decided to terminate its Phase 1b chemoprotection trial of ALRN-6924 in patients with p53-mutated breast cancer and further development of ALRN-6924. The Company determined to reduce the Company's remaining workforce from nine to three full-time employees. The Company also announced that it is exploring a range of strategic alternatives to maximize stockholder value. The Company has engaged a third party to act as a strategic advisor for this process. Strategic alternatives that are being evaluated may include, but are not limited to, an acquisition, a merger, a business combination, a sale of assets or other transaction. There is no set timetable for this process and there can be no assurance that this process will result in the Company pursuing a transaction or that any transaction, if pursued, will be completed.

When used as a chemoprotective agent, ALRN-6924 is designed to activate p53, which in turn upregulates p21, a known inhibitor of the cell replication cycle. ALRN-6924 was the only reported chemoprotective agent in clinical development to employ a biomarker strategy, in which the Company exclusively focused on treating patients with p53-mutated cancers. The Company originally initiated development of ALRN-6924 as an anti-cancer agent to restore p53-dependent tumor suppression in p53 wild-type tumors. When used as an anti-cancer agent, ALRN-6924 is designed to disrupt the interaction of p53 suppressors MDM2 and MDMX with tumor suppressor p53 to reactivate tumor suppression in non-mutant, or wild-type, p53 cancers.

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations, uncertainties in the clinical development of product candidates and in the ability to obtain needed additional financing. ALRN-6924 will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities.

On November 10, 2022, the Company effected a one-for-twenty reverse stock split on its common stock (the “Reverse Stock Split”). The Reverse Stock Split was reflected on the Nasdaq Capital Market beginning with the opening of trading on November 11, 2022. Pursuant to the Reverse Stock Split, every 20 shares of the Company's issued and outstanding shares of common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share of the common stock. The Reverse Stock Split reduced the authorized number of shares of common stock from 300,000,000 to 15,000,000 and, pursuant to the certificate of amendment, such reduced authorized number of shares of common stock was subsequently multiplied by three, such that following the Reverse Stock Split the Company has 45,000,000 shares of common stock authorized. The Reverse Stock Split affected all issued and outstanding shares of the Company's common stock, and the respective numbers of shares of common stock underlying the Company's outstanding stock options, outstanding warrants and the Company's equity incentive plans were proportionately adjusted. All share and per share amounts of the common stock included in the accompanying financial statements have been retrospectively adjusted to give effect to the Reverse Stock Split for all periods presented.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”).

Liquidity

In accordance with Accounting Standards Update (“ASU”) No. 2014-15, *Disclosures of Uncertainties about an Entity’s Ability to Continue as a Going Concern* (Subtopic 205-40), management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company’s ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved before the date that the financial statements are issued.

The Company’s interim financial statements have been prepared on a going concern basis, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. Through September 30, 2023, the Company has financed operations primarily through \$145,467 in net proceeds from sales of common stock and warrants, \$131,211 from sales of preferred stock prior to its IPO, and \$34,910 from a collaboration agreement in 2010.

As of September 30, 2023, the Company had cash, and cash equivalents of \$12,069. The Company has incurred losses and negative cash flows from operations and had an accumulated deficit of \$281,178 as of September 30, 2023. The Company expects to continue to generate losses for the foreseeable future.

While the Company has cash, and cash equivalents of \$12,069 as of September 30, 2023, due to the inherent uncertainty in the timing and cost of potential strategic alternatives, including their impact on its cash consumption, the Company has concluded that as of the date of this Quarterly Report on Form 10-Q there is substantial doubt about its ability to continue as a going concern for a period of twelve months from the issuance of these interim financial statements.

The Company would need substantial funding to support its continuing operations. There can be no assurance that a strategic transaction will be completed and the Company’s board of directors may decide to pursue a dissolution and liquidation. If the Company is unable to enter into a strategic transaction, on a timely basis or at all, the Company may consider seeking protection under the bankruptcy laws. If the Company decides to seek protection under the bankruptcy laws, the Company would expect that it would file for bankruptcy at a time that is earlier than when it would otherwise exhaust its cash resources. If the Company decides to dissolve and liquidate its assets or to seek protection under the bankruptcy laws, it is unclear to what extent the Company will be able to pay its obligations, and, it is further unclear whether and to what extent any resources will be available for distributions to its stockholders. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of common stock and stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company’s estimates.

Unaudited Interim Financial Information

The accompanying unaudited condensed financial statements as of September 30, 2023 and for the nine months ended September 30, 2023 and 2022 have been prepared by the Company pursuant to the rules and regulations of the United States Securities and Exchange Commission (“SEC”) for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the Company’s audited financial statements and the notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 that was filed with the SEC on March 20, 2023.

The unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair

statement of the Company's financial position as of September 30, 2023, the results of its operations for the three and nine months ended September 30, 2023 and 2022 and its cash flows for the nine months ended September 30, 2023 and 2022. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2023 and 2022 are unaudited. The results for the nine months ended September 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period. The accompanying balance sheet as of December 31, 2022 has been derived from the Company's audited financial statements for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 20, 2023.

Our significant accounting policies are described in Note 2 to the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022 that was filed with the SEC on March 20, 2023.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, and cash equivalents. From time to time, the Company has maintained all of its cash, cash equivalents and investment balances at three accredited financial institutions, in amounts that exceed federally insured limits. The Company generally invests its excess cash in money market funds, commercial paper and corporate notes that are subject to minimal credit and market risks. Management has established guidelines relative to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. The investment portfolio is maintained in accordance with the Company's investment policy, which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer.

Prior to the February 2023 decision to discontinue development of ALRN-6924, the Company was dependent on third-party manufacturers to supply products for research and development activities of its programs, including preclinical and clinical testing. In particular, the Company relied on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could have been adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses* (ASU 2016-13 or Topic 326): Measurement of Credit Losses on Financial Instruments, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. The ASU was effective for the Company's fiscal year beginning January 1, 2023, and adoption did not have a material effect on the Company's financial statements or disclosures.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption.

3. Fair Value of Financial Assets

The following tables present information about the Company's assets that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	Fair Value Measurements as of September 30, 2023 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 10,903	\$ —	\$ —	\$ 10,903
	<u>\$ 10,903</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,903</u>
	Fair Value Measurements as of December 31, 2022 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 1,661	\$ —	\$ —	\$ 1,661
Investments:				
Commercial paper	—	12,814	—	12,814
Treasury bills	—	3,234	—	3,234
	<u>\$ 1,661</u>	<u>\$ 16,048</u>	<u>\$ —</u>	<u>\$ 17,709</u>

As of September 30, 2023 and December 31, 2022, the Company's cash equivalents and investments were invested in money market funds, commercial paper and treasury bills and valued based on Level 1 and Level 2 inputs. In determining the fair value of its commercial paper at each date presented above, the Company relied on quoted prices for similar securities in active markets or using other inputs that are observable or can be corroborated by observable market data. The Company's cash equivalents have original maturities of less than 90 days from the date of purchase. All available-for-sale investments have contractual maturities of less than one year. During the nine months ended September 30, 2023 and the year ended December 31, 2022, there were no transfers in or out of Level 3.

4. Investments

The Company had no investments as of September 30, 2023. As of December 31, 2022, the fair value of available-for-sale investments by type of security was as follows:

	December 31, 2022			Fair Value
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	
Investments:				
Commercial paper	\$ 12,846	\$ —	\$ (32)	\$ 12,814
Treasury bills	3,250	—	(16)	3,234
	<u>\$ 16,096</u>	<u>\$ —</u>	<u>\$ (48)</u>	<u>\$ 16,048</u>

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2023	December 31, 2022
Computer equipment and software	\$ 324	\$ 340
Less: Accumulated depreciation and amortization	(295)	(270)
	<u>\$ 29</u>	<u>\$ 70</u>

Depreciation and amortization expense for the nine months ended September 30, 2023 and 2022 was \$37 and \$44 respectively. During the nine months ended September 30, 2023, assets with a cost of \$16 and accumulated depreciation of \$10 were disposed of for no proceeds, resulting in a loss on disposal of \$6. During the nine months ended September 30, 2023, the Company sold fully depreciated assets, resulting in a gain on sale of \$42.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2023	December 31, 2022
External research and development services	\$ 20	\$ 533
Payroll and payroll-related costs	103	425
Professional fees	995	492
Restructuring and other costs (Note 8)	12	—
Other	10	181
	<u>\$ 1,140</u>	<u>\$ 1,631</u>

7. Lease

On March 26, 2021, the Company entered into a sublease agreement (the "Sublease") by and among the Company, Vittoria Industries North America, Inc. (the "Sublessor") and Waterfront Equity Partners, LLC (the "Lessor"), under which the Company was leasing approximately 3,365 square feet of office space located at 285 Summer Street, Unit 101, Boston, Massachusetts (the "Premises"). The Sublease was subject and subordinate to a lease agreement, dated as of July 13, 2012, by and between the Sublessor

and Lessor (the “Prime Lease”), pursuant to which the Sublessor is leasing the Premises from the Lessor. The Sublease expired March 31, 2023 and the Company did not renew the Sublease. Following expiration of the Sublease, the Company is operating virtually, and expects to do so for the foreseeable future.

8. Restructuring and Other Costs

On February 16, 2023, the Board of Directors of the Company determined to reduce the Company’s remaining workforce from nine to three full-time employees. The determination to effect the workforce reduction was made in connection with the Company’s decision to terminate its Phase 1b breast cancer trial of ALRN-6924 and further development of ALRN-6924.

As a result of the above restructuring initiatives, the Company incurred restructuring-related charges of \$940 for the nine months ended September 30, 2023. Restructuring-related charges were comprised of one-time termination costs in connection with the reduction-in-workforce, including severance, benefits, and related costs.

As of September 30, 2023, the short-term portion of the accrued restructuring balance, or \$12, is included in “Accrued expenses and other current liabilities” in the accompanying balance sheets. The Company paid \$10 and \$928, respectively, in costs during the three and nine months ended September 30, 2023, and expects that payment of these remaining costs will be made through the fourth quarter of 2023.

9. Common Stock

On June 16, 2021, the Company filed a certificate of amendment to its restated certificate of incorporation which increased the authorized number of shares of common stock from 7,500,000 shares of \$0.001 par value common stock to 15,000,000 shares of common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company’s stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company’s board of directors, if any, subject to the preferential dividend rights of the preferred stock. As of September 30, 2023 and December 31, 2022, no dividends had been declared.

Reverse Stock Split

The Company’s stockholders approved a reverse stock split of the Company’s common stock on June 15, 2022. The Company effected the Reverse Stock Split on November 10, 2022. Pursuant to the Reverse Stock Split, every 20 shares of the Company’s issued and outstanding shares of common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share of the common stock. The Reverse Stock Split reduced the authorized number of shares of common stock from 300,000,000 to 15,000,000 and, pursuant to the certificate of amendment, such reduced authorized number of shares of common stock was subsequently multiplied by three, such that following the Reverse Stock Split the Company has 45,000,000 shares of common stock authorized. The Reverse Stock Split affected all issued and outstanding shares of the Company’s common stock, and the respective numbers of shares of common stock underlying the Company’s outstanding stock options, outstanding warrants and the Company’s equity incentive plans were proportionately adjusted. All share and per share amounts disclosed give effect to the Reverse Stock Split on a retroactive basis.

Sales of Common Stock

On January 29, 2021, the Company entered into a Capital on Demand™ Sales Agreement (the “ATM Sales Agreement”) with JonesTrading Institutional Services LLC (“JonesTrading”) and William Blair & Company, L.L.C. (“William Blair” and, collectively with JonesTrading, the “Agents”), pursuant to which the Company may offer and sell shares of its common stock having an aggregate offering price of up to \$30,000 from time to time through or to the Agents (the “ATM Offering”). During the year ended December 31, 2021, the Company issued and sold an aggregate of 261,270 shares of its common stock pursuant to the ATM Sales Agreement, resulting in gross proceeds of \$10,922 before deducting expenses of \$329. Pursuant to a prospectus relating to the ATM Sales Agreement filed by the Company with the SEC on June 21, 2022, the Company may from time to time offer and sell shares of its common stock having an aggregate offering price of up to \$14,024 under the ATM Sales Agreement. There were no sales under the ATM Sales Agreement during the nine months ended September 30, 2023, or the year ended December 31, 2022.

During the year ended December 31, 2021, the Company issued and sold an aggregate of 68,750 shares of its common stock to Lincoln Park Capital, LLC pursuant to a purchase agreement entered into between Lincoln Park Capital, LLC (“LPC”) and the Company in September 2020, resulting in gross proceeds of \$2,614. During the year ended December 31, 2020, the Company issued and sold 29,411 shares to LPC under the purchase agreement for proceeds of \$500. There were no sales under the purchase agreement during the nine months ended September 30, 2023, or the year ended December 31, 2022. Under the purchase agreement, the

Company may not effect any sales of shares of common stock on any purchase date that the closing sale price of its common stock on Nasdaq is less than the floor price of \$6.00 per share, which will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction.

On April 2, 2019, the Company issued and sold in a private placement an aggregate of (i) 591,922 units, consisting of 591,922 shares of its common stock and associated warrants, or the common warrants, to purchase an aggregate of 591,922 shares of common stock, for a combined price of \$40.20 per unit and (ii) 54,837 units, consisting of (a) pre-funded warrants to purchase 54,837 shares of our common stock and (b) associated common warrants to purchase 54,837 shares of common stock, for a combined price of \$40.20 per unit. The pre-funded warrants had an exercise price of \$0.20 per share and had no expiration. In July 2019, all outstanding pre-funded warrants were exercised for 54,837 shares of common stock. At September 30, 2023, there were 646,759 common warrants outstanding with an exercise price of \$40.00 per share.

The Company has assessed the warrants for appropriate equity or liability classification and determined the warrants are freestanding instruments that do not meet the definition of a liability pursuant to ASC 480 and do not meet the definition of a derivative pursuant to ASC 815. The warrants are indexed to the Company's common stock and meet all other conditions for equity classification under ASC 480 and ASC 815. Accordingly, the warrants are classified as equity and accounted for as a component of additional paid-in capital at the time of issuance.

10. Stock-Based Awards

2021 Stock Incentive Plan

The Company's 2021 Stock Incentive Plan (the "2021 Plan") was approved by the Company's stockholders on June 15, 2021 and became effective on June 16, 2021. Under the 2021 Plan, the Company may grant incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, awards of restricted stock units and other stock-based awards. The Company's employees, officers, directors, consultants and advisors are eligible to receive awards under the 2021 Plan; however, incentive stock options may only be granted to employees. The 2021 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board. The number of shares of common stock covered by options and the date those options become exercisable, type of options to be granted, exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee if so delegated.

Stock options granted under the 2021 Plan with service-based vesting conditions generally vest over four years and may not have a duration in excess of ten years, although options have been granted with vesting terms of less than four years.

The total number of shares of common stock that may be issued under the 2021 Plan was 796,930 as of September 30, 2023, of which 384,193 shares remained available for grant. The Company initially reserved 625,000 shares of common stock, plus the number of shares of common stock subject to outstanding awards under the Company's 2017 Stock Incentive Plan (the "2017 Plan"), and the Company's 2016 Stock Incentive Plan ("the 2016 Plan") and the Company's 2006 Stock Incentive Plan, as amended (the "2006 Plan") that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right up to 314,006 shares.

Shares that are expired, terminated, surrendered or canceled without having been fully exercised will be available for future awards. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards.

The exercise price for stock options granted may not be less than the fair market value of the common stock as of the date of grant.

2017 Stock Incentive Plan

The 2017 Plan was approved by the Company's stockholders on June 16, 2017, and became effective on June 28, 2017. Under the 2017 Plan, the Company could grant incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, awards of restricted stock units and other stock-based awards. The Company's employees, officers, directors, consultants and advisors were eligible to receive awards under the 2017 Plan; however, incentive stock options could only be granted to employees. The 2017 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board. The number of shares of common stock covered by options and the date those options become exercisable, type of options granted, exercise prices, vesting and other restrictions were determined at the discretion of the board of directors, or its committee if so delegated.

Stock options granted under the 2017 Plan with service-based vesting conditions generally vest over four years and may not have a duration in excess of ten years, although options have been granted with vesting terms of less than four years. The exercise price for stock options granted may not be less than the fair market value of the common stock as of the date of grant.

As of the effective date of the 2021 Plan, the board of directors determined to grant no further awards under the 2017 Plan.

Shares that are expired, terminated, surrendered or canceled without having been fully exercised will be available for future awards under the 2021 Plan. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards under the 2021 Plan.

2017 Employee Stock Purchase Plan

On June 16, 2017, the Company's stockholders approved the 2017 Employee Stock Purchase Plan (the "2017 ESPP"), which became effective on June 28, 2017. A total of 7,500 shares of common stock were initially reserved for issuance under this plan. Under the 2017 ESPP, the number of shares of common stock that may be issued under the 2017 ESPP will automatically increase on each January 1, beginning with the fiscal year ending December 31, 2018 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2027, equal to the least of (i) 31,120 shares, (ii) 1% of the outstanding shares of common stock on such date and (iii) an amount determined by the Company's board of directors. The compensation committee of the board of directors has determined that the number of shares of common stock that may be issued under the 2017 ESPP would not be increased on January 1, 2022 or January 1, 2023. The Company has not issued any shares under the 2017 ESPP.

Stock Option Valuation

There were no options granted to employees or directors during the nine months ended September 30, 2023. The assumptions that the Company used to determine the grant-date fair value of the stock options granted to employees and directors during the nine months ended September 30, 2022 were as follows, presented on a weighted average basis :

	Nine Months Ended September 30, 2022
Risk-free interest rate	2.46 %
Expected term (in years)	5.9
Expected volatility	94.2 %
Expected dividend yield	0 %

Stock Options

The following table summarizes the Company's stock option activity since January 1, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2022	537,112	\$ 29.77	7.9	\$ —
Granted	—			
Exercised	—			
Canceled, forfeited or expired	(68,495)			
Outstanding at September 30, 2023	<u>468,617</u>	\$ 31.76	6.4	\$ —
Options exercisable at September 30, 2023	354,371	\$ 35.80	5.9	\$ —
Options vested and expected to vest at September 30, 2023	465,772	\$ 31.84	6.4	\$ —
Options exercisable at December 31, 2022	288,821	\$ 40.15	7.1	\$ —
Options vested and expected to vest at December 31, 2022	529,549	\$ 29.95	7.8	\$ —

There were no options granted to employees or directors during the nine months ended September 30, 2023. The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2022 was \$7.00.

The aggregate fair value of stock options that vested during the nine months ended September 30, 2023 and 2022 was \$1,033 and \$2,420, respectively.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. There were no stock options exercised during the nine months ended September 30, 2023 and 2022.

Restricted Stock Units

The Company did not have any restricted stock activity during the nine months ended September 30, 2023.

Stock-Based Compensation

The Company recorded stock-based compensation expense related to stock options and restricted stock units in the following expense categories of its statements of operations and comprehensive loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development expenses	\$ 37	\$ 144	\$ 227	\$ 465
General and administrative expenses	192	298	693	1,194
	<u>\$ 229</u>	<u>\$ 442</u>	<u>\$ 920</u>	<u>\$ 1,659</u>

As of September 30, 2023, the Company had an aggregate of \$1,630 of unrecognized stock-based compensation expense, which it expects to recognize over a weighted average period of 1.85 years.

11. Net Loss per Share

Basic and diluted net loss per share was calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	\$ (1,827)	\$ (6,368)	\$ (8,393)	\$ (22,782)
Denominator:				
Weighted average common shares outstanding—basic and diluted	4,541,167	4,541,179	4,541,167	4,538,707
Net loss per share —basic and diluted	<u>\$ (0.40)</u>	<u>\$ (1.40)</u>	<u>\$ (1.85)</u>	<u>\$ (5.02)</u>

The Company's potential dilutive securities as of September 30, 2023 and 2022, which include stock options and warrants, have been excluded from the computation of diluted net loss per share whenever the effect of including them would be to reduce the net loss per share. In periods where there is a net loss, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The following potential shares of common stock, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2023	2022
Warrants to purchase common stock	646,759	646,759
Stock options to purchase common stock	468,617	539,198
Total	<u>1,115,376</u>	<u>1,185,957</u>

12. Commitments and Contingencies

Intellectual Property Licenses

Harvard and Dana-Farber Agreement

In August 2006, the Company entered into an exclusive license agreement with President and Fellows of Harvard College (“Harvard”) and Dana-Farber Cancer Institute (“DFCI”). The agreement granted the Company an exclusive worldwide license, with the right to sublicense, under specified patents and patent applications to develop, obtain regulatory approval for and commercialize specified product candidates based on cell-permeating peptides. Under the agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize one or more licensed products and to achieve specified milestone events by specified dates. In connection with entering into the agreement, the Company paid an upfront license fee and issued to Harvard and DFCI shares of its common stock.

In February 2010, the agreement was amended and restated (the “Harvard/DFCI agreement”) under which additional patent rights were added to the scope of the license agreement and the annual license maintenance fees were increased. Under the Harvard/DFCI agreement, the Company is obligated to make aggregate milestone payments of up to \$7,700 per licensed therapeutic product upon the Company’s achievement of specified clinical, regulatory and sales milestones with respect to such product and up to \$700 per licensed diagnostic product upon the Company’s achievement of specified regulatory and sales milestones with respect to such product. In addition, the Company is obligated to pay royalties of low single-digit percentages on annual net sales of licensed products sold by the Company, its affiliates or its sublicensees. The royalties are payable on a product-by-product and country-by-country basis, and may be reduced in specified circumstances. In addition, the Harvard/DFCI agreement obligates the Company to pay a percentage, up to the mid-twenties, of fees received by the Company in connection with its sublicense of the licensed products. In accordance with the terms of the Harvard/DFCI agreement, the Company’s sublicense payment obligations may be subject to specified reductions.

From time to time, the Company, Harvard, and DFCI have modified the scope of the agreement. In the quarter ended September 30, 2023, the annual license fees the Company is required to pay under the Harvard/DFCI agreement were modified from \$110 to \$35. Any payments made in connection with the annual license maintenance fees will be credited against any royalties due.

The Company incurred license maintenance fees of \$35 and \$110 during each of the nine months ended September 30, 2023 and 2022, respectively. The Company did not make any milestone payments during the three and nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, no additional milestones had been achieved and no liabilities for additional milestone payments had been recorded in the Company’s financial statements.

As of September 30, 2023, the Company had not developed a commercial product using the licensed technologies and no royalties under the Harvard/DFCI agreement had been paid or were due.

Under the Harvard/DFCI agreement, the Company is responsible for all patent expenses related to the prosecution and maintenance of the licensed patents and applications in-licensed under the agreement as well as cost reimbursement of amounts incurred for all documented patent-related expenses. The agreement will expire on a product-by-product and country-by-country basis upon the last to expire of any valid patent claim pertaining to licensed products covered under the agreement.

Umicore Agreement

In December 2006, the Company entered into a license agreement with Materia, Inc. (“Materia”), under which it was granted a non-exclusive worldwide license, with the right to sublicense, under specified patent and patent applications to utilize Materia’s catalysts to develop, obtain regulatory approval for and commercialize specified peptides owned or controlled by Materia and the right to manufacture specified compositions owned or controlled by Materia. In February 2017, Materia assigned the license agreement (the “Umicore agreement”) to Umicore Precious Metals Chemistry USA, LLC (“Umicore”), and Umicore agreed to continue to supply the Company under the agreement.

Under the Umicore agreement, the Company is obligated to make aggregate milestone payments to Umicore of up to \$6,400 upon the Company’s achievement of specified clinical, regulatory and sales milestones with respect to each licensed product. In addition, the Company is obligated to pay tiered royalties ranging in the low single-digit percentages on annual net sales of licensed products sold by the Company or its sublicensees. The royalties are payable on a product-by-product and country-by-country basis and may be reduced in specified circumstances.

The Umicore agreement requires the Company to pay annual license fees of \$50. The Company incurred license fees of \$50 during the nine months ended September 30, 2023 and 2022, respectively. The Company did not make any milestone payments during the three and nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, no additional milestones had been achieved and no liabilities for additional milestone payments had been recorded in the Company's financial statements.

The Umicore agreement expires upon the expiration of the Company's obligation to pay royalties in each territory covered under the agreement.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims for indemnification that would have a material effect on its financial position, results of operations or cash flows, and it had not accrued any liabilities related to such obligations in its financial statements as of September 30, 2023 or December 31, 2022.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis is meant to provide material information relevant to an assessment of the financial condition and results of operations of our company, including an evaluation of the amounts and certainty of cash flows from operations and from outside sources, so as to allow investors to better view our company from management’s perspectives. You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and related notes for the year ended December 31, 2022 included in our Annual Report on Form 10-K for the year ended December 31, 2022 that was filed with the Securities and Exchange Commission, or SEC, on March 20, 2023.

Some of the statements 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 and strategy for our business, constitute forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. The following information and any forward-looking statements should be considered in light of factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on March 20, 2023, and elsewhere in this Quarterly Report on Form 10-Q particularly including those risks identified in our Annual Report on Form 10-K, Part I-Item 1A, “Risk Factors” and in this Quarterly Report on Form 10-Q, Part II-Item 1A “Risk Factors” and our other filings with the SEC.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. Statements made herein are as of the date of the filing of this Quarterly Report on Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made.

Announcement of Exploration of Strategic Alternatives

In February 2023, we announced a review of initial data from our Phase 1b chemoprotection trial of ALRN-6924 in patients with p53-mutated breast cancer showed that patients in the trial experienced severe neutropenia (Grade 4) and alopecia. The primary endpoint of the Phase 1b open-label trial, which was evaluating ALRN-6924 in patients with breast cancer receiving neoadjuvant or adjuvant treatment with docetaxel, doxorubicin, and cyclophosphamide, or TAC chemotherapy, was duration and incidence of severe neutropenia in cycle 1. Incidence of chemotherapy-induced alopecia (hair loss) was a secondary endpoint. Based on these findings, we decided to terminate the Phase 1b breast cancer trial and further development of ALRN-6924.

We also announced that we are exploring a range of strategic alternatives to maximize shareholder value. We have engaged Ladenburg Thalmann & Co., Inc. to act as a strategic advisor for this process. Strategic alternatives that are being evaluated may include, but are not limited to, an acquisition, a merger, a business combination, a sale of assets or other transactions. There is no set timetable for this process and there can be no assurances that this process will result in us pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms. Due to the inherent uncertainty in the timing and cost of these potential strategic alternatives, including their impact on our cash consumption, we have concluded that as of the date of this Quarterly Report on Form 10-Q there is substantial doubt about our ability to continue as a going concern.

In addition, in February 2023, we determined to reduce our workforce from nine to three full-time employees, which we completed in the second quarter of 2023. We plan to retain the remaining employees to assist in executing the strategic alternative review process.

Overview

ALRN-6924 is a MDM2/MDMX dual inhibitor that leverages our proprietary peptide drug technology.

When used as a chemoprotective agent, ALRN-6924 is designed to activate p53, which in turn upregulates p21, a known inhibitor of the cell replication cycle. ALRN-6924 was the only reported chemoprotective agent in clinical development to employ a biomarker strategy, in which we exclusively focused on treating patients with p53-mutated cancers. We originally initiated development of ALRN-6924 as an anti-cancer agent to restore p53-dependent tumor suppression in p53 wild-type tumors. When used as an anti-cancer agent, ALRN-6924 is designed to disrupt the interaction of p53 suppressors MDM2 and MDMX with tumor suppressor p53 to reactivate tumor suppression in non-mutant, or wild-type, p53 cancers.

Our clinical development program for ALRN-6924 as a selective chemoprotective agent in patients with p53-mutated cancer included the following clinical trials:

- A Phase 1b open-label clinical trial that evaluated ALRN-6924 as a chemoprotective agent in patients with p53-mutated breast cancer undergoing either neoadjuvant or adjuvant treatment with TAC chemotherapy;
- A Phase 1b open-label clinical trial that evaluated ALRN-6924 as a chemoprotective agent in patients with p53-mutated small cell lung cancer, or SCLC, undergoing treatment with second-line topotecan;
- A Phase 1 pharmacology study of ALRN-6924 in healthy volunteers that evaluated the safety and tolerability of ALRN-6924, in addition to its cell cycle arrest mechanism of action, pharmacokinetic, and pharmacodynamic effects, including time to onset, magnitude and duration of cell cycle arrest; and
- A Phase 1b randomized, double-blind, placebo-controlled clinical trial that evaluated ALRN-6924 as a chemoprotective agent in patients with p53-mutated non-small cell lung cancer, or NSCLC, undergoing first-line treatment with carboplatin plus pemetrexed with or without immune checkpoint inhibitors.

Our clinical development program for ALRN-6924 as an anti-cancer agent in patients with wild-type p53 included the following clinical trials:

- A single-agent Phase 1 clinical trial that evaluated ALRN-6924 for the treatment of patients with solid tumors and patients with lymphoma;
- A single-agent Phase 2a clinical trial that evaluated ALRN-6924 for the treatment of patients with peripheral T-cell lymphoma
- A single-agent and Ara-C-combination Phase 1/1b trial that evaluated ALRN-6924 for the treatment of patients with acute myeloid leukemia and myelodysplastic syndrome; and
- A combination trial that evaluated ALRN-6924 in combination with palbociclib for the treatment of patients with tumors harboring MDM2 amplifications.

Since our inception, we have devoted a substantial portion of our resources to developing our product candidates, including ALRN-6924, developing our proprietary stabilized cell-permeating peptide platform, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations.

To date, we have financed operations primarily through \$145.5 million in net proceeds from sales of common stock and warrants, \$131.2 million from sales of preferred stock prior to our IPO, and \$34.9 million from a collaboration agreement in 2010.

Since our inception, we have incurred significant losses on an aggregate basis. Our net losses were \$8.4 million and \$22.8 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of \$281.2 million. These losses have resulted primarily from costs incurred in connection with research and development activities, licensing and patent investment and general and administrative costs associated with our operations. In February 2023, we discontinued development of ALRN-6924 which substantially reduced our operating expenses while we undertake a comprehensive assessment of our strategic options. Notwithstanding these events, we expect to continue to incur operating losses for the foreseeable future.

Subject to the outcome of our exploration of strategic alternatives, we believe that, based on our current operating plan, our cash, and cash equivalents of \$12.1 million as of September 30, 2023, will enable us to fund our operating expenses for at least twelve months following the date of this Quarterly Report on Form 10-Q. Due to the inherent uncertainty in the timing and cost of these potential strategic alternatives, including their impact on our cash consumption, we have concluded that as of the date of this Quarterly Report on Form 10-Q there is substantial doubt about our ability to continue as a going concern. Our funding estimates are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, see "Liquidity and Capital Resources." Our future viability is dependent on our ability to consummate a successful acquisition, merger,

business combination, or a sale of assets or other transaction. If we do not, our board of directors may decide to explore other strategic alternatives, including, without limitation, a dissolution of our company.

Reverse Stock Split

On November 10, 2022, we completed a reverse stock split of our outstanding shares of common stock at a ratio of one-for-twenty. The reverse stock split was approved by our stockholders at our Annual Meeting of Stockholders on June 15, 2022. All share and per share amounts of the common stock included in this Quarterly Report on Form 10-Q, including in the accompanying financial statements, have been retrospectively adjusted to give effect to the reverse stock split for all periods presented, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

Components of our Results of Operations

Revenue

We have not generated any revenue from product sales and, as we do not have any product candidates under development, we do not expect to generate any revenue from the sale of products in the future.

Operating Expenses

Our expenses since inception have consisted solely of research and development costs, general and administrative, and restructuring costs.

Research and Development Expenses

For the periods presented in this Quarterly Report on Form 10-Q, research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of ALRN-6924, and include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conducted research, preclinical studies and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufactured ALRN-6924 for use in our preclinical studies and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- third-party license fees;
- costs related to compliance with regulatory requirements; and
- facility-related expenses, which included direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

For the periods presented in this Quarterly Report on Form 10-Q, our employee and infrastructure resources were primarily devoted to the development of ALRN-6924. We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses.

In addition, we typically used our employee and infrastructure resources across our development programs. We tracked outsourced development costs and milestone payments made under our licensing arrangements by product candidate or development program, but we did not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates.

Research and development activities were central to our business model. Our research and development expenses decreased in the nine months ended September 30, 2023, and we expect our research and development expenses will continue to decrease in the fourth quarter of 2023 as a result of our February 2023 decision to discontinue development of ALRN-6924 and our related reduction in workforce.

If we had continued development of ALRN-6924, we could not determine with certainty the duration and costs of any clinical trials of ALRN-6924 or if, when, or to what extent we would generate revenue from the commercialization and sale of any of our product candidates for which we obtained marketing approval. We may never have been successful in obtaining marketing approval for any product candidate. If we had continued development of ALRN-6924, the duration, costs and timing of clinical trials and development of ALRN-6924 would depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of ALRN-6924, or other product candidates that we may have developed and other research and development activities that we may have conducted;
- uncertainties in clinical trial design and patient enrollment rates;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to have required us to conduct clinical trials beyond those that we anticipated would be required for the completion of clinical development of a product candidate, or if we experienced significant trial delays due to patient enrollment or other reasons, we would have been required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance and corporate and administrative functions. General and administrative expenses are comprised of professional fees associated with being a public company including costs of accounting, auditing, legal, regulatory, tax and consulting services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs; and both public and investor relations costs. General and administrative expenses also include legal fees relating to patent and corporate matters; legal and other professional fees relating to our strategic process; other insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

Our general and administrative expenses decreased in the nine months ended September 30, 2023, and we expect our general and administrative expenses will continue to decrease in the fourth quarter of 2023 as a result of our February 2023 decision to discontinue development of ALRN-6924 and the related reduction in workforce. Our future general and administrative expenses will be significantly dependent on the outcome of our strategic process.

Restructuring Costs

Restructuring-related charges are comprised of one-time termination costs in connection with the reduction-in-workforce, including severance, benefits, and related costs.

Interest Income

Interest income consists of interest income earned on our cash, cash equivalents and investments. Historically, our interest income had not been significant due to low investment balances and low interest earned on those balances. We anticipate that our interest income will fluctuate in the future in response to our cash, cash equivalents and investments, and the interest rate environment.

Other Income, net

Other income, net consists of gains or losses recognized from non-routine items such as accretion on investments, and gains or losses recognized from foreign currency transactions, and the disposal of fixed assets.

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Increase (Decrease)
	2023	2022 (in thousands)	
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	22	4,239	(4,217)
General and administrative	1,955	2,243	(288)
Restructuring and Other	6	—	6
Total operating expenses	1,983	6,482	(4,499)
Loss from operations	(1,983)	(6,482)	4,499
Interest income	155	110	45
Other income, net	1	4	(3)
Net loss	\$ (1,827)	\$ (6,368)	\$ 4,541

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2023 were less than \$0.1 million, compared to \$4.2 million for the three months ended September 30, 2022. The decrease of \$4.2 million in research and development spending was primarily a result of reduced spending of \$1.5 million for our completed Phase 1b NSCLC trial, \$0.7 million for our terminated Phase 1b breast cancer trial, \$0.6 million for our completed healthy volunteer study, \$0.3 million for ALRN-6924 manufacturing costs, and reduced spending for employee and related expenses.

General and Administrative Expenses

General and administrative expenses were \$2.0 million for the three months ended September 30, 2023, compared to \$2.2 million for the three months ended September 30, 2022. The decrease of \$0.3 million in general and administrative expenses was primarily the result of lower headcount costs during the three months ended September 30, 2023 as compared to the three months ended September 30, 2022.

Interest Income

Interest income for the three months ended September 30, 2023 and 2022 was \$0.2 million and \$0.1 million, respectively. We anticipate that our interest income will fluctuate in the future in response to our then-current cash, cash equivalents and investments, and then-current interest rates.

Other Income, net

Other income, net for the three months ended September 30, 2023 was less than \$0.1 million. Other income, net, in the three months ended September 30, 2023 was primarily driven by fluctuations in foreign currency exchange rates and accretion of our investments.

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

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	<u>Nine Months Ended September 30,</u>		<u>Increase (Decrease)</u>
	<u>2023</u>	<u>2022</u>	
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	2,019	15,565	(13,546)
General and administrative	6,027	7,379	(1,352)
Restructuring and Other	940	—	940
Total operating expenses	8,986	22,944	(13,958)
Loss from operations	(8,986)	(22,944)	13,958
Interest income	322	180	142
Other income (expense), net	271	(18)	289
Net loss	<u>\$ (8,393)</u>	<u>\$ (22,782)</u>	<u>\$ 14,389</u>

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2023 were \$2.0 million, compared to \$15.6 million for the nine months ended September 30, 2022. The decrease of \$13.5 million in research and development spending was primarily a result of reduced spending of \$6.1 million for our completed Phase 1b NSCLC trial, \$1.5 million for our completed healthy volunteer study, \$1.4 million for our terminated Phase 1b breast cancer trial, \$1.8 million for ALRN-6924 manufacturing costs, and reduced spending for employee and related expenses.

General and Administrative Expenses

General and administrative expenses were \$6.0 million for the nine months ended September 30, 2023, compared to \$7.4 million for the nine months ended September 30, 2022. The decrease of \$1.4 million in general and administrative expenses was primarily the result of lower headcount costs during the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022.

Restructuring and Other

Restructuring-related charges were \$0.9 million for the nine months ended September 30, 2023. Restructuring-related charges were comprised of one time termination costs in connection with the reduction-in-workforce, including severance, benefits, and related costs.

Interest Income

Interest income for the nine months ended September 30, 2023 and 2022 was \$0.3 million and \$0.2 million, respectively. We anticipate that our interest income will fluctuate in the future in response to our then-current cash, cash equivalents and investments, and then-current interest rates.

Other Income (Expense), net

Other income, net for the nine months ended September 30, 2023 was \$0.3 million, compared to other expense of less than \$0.1 million for the nine months ended September 30, 2022. Other income, net, in the nine months ended September 30, 2023 was primarily driven by fluctuations in foreign currency exchange rates and accretion of our investments.

Liquidity and Capital Resources

Since our inception, we have incurred significant losses on an aggregate basis. We have not commercialized any product candidate, and as we do not have any product candidates under development, we do not expect to generate revenue from sales of any products. We have financed our operations through sales of common stock in our initial public offering and follow-on public offerings, sales of common stock and warrants in a private placement, sales of common stock in “at-the-market” offerings, sales of common stock under our equity line with Lincoln Park Capital LLC, or LPC, sales of preferred stock prior to our initial public offering and payments received under a collaboration agreement. As of September 30, 2023, we had cash, and cash equivalents of \$12.1 million.

Public Offerings

On April 2, 2019, we issued and sold in a private placement an aggregate of (i) 591,922 units, consisting of 591,922 shares of our common stock and associated warrants, or the common warrants, to purchase an aggregate of 591,922 shares of common stock,

for a combined price of \$40.20 per unit and (ii) 54,837 units, consisting of (a) pre-funded warrants to purchase 54,837 shares of our common stock and (b) associated common warrants to purchase 54,837 shares of common stock, for a combined price of \$40.20 per unit. The pre-funded warrants had an exercise price of \$0.20 per share and had no expiration. The common warrants are exercisable at an exercise price of \$40.00 per share and expire in April 2024. The securities were sold pursuant to a securities purchase agreement entered into with accredited investors on March 28, 2019. We received aggregate gross proceeds from the private placement of approximately \$26.0 million before deducting placement agent fees and offering expenses of approximately \$2.2 million and excluding the exercise of any warrants. In July 2019, all outstanding pre-funded warrants were exercised for 54,837 shares of common stock. At September 30, 2023, there were 646,759 common warrants outstanding with an exercise price of \$40.00 per share.

In January 2021, we issued and sold an aggregate of 1,631,549 shares of common stock in a registered direct offering at a purchase price per share of \$22.00. The aggregate gross proceeds of the registered direct offering were \$35.9 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by us of approximately \$2.9 million.

At-the-Market Offering

In July 2019, we entered into a Sales Agreement with JonesTrading Institutional Services LLC, or JonesTrading, under which we were able to issue and sell shares of common stock, having an aggregate offering price of up to \$15.0 million, or the Prior Sales Agreement. During the year ended December 31, 2020, we issued and sold an aggregate of 208,044 shares of common stock pursuant to the Prior Sales Agreement for gross proceeds of \$4.0 million, before deducting commissions and fees. Between January 1, 2021 and January 28, 2021, we sold an additional 358,749 shares of common stock pursuant to the Prior Sales Agreement for gross proceeds of \$9.7 million, before deducting commissions and fees. We terminated the Prior Sales Agreement in January 2021.

In January 2021, we entered into a Capital on Demand Sales Agreement, or the ATM Sales Agreement, with JonesTrading Institutional Services LLC, or JonesTrading, and William Blair & Company, L.L.C., or William Blair, as agents, under which we may issue and sell shares of common stock, having an aggregate offering price of up to \$30.0 million. Sales of common stock through JonesTrading and William Blair may be made by any method that is deemed an “at the market” offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. We are not obligated to make any sales of common stock under the ATM Sales Agreement. Pursuant to a prospectus relating to the ATM Sales Agreement we filed with the SEC on June 21, 2022, we may offer and sell shares of our common stock having an aggregate offering price of up to \$14.0 million under the ATM Sales Agreement. There were no sales under the ATM Sales Agreement during the nine months ended September 30, 2023, or the year ended December 31, 2022.

Equity Line Financing

On September 21, 2020, we entered into a purchase agreement, or the Purchase Agreement, with LPC for an equity line financing. The Purchase Agreement provides that, subject to the terms and conditions set forth therein, we have the right, but not the obligation, to sell to LPC, and LPC is obligated to purchase up to \$15.0 million of shares of common stock at our sole discretion, over a 36-month period that commenced in October 2020. We filed a registration statement on Form S-1 covering the sale of shares of common stock that are issued to LPC under the Purchase Agreement, which was declared effective on October 15, 2020.

Upon entering into the Purchase Agreement, we issued and sold 18,382 shares of common stock, or the Initial Purchase Shares, to LPC at a price per share of \$27.20, or \$0.5 million, which is part of the \$15.0 million of shares of common stock that we may sell to LPC under the Purchase Agreement. Additionally, we issued to LPC as a commitment fee of 11,029 shares of common stock as consideration for LPC entering into the Purchase Agreement.

Under the Purchase Agreement, we may, at our discretion, direct LPC to purchase on any single business day, or a Regular Purchase, up to (i) 12,500 shares of common stock if the closing sale price of our common stock is not below \$30.00 per share on Nasdaq, (ii) 10,000 shares of common stock if the closing sale price of our common stock is not below \$20.00 per share on Nasdaq or (iii) 7,500 shares of common stock if the closing sale price of our common stock is below \$20.00 per share on Nasdaq. In any case, LPC’s commitment in any single Regular Purchase may not exceed \$1.0 million. The foregoing share amounts and per share prices will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction.

The purchase price per share for each such Regular Purchase will be based on prevailing market prices of our common stock immediately preceding the time of sale as computed under the Purchase Agreement. Under the Purchase Agreement, we may not effect any sales of shares of common stock on any purchase date that the closing sale price of our common stock on Nasdaq is less than the floor price of \$6.00 per share, which will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction. As of the date of this Quarterly Report on Form 10-Q, the closing sale price of our common stock on Nasdaq is less than the floor price of \$6.00 per share under the Purchase Agreement. As a result, we cannot issue and sell shares of our common stock to LPC under the Purchase Agreement, and we do not expect to be able to do so for the foreseeable future.

In addition to Regular Purchases, we may also direct LPC to purchase other amounts as accelerated purchases or as additional accelerated purchases on the terms and subject to the conditions set forth in the Purchase Agreement.

The net proceeds under the Purchase Agreement to us will depend on the frequency of sales and the number of shares sold to LPC and prices at which we sell shares to LPC.

The Purchase Agreement contains customary representations, warranties, covenants, indemnification and termination provisions. LPC has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our common stock. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings (other than restrictions on our ability to enter into additional “equity line” or a substantially similar transaction whereby a specific investor is irrevocably bound pursuant to an agreement with us to purchase securities over a period of time from us at a price based on the market price of the common stock at the time of such purchase), rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our sole discretion, without any cost or penalty. During any “event of default” under the Purchase Agreement, LPC does not have the right to terminate the Purchase Agreement; however, we may not initiate any purchase of shares by LPC until such event of default is cured. There were no sales under the Purchase Agreement during the nine months ended September 30, 2023, or the year ended December 31, 2022.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Cash used in operating activities	\$ (9,417)	\$ (20,456)
Cash provided by investing activities	16,292	21,695
Cash provided by financing activities	—	—
Net increase in cash, cash equivalents and restricted cash	<u>\$ 6,875</u>	<u>\$ 1,239</u>

Operating Activities.

During the nine months ended September 30, 2023, operating activities used \$9.4 million of cash, resulting primarily from our net loss of \$8.4 million and \$1.8 million of decreased net operating assets and liabilities, offset by \$0.8 million in non-cash expenses. During the nine months ended September 30, 2022, operating activities used \$20.5 million of cash, resulting primarily from our net loss of \$22.8 million, partially offset by \$1.7 million in non-cash expenses.

Investing Activities.

During the nine months ended September 30, 2023, investing activities provided \$16.3 million of cash resulting primarily from \$16.3 million of proceeds from the sale of investments. During the nine months ended September 30, 2022, investing activities provided \$21.7 million of cash primarily resulting from \$41.6 million of proceeds from the sale of investments, partially offset by purchases of \$19.9 million of investments.

Financing Activities.

During the nine months ended September 30, 2023 and 2022, net cash provided by financing activities was \$0 million.

Funding Requirements

Our operating expenses decreased in the nine months ended September 30, 2023, and we expect our operating expenses will continue to decrease in the fourth quarter of 2023 as a result of our February 2023 decision to discontinue development of ALRN-6924 and implement a reduction in workforce. However, we may not realize, in full or in part, the anticipated benefits and savings in operating expenses from these decisions due to unforeseen difficulties, delays or unexpected costs.

Our future capital requirements will depend on many factors, including:

- our ability to consummate a strategic transaction and the nature and type of such transaction;
- the costs associated with operating as a public company.

If we continued to pursue development of ALRN-6924, our capital requirements would have depended on many factors, including:

- the scope, progress, results and costs of our preclinical studies, CMC, and clinical trials;
- the costs, timing and outcome of regulatory review of ALRN-6924;
- our ability to establish and maintain collaborations with third parties on favorable terms, if at all;
- the success of any collaborations that we may have entered into with third parties;
- the extent to which we acquired or invested in businesses, products and technologies, including entering into licensing or collaboration arrangements for ALRN-6924, although we currently have no commitments or agreements to complete any such transactions;
- the costs and timing of commercialization activities, including drug sales, marketing, manufacturing and distribution, for any product candidates for which we may have received marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, or other third-party funding. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

There can be no assurance that a strategic transaction will be completed and our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up. Due to the inherent uncertainty in the timing and cost of these potential strategic alternatives, including their impact on our cash consumption, we have concluded that as of the date of this Quarterly Report on Form 10-Q there is substantial doubt about our ability to continue as a going concern.

If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our strategic process and we may consider seeking protection under the bankruptcy laws in order to continue to pursue potential strategic alternatives. If we decide to seek protection under the bankruptcy laws, we would expect that we would file for bankruptcy at a time that is earlier than when we would otherwise exhaust our cash resources. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs, and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

During the three and nine months ended September 30, 2023, there were no material changes to our critical accounting policies. For further information, refer to our summary of significant accounting policies and estimates in our Annual Report on Form 10-K for the year ended December 31, 2022 as filed with the SEC on March 20, 2023.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

Emerging Growth Company Status

Prior to December 31, 2022, we qualified as an “emerging growth company” as defined in Section 101 of The Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We ceased to qualify as an emerging growth company as of December 31, 2022, and are now subject to Section 14A(a) and (b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, beginning with our fiscal year starting January 1, 2023. However, notwithstanding the loss of our status as an emerging growth company, we will continue to be exempt from Section 404(b) of the Sarbanes-Oxley Act of 2002 for so long as we are neither a “large accelerated filer” nor an “accelerated filer” as those terms are defined in Rule 12b-2 under the Exchange Act.

We are a “smaller reporting company” as defined in Rule 12b-2 under the Exchange Act. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. For so long as we continue to be a smaller reporting company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined in Rule 12b-2 under the Exchange Act for this reporting period and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Interim Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Interim Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2023.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) has occurred during the quarter ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

For a discussion of our risk factors, see “Part I, Item 1A-Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022. You should carefully consider the risks included in our Annual Report on Form 10-K, together with all of the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q. The occurrence of any single risk or any combination of risks could materially and adversely affect our business, financial condition, results of operations, cash flows and the trading price of our common stock.

Item 6. Exhibits.

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report on Form 10-Q.

Exhibit Number	Description
10.1	<u>Waiver Under Amended and Restated License Agreement, dated as of February 19, 2010, by and among the Registrant, President and Fellows of Harvard College and Dana-Farber Cancer Institute, Inc.</u>
31.1	<u>Certification of Principal Executive Officer 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.</u>
31.2	<u>Certification of Principal Financial Officer 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.</u>
32.1	<u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2	<u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**WAIVER UNDER
LICENSE AGREEMENT**

July 19, 2023

THIS WAIVER UNDER LICENSE AGREEMENT (this “**Waiver**”) is made as of the date first written above (the “**Effective Date**”) by and among President and Fellows of Harvard College (“**Harvard**”), Dana-Farber Cancer Institute, Inc. (“**DFCI**”, and together with Harvard, the “**Licensors**”) and Aileron Therapeutics, Inc. (“**Licensee**”) with respect to that certain Amended and Restated License Agreement dated as of February 19, 2010 (the “**License Agreement**”). Capitalized terms not defined in this Waiver shall have the meanings given to them in the License Agreement.

WHEREAS, pursuant to Sections 3.3 of the License Agreement, on June 15, 2023, Licensee provided notification by electronic mail to Harvard that it intends to abandon the remaining Original Patent Rights subject to the License Agreement, which remaining Original Patent Rights are referenced in Harvard Case No. 2266 and DFCI Case No. 937-02 (the “**Abandonment**”);

WHEREAS, in connection with the Abandonment, Licensee is seeking: (i) a waiver of payment by Licensee of the 2023 annual license maintenance fee for the Original Patent Rights as set forth in 6.3.1 of the License Agreement, which payment was due as of January 1, 2023 (the “**2023 Maintenance Fee**”), (ii) a waiver of the prior notice requirements for the Abandonment as set forth in Section 3.3 of the License Agreement, such that the Abandonment will become effective as of the Effective Date, and (iii) a waiver of the method of notification to Licensors’ as set forth in Section 12.6 of the License Agreement, such that the email notification shall suffice as notification to the Licensors of the Abandonment; and

WHEREAS, pursuant to Section 12.10 of the License Agreement, any term of the License Agreement may be waived only by written instrument executed by the parties waiving compliance.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, Licensors and Licensee hereby agrees as follows:

1. Waiver. As of the Effective Date, pursuant to Section 12.10 of the License Agreement, the Licensors waive: (i) payment of the 2023 Maintenance Fee by Licensee, (ii) the prior notification requirements for the Abandonment as set forth in Section 3.3 of the License Agreement, such that the Abandonment shall be effective as of the Effective Date, and (iii) the method of notification of the Abandonment pursuant to Section 12.6 of the License Agreement, whereby the email notification of the Abandonment from Licensee to Harvard shall suffice as proper notification to the Licensors.
 2. Acknowledgment. The Licensors acknowledge that, following the effectiveness of the Abandonment, no annual license maintenance fee shall be due thereafter for the Original Patent Rights pursuant to Section 6.3.1 of the License Agreement.
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3. Miscellaneous. Except as explicitly set forth herein, this Waiver does waive, amend or forgive any obligation of Licensee that accrued prior to the Effective Date as to the subject matter hereof and no other term of the License Agreement is waived, amended or forgiven hereby. This Waiver will be governed by, and construed in accordance with, the substantive laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. Any dispute will be resolved by the state courts of the Commonwealth of Massachusetts or the federal courts of the District of Massachusetts, without restricting any right of appeal.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned has executed this Waiver to be effective as of the date first written above.

LICENSEE:

AILERON THERAPEUTICS, INC.

By: /s/ Manuel C. Alves Aivado, M.D., Ph.D.
Name: Manuel C. Alves Aivado, M.D., Ph.D.
Title: President and Chief Executive Officer

LICENSORS:

PRESIDENT AND FELLOWS OF HARVARD COLLEGE

By: /s/ Isaac T. Kolhberg
Name: Isaac T. Kolhberg
Title: Chief Technology Development Officer

DANA-FARBER CANCER INSTITUTE, INC.

By: /s/ Emy Chen
Name: Emy Chen
Title: VP, Innovations

[Signature Page to Waiver]

**Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a)
and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002**

I, Manuel C. Alves Aivado, M.D., Ph.D., certify that:

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

Aileron Therapeutics, Inc.

/s/ Manuel C. Alves Aivado, M.D., Ph.D.

Manuel C. Alves Aivado, M.D., Ph.D.

President and Chief Executive Officer

Dated: October 13, 2023

**Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a)
and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002**

I, Susan L. Drexler certify that:

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

Aileron Therapeutics, Inc.

/s/ Susan L. Drexler

Susan L. Drexler

Interim Chief Financial Officer

Dated: October 13, 2023

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT
TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Aileron Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Manuel C. Alves Aivado, M.D., Ph.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 13, 2023

/s/ Manuel C. Alves Aivado, M.D., Ph.D.

Manuel C. Alves Aivado, M.D., Ph.D.
President and Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT
TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Aileron Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Susan L. Drexler, Interim Chief Financial Officer of the Company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 13, 2023

/s/ Susan L. Drexler

Susan L. Drexler
Interim Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
