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, 2022

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.)**
285 Summer Street, Suite 101 **Boston, MA** **(Address of principal executive offices)**	**02210** **(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 28, 2022, the registrant had 90,823,597 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 plans to develop and commercialize ALRN-6924, including the potential benefits thereof;
- our clinical trials for ALRN-6924, whether conducted by us or by any future collaborators, including with respect to the design of the trials or the timing of initiation of these trials and of the anticipated results;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash, cash equivalents and investments;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the timing of and our ability to obtain and maintain marketing approvals for ALRN-6924;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our plans to enter into collaborations for the development and commercialization of ALRN-6924 and any additional product candidates;
- potential benefits of any future collaboration;
- developments relating to our competitors and our industry;
- the impact of government laws and regulations;
- the impact the coronavirus pandemic may have on the timing of our clinical development and 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, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 4,839	$ 3,600
Investments	20,638	42,333
Prepaid expenses and other current assets	1,552	2,219
Restricted cash	25	25
Total current assets	27,054	48,177
Operating lease, right-of-use asset	70	152
Other non-current assets	24	24
Property and equipment, net	84	128
Total assets	$ 27,232	$ 48,481
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 945	$ 1,210
Accrued expenses and other current liabilities	3,524	3,205
Operating lease liability, current portion	67	93
Total current liabilities	4,536	4,508
Operating lease liability, net of current portion	—	69
Total liabilities	4,536	4,577
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized and no shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized at September 30, 2022 and December 31, 2021; 90,823,597 and 90,573,597 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	91	91
Additional paid-in capital	290,941	289,282
Accumulated other comprehensive loss	(98)	(13)
Accumulated deficit	(268,238)	(245,456)
Total stockholders' equity	22,696	43,904
Total liabilities and stockholders' equity	$ 27,232	$ 48,481

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,	
	2022	2021	2022	2021
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,239	4,278	15,565	12,447
General and administrative	2,243	2,513	7,379	7,342
Total operating expenses	6,482	6,791	22,944	19,789
Loss from operations	(6,482)	(6,791)	(22,944)	(19,789)
Interest income	110	21	180	54
Other income (expense), net	4	66	(18)	370
Net loss	(6,368)	(6,704)	(22,782)	(19,365)
Net loss per share — basic and diluted	$ (0.07)	$ (0.07)	$ (0.25)	$ (0.22)
Weighted average common shares outstanding—basic and diluted	90,823,597	90,548,972	90,774,146	88,211,362
Comprehensive loss:				
Net loss	$ (6,368)	$ (6,704)	$ (22,782)	$ (19,365)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net of tax of $0	3	(5)	(85)	3
Total other comprehensive income (loss)	3	(5)	(85)	3
Total comprehensive loss	$ (6,365)	$ (6,709)	$ (22,867)	$ (19,362)

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	Accumulated Other		Total
	Shares	Par Value	Paid-in Capital	Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
Balances at December 31, 2021	90,573,597	$ 91	$ 289,282	$ (13)	$ (245,456)	$ 43,904
RSUs vested, net of shares repurchased for tax	250,000	—	—	—	—	0
Stock-based compensation expense	—	—	689	—	—	689
Unrealized loss on investments	—	—	—	(62)	—	(62)
Net loss	—	—	—	—	(8,422)	(8,422)
Balances at March 31, 2022	90,823,597	$ 91	$ 289,971	$ (75)	$ (253,878)	$ 36,109
Stock-based compensation expense	—	—	528	—	—	528
Unrealized loss on investments	—	—	—	(26)	—	(26)
Net loss	—	—	—	—	(7,992)	(7,992)
Balances at June 30, 2022	90,823,597	$ 91	$ 290,499	$ (101)	$ (261,870)	$ 28,619
Stock-based compensation expense	—	—	442	—	—	442
Unrealized gain on investments	—	—	—	3	—	3
Net loss	—	—	—	—	(6,368)	(6,368)
Balances at September 30, 2022	90,823,597	$ 91	$ 290,941	$ (98)	$ (268,238)	$ 22,696
Balances at December 31, 2020	43,804,175	$ 44	$ 231,412	$ (2)	$ (219,292)	$ 12,162
Issuance of common stock	46,406,382	46	59,042	—	—	59,088
Issuance costs	—	—	(3,482)	—	—	(3,482)
Stock-based compensation expense	—	—	631	—	—	631
Unrealized loss on investments	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(6,975)	(6,975)
Balances at March 31, 2021	90,210,557	$ 90	$ 287,603	$ (7)	$ (226,267)	$ 61,419
Exercise of stock options	67,357	—	47	—	—	47
Issuance costs	—	—	(24)	—	—	(24)
RSU's vested, net of shares withheld	250,000	—	—	—	—	0
Stock-based compensation expense	—	—	361	—	—	361
Unrealized gain on investments	—	—	—	13	—	13
Net loss	—	—	—	—	(5,686)	(5,686)
Balances at June 30, 2021	90,527,914	$ 90	$ 287,987	$ 6	$ (231,953)	$ 56,130
Exercise of stock options	44,641	1	26	—	—	27
Stock-based compensation expense	—	—	661	—	—	661
Unrealized gain on investments	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(6,704)	(6,704)
Balances at September 30, 2021	90,572,555	$ 91	$ 288,674	$ 1	$ (238,657)	$ 50,109

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,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (22,782)	$ (19,365)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	126	81
Forgiveness of paycheck protection program loan	—	(387)
Net amortization of premiums and discounts on investments	(85)	212
Stock-based compensation expense	1,659	1,653
Gain on sale of property and equipment	—	(66)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	667	(238)
Other assets	—	(24)
Accounts payable	(265)	(564)
Operating lease liabilities	(95)	(36)
Accrued expenses and other current liabilities	319	1,235
Net cash used in operating activities	(20,456)	(17,499)
Cash flows from investing activities:		
Purchases of property and equipment	—	(157)
Proceeds from sale of property and equipment	—	66
Purchases of investments	(19,912)	(70,828)
Proceeds from sales or maturities of investments	41,607	32,751
Net cash provided by (used in) investing activities	21,695	(38,168)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	—	55,583
Proceeds from exercise of stock options	—	73
Net cash provided by financing activities	—	55,656
Net increase (decrease) in cash, cash equivalents and restricted cash	1,239	(11)
Cash, cash equivalents and restricted cash at beginning of period	3,625	7,639
Cash, cash equivalents and restricted cash at end of period	$ 4,864	$ 7,628

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

1. Nature of the Business and Basis of Presentation

Aileron Therapeutics, Inc. ("Aileron" or the "Company") is a clinical stage chemoprotection oncology company focused on developing medicines to make chemotherapy safer and thereby more effective to save more patients' lives. ALRN-6924, the Company's first-in-class MDM2/MDMX dual inhibitor, is designed to activate p53, which in turn upregulates p21, a known inhibitor of the cell replication cycle. ALRN-6924 is the only reported chemoprotective agent in clinical development to employ a biomarker strategy, in which the Company exclusively focuses on treating patients with p53-mutated cancers. The Company's targeted strategy is designed to selectively protect multiple healthy cell types throughout the body from chemotherapy without protecting cancer cells.

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, and 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.

There can be no assurance that the Company's research and development of ALRN-6924 will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that ALRN-6924 will obtain necessary governmental regulatory approval or that if approved, will be commercially viable. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its key employees and consultants.

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, 2022, the Company has financed operations primarily through $145,467 in net proceeds from sales of common stock, $131,211 from sales of preferred stock prior to its IPO, and $34,910 from a collaboration agreement in 2010.

As of September 30, 2022, the Company had cash, cash equivalents and investments of $25,477. The Company has incurred losses and negative cash flows from operations and had an accumulated deficit of $268,238 as of September 30, 2022. The Company expects to continue to generate losses for the foreseeable future.

The Company believes that, based on its current operating plan, its cash, cash equivalents and investments of $25,477 as of September 30, 2022 will enable the Company to fund its operating expenses for greater than twelve months from the date of issuance of these financial statements.

To execute its business plans beyond the next twelve months, the Company will need substantial funding to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through the sale of common stock in public offering and/or private placements, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing when needed, on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its clinical programs or future commercialization efforts, which could adversely affect its business prospects. The interim 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 as of the date of the financial statements and the reported amounts of 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 based on 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, 2022 and for the three and nine months ended September 30, 2022 and 2021 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, 2021 that was filed with the SEC on March 28, 2022.

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, 2022, the results of its operations for the three and nine months ended September 30, 2022 and 2021 and its cash flows for the nine months ended September 30, 2022 and 2021. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2022 and 2021 are unaudited. The results for the nine months ended September 30, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022, any other interim periods, or any future year or period. The accompanying balance sheet as of December 31, 2021 has been derived from the Company's audited financial statements for the year ended December 31, 2021 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 28, 2022.

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, 2021 that was filed with the SEC on March 28, 2022.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and investments. 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.

The Company is 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 relies and expects to continue to rely 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 be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Risks and Uncertainties

The ongoing COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce. The future progression of the pandemic and its effects on our business and operations are uncertain.

Potential impacts to the Company's business include disruptions in supply of the Company's product candidate and/or procurement of items that are essential for the Company's research and development activities, including, for example, raw materials used in the manufacturing of ALRN-6924, medical and laboratory supplies used in the Company's clinical trials or preclinical studies or animals that are used for preclinical testing, in each case, for which there may be shortages because of ongoing efforts to address the COVID-19 pandemic. While the Company believes that it currently has sufficient supply of its product candidate to conduct the Company's Phase 1b clinical trial in breast cancer, its product candidate, or materials contained therein, come from facilities located in areas impacted by the COVID-19 pandemic.

Additionally, the Company has enrolled, and is seeking to enroll, cancer patients in the Company's clinical trials at sites located both in the United States and Europe, which are areas that continue to be impacted by the COVID-19 pandemic. Enrollment at clinical trial sites has been and may continue to be disrupted as the effects of the COVID-19 pandemic persist. In the event that clinical trial sites close to enrollment in the Company's trials or shift resources to address COVID-19, this could have a material adverse impact on the Company's clinical trial plans and timelines. The Company may face difficulties recruiting or retaining patients in its clinical trials if patients are affected by the virus or are fearful of visiting or traveling to the Company's clinical trial sites because of the COVID-19 pandemic.

Any negative impact that the COVID-19 outbreak has on the ability of the Company's suppliers to provide materials necessary for the Company's product candidate or on recruiting or retaining patients in the Company's clinical trials could cause costly delays to clinical trial activities, which could adversely affect the Company's ability to obtain regulatory approval for and to commercialize the Company's product candidate, increase the Company's operating expenses, affect the Company's ability to raise additional capital, and impact the Company's operating and financial results. The capital markets have also experienced significant volatility as a result of the pandemic. Future disruptions in the capital markets could negatively impact the Company's ability to raise capital in the future.

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 will be effective for the Company's fiscal year beginning January 1, 2023. The Company is currently evaluating the impact of the adoption of ASU 2016-13 and does not expect adoption to have a material effect on the Company's consolidated 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, 2022 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 2,366	$ —	$ —	$ 2,366
Investments:				
Commercial paper	—	14,683	—	14,683
Corporate notes	—	1,248	—	1,248
Treasury bills	—	4,707	—	4,707
Total Fair Value of Financial Instruments as of September 30, 2022	$ 2,366	$ 20,638	$ —	$ 23,004

	Fair Value Measurements as of December 31, 2021 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 2,438	$ —	$ —	$ 2,438
Investments:				
Commercial paper	—	33,969	—	33,969
Corporate notes	—	6,366	—	6,366
Treasury Bills	—	1,998	—	1,998
Total Fair Value of Financial Instruments as of December 31, 2021	$ 2,438	$ 42,333	$ —	$ 44,771

As of September 30, 2022 and December 31, 2021, the Company's cash equivalents and investments were valued based on Level 1 and Level 2 inputs. In determining the fair value of its corporate notes and 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, 2022 and the year ended December 31, 2021, there were no transfers in or out of Level 3.

4. Investments

As of September 30, 2022 and December 31, 2021, the fair value of available-for-sale investments by type of security was as follows:

	September 30, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	$ 14,738	$ —	$ (55)	$ 14,683
Corporate notes	1,252	—	(4)	1,248
Treasury Bills	4,746	—	(39)	4,707
Total Investments as of September 30, 2022	$ 20,736	$ —	$ (98)	$ 20,638

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	$ 33,976	$ —	$ (7)	$ 33,969
Corporate notes	6,368	—	(2)	6,366
Treasury bills	2,002	—	(4)	1,998
Total Investments as of December 31, 2021	$ 42,346	$ —	$ (13)	$ 42,333

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2022	December 31, 2021
Computer equipment and software	$ 340	$ 340
Less: Accumulated depreciation and amortization	(256)	(212)
Total Property and Equipment, Net	$ 84	$ 128

Depreciation and amortization expense for the nine months ended September 30, 2022 and 2021 was $44 and $15 respectively. During the third quarter of 2021, the Company received payment for disposed, fully depreciated assets, resulting in a gain on sale of $66.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2022	December 31, 2021
External research and development services	$ 1,850	$ 1,575
Payroll and payroll-related costs	1,063	1,182
Professional fees	533	388
Other	78	60
Total Accrued Expenses and Other Liabilities	$ 3,524	$ 3,205

7. Paycheck Protection Loan

On April 30, 2020, the Company received loan proceeds in the amount of approximately $384 under the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times the average monthly payroll expenses of the qualifying business. The loan and accrued interest are forgivable after eight weeks if the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities. The amount of loan forgiveness may be reduced if the borrower terminates employees or reduces salaries during the eight-week period. The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1%, with a deferral of payments for the first six months. The Company used the proceeds for purposes consistent with the PPP.

The Company determined to account for the PPP loan as debt under Accounting Standards Update ("ASC 470"), "Debt", and allocated and recorded the loan proceeds between current and non-current liabilities.

On May 20, 2021, the Small Business Administration notified the Company that the PPP loan had been forgiven in full. During the year ended December 31, 2021, the Company recognized income for debt extinguishment pursuant to ASC 470-50-15-4 as other income.

8. 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 is leasing approximately 3,365 square feet of office space located at 285 Summer Street, Unit 101, Boston, Massachusetts (the "Premises"). The Sublease is 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 term of the Sublease (the "Term") commenced on April 1, 2021 and terminates upon the earliest to occur of (i) March 31, 2023, (ii) early termination of the Prime Lease or (iii) termination of the Sublease pursuant to the terms thereof. The Company is obligated to pay monthly base rent under the Sublease to the Sublessor in an approximate amount of $12 per month during the Term. The Company recorded a right of use asset of $228 and operating lease liabilities of $217 upon the inception of the Sublease.

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 150,000,000 shares of $0.001 par value common stock to 300,000,000 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, 2022 and December 31, 2021, no dividends had been declared.

On January 6, 2021, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company issued and sold, in a registered direct offering (the "Offering"), an aggregate of 32,630,983 shares of common stock, $0.001 par value per share, at a purchase price per share of $1.10 (the "Shares"). The aggregate gross proceeds of the Offering were $35,894, before deducting $2,887 of fees payable to the placement agent and other offering expenses payable by the Company. The Offering closed on January 8, 2021.

Between January 1, 2021 and January 28, 2021, the Company issued and sold an aggregate 7,174,993 shares of its common stock pursuant to its sales agreement with JonesTrading Institutional Services LLC ("JonesTrading"), resulting in gross proceeds of $9,658, before deducting expenses of $290. The Company terminated its sales agreement with Jones Trading in January 2021.

On January 29, 2021, the Company entered into a Capital on Demand™ Sales Agreement (the "ATM Sales Agreement") with 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 5,225,406 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, 2022.

During the year ended December 31, 2021, the Company issued and sold an aggregate of 1,375,000 shares of its common stock to Lincoln Park Capital, LLC pursuant to a purchase agreement entered into between Lincoln Park Capital, LLC and the Company in September 2020, resulting in gross proceeds of $2,614. There were no sales under the purchase agreement during the nine months ended September 30, 2022.

On April 2, 2019, the Company issued and sold in a private placement an aggregate of (i) 11,838,582 units, consisting of 11,838,582 shares of its common stock and associated warrants, or the common warrants, to purchase an aggregate of 11,838,582 shares of common stock, for a combined price of $2.01 per unit and (ii) 1,096,741 units, consisting of (a) pre-funded warrants to purchase 1,096,741 shares of our common stock and (b) associated common warrants to purchase 1,096,741 shares of common stock, for a combined price of $2.01 per unit resulting in gross proceeds of $26,000. The pre-funded warrants had an exercise price of $0.01 per share and had no expiration. In July 2019, all outstanding pre-funded warrants were exercised for 1,096,741 shares of common stock. At September 30, 2022 there were warrants outstanding to purchase 12,935,323 shares of common stock with an exercise price of $2.00 per share. The warrants expire in April 2024.

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 14,257,344 as of September 30, 2022, of which 6,009,334 shares remained available for grant. The Company initially reserved 12,500,000 shares of common stock, plus the number of shares of common stock subject to then outstanding awards under the Company's 2017 Stock Incentive Plan (the "2017

Plan"), 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 6,280,135 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 150,000 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) 622,408 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, 2021 or January 1, 2022. The Company has not issued any shares under the 2017 ESPP.

Stock Option Valuation

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 and 2021 were as follows, presented on a weighted average basis:

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Risk-free interest rate	2.46%	0.96%
Expected term (in years)	5.9	6.2
Expected volatility	94.2%	91.0%
Expected dividend yield	0%	0%

Stock Options

The following table summarizes the Company's stock option activity since January 1, 2022:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2021	9,375,497	$ 1.79	8.5	$ 4
Granted	3,148,500	0.46		
Exercised	—	0.00		
Canceled, forfeited or expired	(1,740,022)	1.19		
Outstanding at September 30, 2022	10,783,975	$ 1.50	8.1	$ —
Options exercisable at September 30, 2022	5,339,399	$ 2.11	7.2	$ —
Options vested and expected to vest at September 30, 2022	10,601,564	$ 1.51	8.1	$ —

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2022 and 2021 was $0.35 and $0.97, respectively.

The aggregate fair value of stock options that vested during the nine months ended September 30, 2022 and 2021 was $2,420 and $918, 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. The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2022 and 2021 was $0 and $66, respectively.

Restricted Stock Units

The following table summarizes the Company's restricted stock activity since January 1, 2022:

	Number of Units	Weighted-Average Grant Date Fair Value per Unit
Outstanding, non-vested at December 31, 2021	—	$ —
Issued	250,000	0.39
Vested	(250,000)	0.39
Canceled/forfeited	—	—
Outstanding, non-vested at September 30, 2022	—	—

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,	
	2022	2021	2022	2021
Research and development expenses	$ 144	$ 180	$ 465	$ 383
General and administrative expenses	298	481	1,194	1,270
Total Stock Based Compensation	$ 442	$ 661	$ 1,659	$ 1,653

As of September 30, 2022, the Company had an aggregate of $3,560 of unrecognized stock-based compensation expense, which it expects to recognize over a weighted average period of 2.68 years.

11. Net Loss per Share

The Company's potential dilutive securities as of September 30, 2022 and 2021, 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,	
	2022	2021
Warrants to purchase common stock	12,935,323	12,935,323
Stock options to purchase common stock	10,783,975	9,389,208
Total	23,719,298	22,324,531

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 milestones 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 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 agreement, the Company's sublicense payment obligations may be subject to specified reductions. The Company has not recorded a liability for the aforementioned payments given the achievement of specified clinical, regulatory and sales milestones is not probable as of September 30, 2022.

The Harvard/DFCI agreement requires the Company to pay annual license maintenance fees of $110. 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 $110 and $145 during each of the nine months ended September 30, 2022 and 2021. The Company did not make any milestone payments during the three and nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, no additional milestones had been achieved and no liabilities for additional milestone payments had been recorded in the Company's accompanying unaudited condensed financial statements.

As of September 30, 2022, the Company had not developed a commercial product using the licensed technologies and no royalties under the 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 Company has not recorded a liability for the aforementioned payments given the achievement of specified regulatory approval and commercial sales milestones is not probable as of September 30, 2022.

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, 2022 and 2021, respectively and did not make any milestone payments during the same period. As of September 30, 2022, 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, 2022 or December 31, 2021.

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

The following discussion and analysis of our financial condition and results of operations should be read 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, 2021 included in our Annual Report on Form 10-K for the year ended December 31, 2021 that was filed with the Securities and Exchange Commission, or SEC, on March 28, 2022.

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, 2021, as filed with the SEC on March 28, 2022, 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 IA, "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.

Overview

We are a clinical stage chemoprotection oncology company that aspires to make chemotherapy safer and thereby more effective to save more patients' lives. ALRN-6924, our first-in-class MDM2/MDMX dual inhibitor, is designed to activate p53, which in turn upregulates p21, a known inhibitor of the cell replication cycle. ALRN-6924 is the only reported chemoprotective agent in clinical development to employ a biomarker strategy, in which we exclusively focus on treating patients with p53-mutated cancers. Our targeted strategy is designed to selectively protect multiple healthy cell types throughout the body from chemotherapy without protecting cancer cells. As a result, healthy cells are spared from chemotherapeutic destruction while chemotherapy continues to kill cancer cells. By reducing or eliminating multiple chemotherapy-induced side effects, ALRN-6924 may improve patients' quality of life and help them better tolerate chemotherapy. Enhanced tolerability may result in fewer dose reductions or delays of chemotherapy and the potential for improved efficacy. Our vision is to bring chemoprotection to all patients with p53-mutated cancer regardless of type of cancer or chemotherapy.

Our clinical development program for ALRN-6924 as a selective chemoprotective agent includes:

- An ongoing Phase 1b open-label clinical trial to evaluate ALRN-6924 as a chemoprotective agent in patients with p53-mutated breast cancer undergoing either neoadjuvant or adjuvant treatment with docetaxel, doxorubicin and cyclophosphamide, a chemotherapy regimen also known as TAC;
- A completed Phase 1b open-label clinical trial evaluating ALRN-6924 as a chemoprotective agent in patients with p53-mutated small cell lung cancer, or SCLC, undergoing treatment with second-line topotecan;
- A completed Phase 1 pharmacology study of ALRN-6924 in healthy volunteers evaluating 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 completed Phase 1b randomized, double-blind, placebo-controlled clinical trial evaluating 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, for which we announced on

June 29, 2022 that, based on interim data from the first 20 patients enrolled, we would stop further enrollment in the NSCLC trial and focus our clinical development strategy and resources on our Phase 1b breast cancer trial..

Our Phase 1b breast cancer trial is designed to evaluate the safety, tolerability and chemoprotective effect of ALRN-6924 in up to 24 patients with p53-mutated breast cancer undergoing either neoadjuvant or adjuvant treatment with TAC.

In August 2022, we announced modifications to the trial designed to improve the opportunity to demonstrate protection against chemotherapy-induced severe neutropenia, alopecia and potentially other toxicities in patients with p53-mutated breast cancer. The primary endpoints of the trial are duration and incidence of severe neutropenia (Grade 4) in cycle 1. Secondary endpoints of the trial include the chemoprotective effect of ALRN-6924 on chemotherapy-induced alopecia, as well as other hematologic and non-hematologic toxicities. We plan to report data from initial patients in this trial in the fourth quarter of 2022, data from an interim analysis on 12 patients in the second quarter of 2023 and topline results from 20 patients in the third quarter of 2023.Subject to the successful demonstration of chemoprotection in our Phase 1b breast cancer trial in the topline readout planned, we anticipate initiating preparation for a potential pivotal trial.

Additionally, upon successful completion of the Phase 1b breast cancer trial, and subject to obtaining additional funding, we may expand our clinical program to evaluate ALRN-6924 as a chemoprotective agent across additional p53-mutated tumor types and chemotherapy regimens.

In October 2022, we presented additional results from our completed Phase 1 study of ALRN-6924 in healthy volunteers, which showed that ALRN-6924 induced p53-mediated cell cycle arrest in bone marrow stem cells and hair follicles. The data from the study support the potential of ALRN-6924 to prevent chemotherapy-induced neutropenia, thrombocytopenia and anemia, as well as chemotherapy-induced alopecia.

In this study, cell cycle arrest was directly measured in the bone marrow and hair follicles of an additional 41 females. ALRN-6924 was administered as a single one-hour IV infusion or three-minute bolus injection at 0.3, 0.6, or 0.9 mg/kg to cohorts of three to nine subjects and compared to placebo. Subjects were evaluated for safety and tolerability. Plasma and serum samples were obtained to determine pharmacokinetics and levels of macrophage inhibitory cytokine-1, or MIC-1, a biomarker of p53 activation. Bone marrow was sampled 12 hours post-dose to directly measure cell cycle arrest by flow cytometry in CD34+, lineage-negative bone marrow stem cells. Occipital scalp skin was sampled by 2 mm punch biopsy for p21 immunohistochemistry in hair follicles.

ALRN-6924 continued to demonstrate a favorable safety and tolerability profile, with subjects experiencing only mild, transient adverse events, with nausea/vomiting as the most frequent related adverse events. The degree and duration of serum MIC-1 elevation was dose-dependent, indicating more durable p53 activation at higher ALRN-6924 doses. At 12 hours post-dose, the proportion of cycling bone marrow stem cells was significantly reduced at all dose levels. A blinded pathology review suggested that there was ALRN-6924-dependent p21 induction in anagen-phase hair follicles. Safety profiles, PK and PD were similar for both the three-minute bolus injection and one-hour IV infusion, providing a rationale for future development of ALRN-6924 bolus administration.

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, $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 $22.8 million and $19.4 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $268.2 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. We expect to continue to incur significant expenses and operating losses for at least the next several years.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity offerings, collaborations and licensing arrangements, or other sources of capital. Adequate additional financing may not be available to us on acceptable terms, if at all. Market conditions are volatile and may continue to be volatile for the foreseeable future, which may limit our ability to raise capital. In addition, while we may seek one or more collaborators for future development of ALRN-6924 for one or more indications, we may not be able to enter into a collaboration for ALRN-6924 for such indications on suitable terms, on a timely basis or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. If we are unable to raise capital when needed, or on

acceptable terms, we may be forced to delay, reduce and/or eliminate some or all of our clinical and drug development programs and future commercialization efforts. We may also be forced to take other actions that could adversely affect our business.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We believe that, based on our current operating plan, our cash, cash equivalents and investments of $25.5 million as of September 30, 2022, will enable us to fund our operating expenses through the first quarter of 2024. 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. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate. In any event, our cash, cash equivalents and investments will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development or commercialization of ALRN-6924, see "Liquidity and Capital Resources." Our future viability is dependent on our ability to raise additional capital to finance our operations.

COVID-19

In March 2020, we began precautionary measures to protect the health and safety of our employees and partners and prospective clinical trial participants during the COVID-19 pandemic. Because millions of COVID-19 infections have been reported throughout the United States and worldwide, certain national, state and local governmental authorities have issued orders, proclamations and/or directives aimed at minimizing the spread of COVID-19. Additionally, more restrictive orders, proclamations and/or directives may be issued in the future. As a result, the conduct of our clinical studies with our external partners has been adjusted to institute virtual clinical trial site training and site monitoring, along with partnering with sites to minimize patient visits and institute telemedicine to minimize patient exposure. We have enrolled, and are seeking to enroll, cancer patients in our clinical trials at sites located both in the United States and Europe, which are areas that continue to be impacted by the COVID-19 pandemic.

In particular, the COVID-19 pandemic impacted our ability to activate clinical trial sites and resulted in slower-than-anticipated enrollment in our Phase 1b clinical trial of ALRN-6924 in patients with advanced p53-mutated NSCLC and could result in slower than anticipated enrollment in our Phase 1b clinical trial in patients with breast cancer. The ultimate impact of the COVID-19 pandemic on our operations is unknown and will depend on future developments. Such future events are highly uncertain and cannot be predicted with confidence, including the duration of the COVID-19 pandemic, new information which may emerge concerning the severity of the COVID-19 pandemic, including the new variants and subvariants of the virus that causes COVID-19 that have been identified and are spreading in the United States and around the world, and any additional preventative and protective actions that governments or we may direct, which may result in an extended period of continued business disruption, reduced patient traffic and reduced operations. In particular, the continued spread of COVID-19 will determine whether the pandemic will continue to have an impact on our business, including our clinical trials. We are continuing to monitor the latest developments regarding the COVID-19 pandemic and its impact on our business, financial condition, results of operations and prospects.

Components of our Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for ALRN-6924 or other product candidates that we may develop in the future are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties.

Operating Expenses

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

We expect that our operating expenses will increase if and as we increase our level of clinical development of ALRN-6924 and hire additional personnel to carry out such clinical development.

Research and Development Expenses

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 conduct research, preclinical studies and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufacture 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 include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

Our employee and infrastructure resources are 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.

We typically use our employee and infrastructure resources across our development programs. We track outsourced development costs and milestone payments made under our licensing arrangements by product candidate or development program, but we do 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 are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect to incur significant research and development expenses in the foreseeable future as we continue clinical development of ALRN-6924, initiate additional clinical trials of ALRN-6924, and pursue later stages of clinical development of ALRN-6924.

We cannot determine with certainty the duration and costs of the current, planned, or future clinical trials of ALRN-6924 or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs, and timing of clinical trials and development of ALRN-6924 will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of our Phase 1b breast cancer trial, as well as of any future clinical trials of ALRN-6924 or other product candidates that we may develop and other research and development activities that we may conduct;
- 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 require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant trial delays due to patient enrollment or other reasons, we would be 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; 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.

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 amount of 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 debt forgiveness under the Paycheck Protection Program, 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, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Increase (Decrease)
	2022	2021	
		(in thousands)	
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	4,239	4,278	(39)
General and administrative	2,243	2,513	(270)
Total operating expenses	6,482	6,791	(309)
Loss from operations	(6,482)	(6,791)	309
Interest income	110	21	89
Other income, net	4	66	(62)
Net loss	$ (6,368)	$ (6,704)	$ 336

Research and Development Expenses

Research and development expenses decreased by less than $0.1 million for the three months ended September 30, 2022, which was primarily due to $0.7 million of decreased manufacturing costs for ALRN-6924, offset by $0.7 million of increased spending for our Phase 1b breast cancer trial, during the third quarter of 2022 as compared to the same period in 2021.

General and Administrative Expenses

General and administrative expenses decreased by $0.3 million for the three months ended September 30, 2022, which was primarily due to a decrease in stock compensation expense during the third quarter of 2022 as compared to the same period in 2021.

Interest Income

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

The decrease in other income, net, for the three months ended September 30, 2022, was due to payment received in 2021 for equipment sold in 2020.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Increase (Decrease)
	2022	2021	
		(in thousands)	
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	15,565	12,447	3,118
General and administrative	7,379	7,342	37
Total operating expenses	22,944	19,789	3,155
Loss from operations	(22,944)	(19,789)	(3,155)
Interest income	180	54	126
Other income, net	(18)	370	(388)
Net loss	$ (22,782)	$ (19,365)	$ (3,417)

Research and Development Expenses

Research and development expenses increased $3.1 million for the nine months ended September 30, 2022, primarily due to $2.3 million of increased spending for our Phase 1b clinical trial in breast cancer, $0.5 million of increased manufacturing costs for ALRN-6924, and $0.3 million of increased spending on research related to the clinical development of ALRN-6924.

General and Administrative Expenses

General and administrative increased less than $0.1 million for the nine months ended September 30, 2022, which was due to higher professional services fees.

Interest Income

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

The decrease in other income, net, for the nine months ended September 30, 2022, was primarily due to the forgiveness of the Paycheck Protection Program loan during the nine months ended September 30, 2021.

Liquidity and Capital Resources

Since our inception, we have incurred significant losses on an aggregate basis. We have not yet commercialized any product candidate, including ALRN-6924, which is in clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. 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, 2022, we had cash, cash equivalents and investments of $25.5 million.

Private Offerings

On April 2, 2019, we issued and sold in a private placement an aggregate of (i) 11,838,582 units, consisting of 11,838,582 shares of our common stock and associated warrants, or the common warrants, to purchase an aggregate of 11,838,582 shares of

common stock, for a combined price of $2.01 per unit and (ii) 1,096,741 units, consisting of (a) pre-funded warrants to purchase 1,096,741 shares of our common stock and (b) associated common warrants to purchase 1,096,741 shares of common stock, for a combined price of $2.01 per unit. The pre-funded warrants had an exercise price of $0.01 per share and had no expiration. The common warrants are exercisable at an exercise price of $2.00 per share and expire five years from the date of issuance. 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 1,096,741 shares of common stock.

In January 2021, we issued and sold an aggregate of 32,630,983 shares of common stock in a registered direct offering at a purchase price per share of $1.10. 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 Offerings

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 4,160,899 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 7,174,993 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. During the year ended December 31, 2021, we issued and sold an aggregate of 5,225,406 shares of common stock pursuant to the ATM Sales Agreement for proceeds of $10.6 million, after deducting commissions and fees. 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 $14,024,100 under the ATM Sales Agreement. There were no sales under the ATM Sales Agreement during the three and nine months ended September 30, 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 367,647 shares of common stock, or the Initial Purchase Shares, to LPC at a price per share of $1.36, 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 220,588 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) 250,000 shares of common stock if the closing sale price of our common stock is not below $1.50 per share on Nasdaq, (ii) 200,000 shares of common stock if the closing sale price of our common stock is not below $1.00 per share on Nasdaq or (iii) 150,000 shares of common stock if the closing sale price of our common stock is below $1.00 per share on Nasdaq. In any case, LPC's commitment in any single Regular Purchase may not exceed $1,000,000. 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 $0.30 per share, which will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction.

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. In the year ended December 31, 2020, we issued and sold an aggregate of 1,417,647 shares of common stock to LPC for gross proceeds of $1.8 million. In the year ended December 31, 2021, we issued and sold an aggregate of 1,375,000 shares of common stock to LPC for gross proceeds of $2.6 million. There were no sales under the Purchase Agreement during the three and nine months ended September 30, 2022.

Cash Flows

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

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Cash used in operating activities	$ (20,456)	$ (17,499)
Cash provided by/(used in) investing activities	21,695	(38,168)
Cash provided by financing activities	—	55,656
Net increase/(decrease) in cash, cash equivalents and restricted cash	$ 1,239	$ (11)

Operating Activities.

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. During the nine months ended September 30, 2021 operating activities used $17.5 million of cash, resulting primarily from our net loss of $19.4 million, partially offset by $0.4 million of decreased net operating assets and liabilities and $1.5 million in non-cash expenses.

Investing Activities.

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. During the nine months ended September 30, 2021, investing activities used $38.2 million of cash primarily resulting from the purchase of $70.8 million of investments and partially offset by $32.7 million of proceeds from the sale of investments.

Financing Activities.

During the nine months ended September 30, 2021, net cash provided by financing activities was $55.7 million due to the proceeds received from the sale of common stock during the first quarter of 2021.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing development activities related to ALRN-6924, which is still in clinical development, and any other product candidates and programs that we may pursue in the future. We expect that our expenses will increase substantially if and as we:

- conduct our current, planned, and future preclinical studies and clinical trials of ALRN-6924;

- initiate and resume research and preclinical and clinical development of any other product candidates that we may develop;
- seek to identify additional product candidates;
- seek marketing approvals for any product candidate that successfully completes clinical trials, if any;
- require the manufacture of larger quantities of ALRN-6924 for clinical development and potential commercialization;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other drugs and technologies;
- hire and retain additional clinical, quality control, and scientific personnel;
- build out new facilities or expand existing facilities to support our ongoing development activity; and
- add operational, financial, and management information systems and personnel, including personnel to support our drug development, any future commercialization effort and our compliance with our obligations as a public company.

We believe, based on our current operating plan, that our cash, cash equivalents, and investments of $25.5 million as of September 30, 2022 will enable us to fund our operating expenses through the first quarter of 2024. We expect that these cash resources will allow us to fund our operations beyond the planned topline readout from our Phase 1b breast cancer trial in the third quarter of 2023, and if warranted by the trial results, to initiate preparation for a potential pivotal trial. 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. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate. In any event, our cash, cash equivalents and investments will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of, the development or commercialization of ALRN-6924. Our future viability is dependent on our ability to raise additional capital to finance our operations.

Accordingly, we will be required to obtain further funding through public or private equity offerings, collaborations and licensing arrangements, or other sources of capital. We may also explore other strategic alternatives. Adequate additional financing may not be available to us on acceptable terms, if at all. In addition, while we may seek to enter into a collaboration or other strategic alternative, we may not be able to enter into such a transaction on suitable terms, on a timely basis or at all.

Because of the numerous risks and uncertainties associated with the development of ALRN-6924 and other product candidates that we may develop and programs we may pursue, and because the extent to which we may enter into collaborations with third parties for the development of ALRN-6924 is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of ALRN-6924 or other product candidates that we may develop. Our future capital requirements will depend on many factors, including:

- the scope, progress, results, and costs of our ongoing, planned and future preclinical studies and clinical trials of ALRN-6924;
- the impact of the COVID-19 pandemic on our business and operations;
- the scope, progress, results, and costs of drug discovery, preclinical studies and clinical trials for any other product candidates that we may develop;
- the number of future product candidates that we pursue and their development requirements;
- the costs, timing, and outcome of regulatory review of ALRN-6924;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the success of any collaborations that we may enter into with third parties;
- the extent to which we acquire or invest in businesses, products, and technologies, including entering into licensing or collaboration arrangements for product candidates, although we currently have no commitments or agreements to complete any such transactions;
- the costs and timing of future commercialization activities, including drug sales, marketing, manufacturing and distribution, for any product candidate for which we receive marketing approval;

- the amount of revenue, if any, received from commercial sales of ALRN-6924, should ALRN-6924 receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs, as we expand our business operations and our research and development activities; and
- the costs of operating as a public company.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any products for which we may obtain marketing approval. In addition, ALRN-6924, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. Other than the Purchase Agreement with LPC, which is subject to certain limitations and conditions, including a floor price condition of $0.30 per share (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction, we do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt, making capital expenditures, or declaring dividends, which could adversely impact our ability to conduct our business.

On December 6, 2021, we received a deficiency letter from the Nasdaq Stock Market notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2), or the Bid Price Rule. There can be no assurance that we regain compliance with the Bid Price Rule. Any potential delisting of our common stock from the Nasdaq Capital Market would likely result in decreased liquidity and increased volatility for our common stock and would adversely affect our ability to raise additional capital or to enter into strategic transactions. On June 7, 2022, we received notification from the Nasdaq Stock Market notifying us that we were provided an additional 180 calendar day period or until December 5, 2022 to regain compliance with the Bid Price Rule.

As of the date of this Quarterly Report on Form 10-Q, we have not yet regained compliance with the Bid Price Rule. We intend to monitor the closing bid price of our common stock and intend to effect a reverse stock split to regain compliance with the Bid Price Rule prior to December 6, 2022. On June 15, 2022, our stockholders approved an amendment to our restated certificate of incorporation to effect a reverse stock split at a ratio of not less than 1-for-5 and not greater than 1-for-25, with the exact ratio to be set within that range at the discretion of our board of directors prior to December 31, 2022 without further approval or authorization of our stockholders, in its sole discretion.

If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, if, during the course of our Phase 1b breast cancer trial, we determine, based on interim data from that trial, that ALRN-6924 is not demonstrating sufficient chemoprotection to support continued clinical development, and have not obtained additional funding, our ability to pursue strategic alternatives may be limited and we may consider seeking protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of our company. If we decide to seek protection under the bankruptcy laws, we would expect that we would file for bankruptcy at a time that is significantly 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, 2022, 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, 2021 as filed with the SEC on March 28, 2022.

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

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

We will cease to qualify as an emerging growth company on December 31, 2022.

We are also a "smaller reporting company" as defined in Rule 12b-2 under the Securities and Exchange Act of 1934, as amended. 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. If we are a smaller reporting company at the time we cease to be an emerging growth 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 Securities Exchange Act of 1934, as amended, 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-15I and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or 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, 2022.

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, 2022 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.

Except as discussed below, there have been no material changes to the risks described in "Part I, Item 1A-Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021. You should carefully consider the following risks and 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.

We are dependent on the success of the clinical trial of our product candidate, ALRN-6924 as a chemoprotective agent in patients with p53-mutated HER2- breast cancer receiving neoadjuvant or adjuvant treatment with docetaxel, doxorubicin and cyclophosphamide.

In June 2022, we announced that, based on interim data from the first 20 patients enrolled in our Phase 1b randomized, double-blind, placebo-controlled clinical trial evaluating 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, we planned to stop further enrollment in the NSCLC trial and to focus our resources on our Phase 1b clinical trial of ALRN-6924 as a chemoprotective agent in patients with p53-mutated breast cancer undergoing either neoadjuvant or adjuvant treatment with docetaxel, doxorubicin and cyclophosphamide, a chemotherapy regimen also known as TAC. Our business depends entirely on the successful development and commercialization of ALRN-6924. If our Phase 1b breast cancer clinical trial does not demonstrate sufficient chemoprotection to support continued clinical development of ALRN-6924, we will likely determine to cease further development of ALRN-6924, and our business will be materially harmed.

We have applied key learnings from the interim analysis from the NSCLC trial to strengthen our Phase 1b breast cancer clinical trial, including revising the primary endpoint to duration of severe neutropenia in cycle 1 and changing the chemotherapy regimen to a simultaneous administration of the TAC chemotherapy regimen . Additionally, we have modified the dosing strategy for the breast cancer trial. We are evaluating a single dose of 1.2 mg/kg administered to all patients and no additional patients are being enrolled in the 0.3 mg/kg and 0.6 mg/kg dose cohorts. These changes have resulted in delays in the timing of the clinical trial, and we cannot provide assurances that these changes will not result in additional delays. In addition, we cannot be certain that the changes we are making to this clinical trial will increase the likelihood of success of the clinical trial. For instance, we have never evaluated ALRN-6924 with the TAC chemotherapy regimen we are using in the breast cancer clinical trial.

We plan to enroll up to 24 patients in the Phase 1b breast cancer clinical trial. If we are unable to enroll a sufficient number of patients to participate in this trial, we may not be able to complete the trial on the planned timeline, or at all. In particular, patients may be less willing to enroll in the trial as a result of the interim analysis from our NSCLC clinical trial. In addition, because our breast cancer clinical trial is targeted at a subset of patients with breast cancer, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. Further, the TAC chemotherapy regimen that is being administered to patients in our breast cancer clinical trial is not the standard of care for breast cancer as it is highly toxic and causes severe neutropenia in up to 75% of patients despite prophylaxis with myeloid growth factors and alopecia in approximately 90% of patients. As a result, physicians may be unwilling to enroll patients, and patients may be unwilling to enroll, in the trial. If we are not able to enroll patients on the planned timeline, we may not generate trial data when anticipated and may not have sufficient cash resources to complete the trial.

We will need substantial additional funding to continue our operations. If we are unable to raise capital when needed, we may be forced to delay, reduce and/or eliminate our research and drug development programs.

We believe that, based on our current operating plan, our cash, cash equivalents and investments as of September 30, 2022 will enable us to fund our operating expenses through the first quarter of 2024. 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. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate. In any event,

our cash, cash equivalents and investments will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development or commercialization of ALRN-6924. While we have implemented certain cash preservation measures, we cannot be certain that such measures will result in the savings anticipated.

Accordingly, we will need to obtain further funding through public or private equity offerings, collaborations and licensing arrangements, or other sources of capital. We may also explore other strategic alternatives. Adequate additional financing may not be available to us on acceptable terms, if at all, particularly in light of the interim data from our NSCLC trial. Market conditions are volatile and may continue to be volatile for the foreseeable future, which may limit our ability to raise capital. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate some or all of our clinical and drug development programs and future commercialization efforts. In addition, if, during the course of our breast cancer clinical trial, we determine, based on interim data from that trial, that ALRN-6924 is not demonstrating sufficient chemoprotection to support continued clinical development, and have not obtained additional funding, our ability to pursue strategic alternatives may be limited and we may consider seeking protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of our company. If we decide to seek protection under the bankruptcy laws, we would expect that we would file for bankruptcy at a time that is significantly 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, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

If we fail to maintain compliance with the requirements for continued listing on the Nasdaq Capital Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital or enter into strategic transactions.

On December 6, 2021, we received a deficiency letter from the Listing Qualifications Department, or the Staff, of the Nasdaq Stock Market, or Nasdaq, notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2), or the Bid Price Rule. The deficiency letter does not result in the immediate delisting of our common stock from the Nasdaq Capital Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), or the Compliance Period Rule, we were initially provided an initial period of 180 calendar days, or until June 7, 2022 to regain compliance with the Bid Price Rule and on June 7, 2022, we were provided an additional period of 180 calendar days, or until December 5, 2022, or the Compliance Date. If, at any time before the Compliance Date, the bid price for the Company's common stock closes at $1.00 or more per share for a minimum of 10 consecutive business days, as required under the Compliance Period Rule, the Staff will provide written notification to us that we are in compliance with the Bid Price Rule, unless the Staff exercises its discretion to extend this 10-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H). As of the date of this Quarterly Report on Form 10-Q, we have not yet regained compliance with the Bid Price Rule

If we do not comply with the Bid Price Rule by the Compliance Date, then Nasdaq will provide notice to us that our common stock will be delisted. At that time, we may appeal the Staff's delisting determination to a Nasdaq Listing Qualifications Panel, or the Panel. We expect that our common stock would remain listed pending the Panel's decision. There can be no assurance that, if we do appeal the Staff's delisting determination to the Panel, such appeal would be successful.

As of the date of this Quarterly Report on Form 10-Q, we have not yet regained compliance with the Bid Price Rule. We intend to monitor the closing bid price of our common stock and intend to effect a reverse stock split to regain compliance with the Bid Price Rule prior to the Compliance Date. On June 15, 2022, our stockholders approved an amendment to our restated certificate of incorporation to effect a reverse stock split at a ratio of not less than 1-for-5 and not greater than 1-for-25, with the exact ratio to be set within that range at the discretion of our board of directors prior to December 31, 2022 without further approval or authorization of our stockholders, in its sole discretion. However, there can be no assurance that we will be able to regain compliance with the Bid Price Rule.

There are many factors that may adversely affect our minimum bid price. Many of these factors are outside of our control. As a result, we may not be able to sustain compliance with the Bid Price Rule in the long term. Any potential delisting of our common stock from the Nasdaq Capital Market would likely result in decreased liquidity and increased volatility for our common stock and would adversely affect our ability to raise additional capital or to enter into strategic transactions. Any potential delisting of our common stock from the Nasdaq Capital Market would also make it more difficult for our stockholders to sell our common stock in the public market.

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
31.1	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.
31.2	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.
32.1	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.
32.2	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.
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)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Aileron Therapeutics, Inc.

Date: November 1, 2022 By: /s/ Manuel C. Alves Aivado, M.D., Ph.D.

Manuel C. Alves Aivado, M.D., Ph.D.
President and Chief Executive Officer
(principal executive officer)

Date: November 1, 2022 By: /s/ Susan L. Drexler

Susan L. Drexler
Interim Chief Financial Officer
(principal financial officer)

Exhibit 31.1

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: November 1, 2022

Exhibit 31.2

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: November 1, 2022

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Aileron Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2022 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: November 1, 2022

/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.

Exhibit 32.2

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, 2022 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 her 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: November 1, 2022

/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.