

**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 June 30, 2024

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)

12407 N. Mopac Expy.  
Suite 250 #390  
Austin, TX

(Address of principal executive offices)

**13-4196017**

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

**78758**

(Zip Code)

Registrant's telephone number, including area code: (737) 802-1989

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

As of August 12, 2024, the registrant had 21,665,799 shares of common stock, \$0.001 par value per share, outstanding.

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q of Aileron Therapeutics, Inc. (“Aileron,” “we,” “us,” “our,” or the “Company”) 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 LTI-03, including the potential benefits thereof;
- our decision to postpone further clinical development of LTI-01;
- the timing and expectation of the results from Cohort 2 of the ongoing Phase 1b clinical trial of LTI-03;
- our unproven approach to drug research and development in the area of fibrotic diseases, with a focus on Caveolin-1, or Cav1, -related peptides, and our ability to develop marketable products;
- our ongoing and future clinical trials for LTI-03 and LTI-01, whether conducted by us or by any future collaborators, including our ability to enroll patients in our clinical trials, the timing of initiation of these trials and of the anticipated results;
- the possibility that we may be adversely affected by economic, business, and/or competitive factors, including risks inherent in pharmaceutical research and development, such as: adverse results in our drug discovery, preclinical and clinical development activities, the risk that the results of our preclinical studies and early clinical trials may not be replicated in later clinical trials or that partial results of a trial, such as the results from Cohort 1 of our ongoing Phase 1b trial of LTI-03, may not be indicative of the full results of the trial, and the risk that any of our clinical trials may not commence, continue or be completed on time, or at all;
- our ability to recognize the anticipated benefits of our acquisition of Lung Therapeutics, Inc. in October 2023;
- our expectations regarding our ability to fund our operating expenses, our planned activities, and capital expenditure requirements with our cash, cash equivalents and investments;
- the success of our remediation efforts related to the material weaknesses identified in our internal controls over financial reporting and disclosure controls and procedures;
- 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 LTI-03 and LTI-01;
- 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, and our ability to obtain, maintain and enforce intellectual property rights for our platform and development candidates;
- our ability to identify additional product candidates with significant commercial potential;
- our plans to enter into collaborations for the development and commercialization of LTI-03, LTI-01 and any additional product candidates;
- our reliance on third-party manufacturing and supply vendors;
- potential benefits of any future collaboration;
- developments relating to our competitors and our industry; and
- the impact of government laws and regulations.

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

included or incorporated by reference in our Annual Report on Form 10-K, and this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, which 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 or incorporates by reference 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 CONSOLIDATED BALANCE SHEETS  
(UNAUDITED)**

(In thousands, except share and per share data)

	June 30, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 21,917	\$ 17,313
Prepaid expenses and other current assets	1,217	882
Restricted cash	25	25
Operating lease, right-of-use asset, current portion	—	46
Total current assets	23,159	18,266
Property and equipment, net	2	19
Goodwill	6,330	6,330
Intangible assets	79,200	79,200
Other non-current assets	709	2,193
Total assets	\$ 109,400	\$ 106,008
<b>Liabilities, Convertible Preferred Stock and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 782	\$ 1,190
Accrued expenses and other current liabilities	4,155	3,147
Operating lease liabilities, current portion	—	48
Total current liabilities	4,937	4,385
Deferred tax liability	3,326	3,326
Other long-term liability	116	—
Total liabilities	8,379	7,711
Commitments and contingencies (Note 15)		
Convertible preferred stock, \$0.001 par value, 5,000,000 shares authorized at June 30, 2024 and at December 31, 2023; 24,610 shares issued and 12,232 shares outstanding at June 30, 2024 and 24,610 shares issued and outstanding at December 31, 2023	45,005	91,410
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized at June 30, 2024 and 45,000,000 at December 31, 2023; 21,625,085 shares and 4,885,512 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	107	91
Additional paid-in capital	360,503	295,376
Accumulated other comprehensive loss	(22)	(63)
Accumulated deficit	(304,572)	(288,517)
Total liabilities, convertible preferred stock and stockholders' equity	\$ 109,400	\$ 106,008

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

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

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	3,741	187	7,204	1,997
General and administrative	5,298	1,893	9,040	4,072
Restructuring and other costs	—	(88)	—	934
Total operating expenses	9,039	1,992	16,244	7,003
Loss from operations	(9,039)	(1,992)	(16,244)	(7,003)
Other income, net	97	205	189	437
Net loss	\$ (8,942)	\$ (1,787)	\$ (16,055)	\$ (6,566)
Net loss per share—basic and diluted	\$ (0.45)	\$ (0.39)	\$ (1.13)	\$ (1.45)
Weighted average common shares outstanding—basic and diluted	19,911,462	4,541,167	14,172,326	4,541,167
Comprehensive loss:				
Net loss	\$ (8,942)	\$ (1,787)	\$ (16,055)	\$ (6,566)
Other comprehensive gain:				
Unrealized gain on investments, net of tax of \$0	41	8	41	46
Total other comprehensive gain	41	8	41	46
Total comprehensive loss	\$ (8,901)	\$ (1,779)	\$ (16,014)	\$ (6,520)

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

**AILERON THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY**  
**(UNAUDITED)**

(In thousands, except share data)

	Series X Non-Voting Convertible Preferred Stock		Common Stock			Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Convertible Preferred Stock and Stockholders' Equity
	Shares	Amount	Shares	Amount	Amount				
<b>Balances at December 31, 2023</b>	24,610	\$ 91,410	4,885,512	\$ 91	\$ 295,376	\$ (63)	\$ (288,517)	\$ 98,297	
Issuance of common stock in connection with conversion of Series X non-voting convertible preferred stock	(11,957)	(44,826)	11,957,000	12	44,814	—	—	—	
Stock-based compensation expense	—	—	—	—	150	—	—	150	
Net loss	—	—	—	—	—	—	(7,113)	(7,113)	
<b>Balances at March 31, 2024</b>	<u>12,653</u>	<u>\$ 46,584</u>	<u>16,842,512</u>	<u>\$ 103</u>	<u>\$ 340,340</u>	<u>\$ (63)</u>	<u>\$ (295,630)</u>	<u>\$ 91,334</u>	
Issuance of common stock in connection with conversion of Series X non-voting convertible preferred stock	(421)	\$ (1,579)	421,000	\$ —	\$ 1,578	\$ —	\$ —	\$ (1)	
Issuance of common stock	—	—	4,273,505	4	10,933	—	—	10,937	
Issuance of warrants	—	—	—	—	7,225	—	—	7,225	
Stock-based compensation expense	—	—	—	—	326	—	—	326	
Exercises of stock options	—	—	88,068	—	101	—	—	101	
Unrealized gain on investments	—	—	—	—	—	41	—	41	
Net loss	—	—	—	—	—	—	(8,942)	(8,942)	
<b>Balance at June 30, 2024</b>	<u>12,232</u>	<u>\$ 45,005</u>	<u>21,625,085</u>	<u>\$ 107</u>	<u>\$ 360,503</u>	<u>\$ (22)</u>	<u>\$ (304,572)</u>	<u>\$ 101,021</u>	
<b>Balances at December 31, 2022</b>	—	\$ —	4,541,167	\$ 91	\$ 291,365	\$ (48)	\$ (272,785)	\$ 18,623	
Stock-based compensation expense	—	—	—	—	391	—	—	391	
Unrealized gain on investments	—	—	—	—	—	38	—	38	
Net loss	—	—	—	—	—	—	(4,779)	(4,779)	
<b>Balances at March 31, 2023</b>	<u>—</u>	<u>\$ —</u>	<u>4,541,167</u>	<u>\$ 91</u>	<u>\$ 291,756</u>	<u>\$ (10)</u>	<u>\$ (277,564)</u>	<u>\$ 14,273</u>	
Stock-based compensation expense	—	—	—	—	300	—	—	300	
Unrealized gain on investments	—	—	—	—	—	8	—	8	
Net loss	—	—	—	—	—	—	(1,787)	(1,787)	
<b>Balances at June 30, 2023</b>	<u>—</u>	<u>\$ —</u>	<u>4,541,167</u>	<u>\$ 91</u>	<u>\$ 292,056</u>	<u>\$ (2)</u>	<u>\$ (279,351)</u>	<u>\$ 12,794</u>	

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

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

(In thousands)

	Six Months Ended June 30,	
	2024	2023
<b>Cash flows from operating activities:</b>		
Net loss	\$ (16,055)	\$ (6,566)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	63	55
Net amortization of premiums and discounts on investments	—	(155)
Stock-based compensation expense	476	691
Loss on disposition of property and equipment	—	16
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(295)	345
Other assets	1,484	24
Accounts payable	(408)	(1,584)
Operating lease liabilities	(48)	(33)
Accrued expenses and other current liabilities	1,007	(570)
Other long-term liabilities	116	0
Net cash used in operating activities	<u>(13,660)</u>	<u>(7,777)</u>
<b>Cash flows from investing activities:</b>		
Proceeds from sales or maturities of investments	—	15,750
Net cash provided by investing activities	<u>—</u>	<u>15,750</u>
<b>Cash flows from financing activities:</b>		
Issuance of common stock	10,937	—
Issuance of common stock in connection with stock option exercises	101	—
Issuance of warrants	7,225	—
Net cash provided by financing activities	<u>18,263</u>	<u>—</u>
Effect of exchange rate changes on cash and cash equivalents	1	—
<b>Net increase in cash, cash equivalents and restricted cash</b>	<b>4,604</b>	<b>7,973</b>
Cash, cash equivalents and restricted cash at beginning of period	17,338	5,219
Cash, cash equivalents and restricted cash at end of period	<u>\$ 21,942</u>	<u>\$ 13,192</u>
Cash and cash equivalents at end of period	\$ 21,917	\$ 13,167
Restricted cash at end of period	25	25
<b>Cash, cash equivalents and restricted cash at end of period</b>	<u>\$ 21,942</u>	<u>\$ 13,192</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Conversion of Series X non-voting convertible preferred stock into common stock shares	\$ 46,405	\$ —

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



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

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

**1. Nature of the Business**

Aileron Therapeutics, Inc. (“Aileron” or the “Company”) is a clinical stage biopharmaceutical company focused on developing novel therapies for the treatment of orphan pulmonary and fibrosis indications with no approved or limited effective treatments. The Company currently has two product candidates in clinical development, LTI-03 and LTI-01, and multiple candidates in preclinical development focused on fibrosis indications.

On October 31, 2023, Aileron acquired Lung Therapeutics, Inc. (“Lung Therapeutics” or “Lung”) pursuant to an Agreement and Plan of Merger, dated October 31, 2023 (the “Lung Acquisition Agreement”), by and among the Company, AT Merger Sub I, Inc., a Delaware corporation and its wholly owned subsidiary (“First Merger Sub”), AT Merger Sub II, LLC, a Delaware limited liability company and its wholly owned subsidiary (“Second Merger Sub”), and Lung. Pursuant to the Lung Acquisition Agreement, First Merger Sub merged with and into Lung, pursuant to which Lung was the surviving entity and became its wholly owned subsidiary (the “First Merger”). Immediately following the First Merger, Lung merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity (such merger, together with the First Merger, the “Lung Acquisition”). Lung was incorporated on November 13, 2012 under the laws of the state of Texas. Following the Lung Acquisition, the Company shifted its operating disease focus to advancing a pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications with the potential to greatly improve patient outcomes over currently available treatments. Following expiration of the operating lease agreement to rent an office space for its corporate headquarters in Austin, Texas, on March 31, 2024, the Company expects to operate virtually for the foreseeable future (see Note 15 for further details).

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to the risk that the Company never achieves profitability, the need for substantial additional financing, the risk of relying on third parties, risks of clinical trial failures, dependence on key personnel, protection of proprietary technology, and compliance with government regulations. The Company’s lead product candidate, LTI-03, is being developed for the treatment of Idiopathic Pulmonary Fibrosis (“IPF”) and has completed a healthy volunteer Phase 1a clinical trial. LTI-03 is currently in a Phase 1b clinical trial in IPF patients. The Company’s second product candidate, LTI-01, is in development for loculated pleural effusion (“LPE”). The Company has completed Phase 1b and Phase 2a clinical trials in LPE patients. In June 2024, the Company decided to temporarily delay clinical development of LTI-01 in an effort to focus the Company’s resources on clinical development of LTI-03 and until additional funds are raised.

***Liquidity and Going Concern***

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), the Company has evaluated whether there are conditions and 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 the accompanying consolidated 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 condensed consolidated financial statements are issued. When substantial doubt exists, 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 consolidated 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 consolidated financial statements are issued.

The Company’s condensed consolidated financial statements have been prepared assuming that the Company will continue to operate as a going concern, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. Through June 30, 2024, the Company has financed its operations primarily through \$145,467 in net proceeds from sales of common stock and warrants, \$131,211 from sales of preferred stock prior to its initial public offering (“IPO”), \$34,910 from a collaboration agreement in 2010, \$17,536 in net proceeds in connection with a private placement following the Lung Acquisition in 2023, and \$18,162 in net proceeds in connection with an underwritten offering of the Company’s common stock and accompanying warrants to purchase common stock in May 2024. As of June 30, 2024, the Company had \$21,917 in cash and cash equivalents.

In May 2024, Aileron completed an underwritten follow-on public offering (the “Offering”), pursuant to which the Company issued and sold 4,273,505 shares of the Company’s common stock, par value \$0.001 per share (the “Offering Shares”) and accompanying warrants (the “Offering Warrants”) to purchase 4,273,505 shares of common stock (the “Offering Warrant Shares”). All of the Offering Shares and Offering Warrants were sold by the Company. Each Offering Share was offered and sold together with an accompanying Offering Warrant at a combined offering price of \$4.68, and the underwriter purchased each Offering Share with an accompanying Offering Warrant from the Company at a combined price of \$4.35. Net proceeds from the Offering were \$18,162, after deducting

underwriting discounts and commissions and offering expenses, and excluding any proceeds that may be received from exercise of the Offering Warrants.

Management believes that, based on the Company's current operating plan, the Company's cash and cash equivalents of \$21,917 as of June 30, 2024 will enable the Company to fund its operating expenses and capital expenditure requirements for at least twelve months from the date of issuance of these condensed consolidated financial statements. Since its inception, the Company has not generated any revenue from product sales and has never generated an operating profit. The Company has incurred significant losses on an aggregate basis. The Company's net losses were \$16,055 and \$6,566 for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, the Company had an accumulated deficit of \$304,572. 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 the Company's operations. Management expects to continue to incur operating losses for the foreseeable future. The Company expects to finance its operations primarily through utilization of its current financial resources and through the sale of additional equity or debt financings, collaborations, licensing arrangements or other sources.

The Company could use its available capital resources sooner than it currently expects. The Company's future viability is dependent on its ability to raise additional capital, enter into a financing, consummate a successful acquisition, merger, business combination, or a sale of assets or other transaction. If the Company becomes unable to continue as a going concern, it may have to liquidate its assets and the values it receives for its assets in liquidation or dissolution could be significantly lower than the values reflected in its consolidated financial statements.

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

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

The accompanying condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and as amended by ASUs of the Financial Accounting Standards Board ("FASB").

### ***Principles of Consolidation***

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Lung Therapeutics, LLC, Lung Therapeutics Australia Pty Ltd, and Lung Therapeutics Limited. All intercompany balances and transactions have been eliminated in consolidation.

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

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual for research and development expenses, the prepaid research and development expenses, and the value of stock-based compensation. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

### ***Unaudited Interim Financial Information***

The accompanying unaudited condensed consolidated financial statements as of June 30, 2024 and for the six months ended June 30, 2024 and 2023 have been prepared by the Company pursuant to the rules and regulations of the United States Securities and Exchange Commission (the "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 consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 that was filed with the SEC on April 15, 2024.

The condensed consolidated financial statements have been prepared on the same basis as the audited consolidated 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 June 30, 2024, the results of its operations for the three and six months ended June 30, 2024 and 2023 and its cash flows for the six months ended June 30, 2024 and 2023. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2024 and 2023 are unaudited. The results for the six months ended June 30, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, any other interim periods, or any future year or period. The accompanying balance sheet as of December 31, 2023 has been derived from the Company's audited consolidated financial statements for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K.

The Company's significant accounting policies are described in Note 2 to the consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2023.

### ***Concentration of Credit Risk and of Significant Suppliers***

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Periodically, the Company maintains balances in operating accounts above federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality. The Company has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

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 on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could have been adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

### ***Accounting Pronouncements Not Yet Adopted***

There were no accounting pronouncements issued by the FASB during the three months ended June 30, 2024.

In March 2024, the FASB issued ASU 2024-02—Codification Improvements—Amendments to Remove References to the Concepts Statements, that contains amendments to the Codification that remove references to various FASB Concepts Statements. This effort facilitates Codification updates for technical corrections such as conforming amendments, clarifications to guidance, simplifications to wording or the structure of guidance, and other minor improvements. The amendments are effective for public business entities for fiscal years beginning after December 15, 2024, with early adoption permitted. Early application of the amendments in this ASU is permitted for all entities, for any fiscal year or interim period for which financial statements have not yet been issued (or made available for issuance). If an entity adopts the amendments in an interim period, it must adopt them as of the beginning of the fiscal year that includes that interim period. The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

In March 2024, the FASB issued ASU 2024-01—Compensation—Stock Compensation (Topic 718): Scope Application of Profits Interest and Similar Awards, to improve GAAP by adding an illustrative example that includes four fact patterns to demonstrate how an entity should apply the scope guidance in paragraph 718-10-15-3 to determine whether a profits interest award should be accounted for in accordance with Topic 718, Compensation—Stock Compensation. For public business entities, the amendments in this ASU are effective for annual periods beginning after December 15, 2024, and interim periods within those annual periods. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. If an entity adopts the amendments in an interim period, it should adopt them as of the beginning of the annual period that includes that interim period. The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

### **3. Business Acquisition**

On October 31, 2023, Aileron acquired 100% of Lung, pursuant to the Lung Acquisition Agreement. At the closing of the Lung Acquisition, Aileron issued to the stockholders of Lung 344,345 shares of its common stock (excluding 221 fractional shares from the total 344,566 shares pursuant to the Lung Acquisition Agreement) and 19,903 shares of its newly designated Series X non-voting convertible preferred stock (the “Series X Preferred Stock”) (excluding 238 fractional shares from the total 20,141 shares pursuant to the Lung Acquisition Agreement). Each share of Series X Preferred Stock is convertible into 1,000 shares of common stock. The Company paid \$290 cash in lieu of fractional shares of both common stock and Series X Preferred Stock. In addition, Aileron assumed all of Lung’s stock options (1,780,459) and all warrants (726,437) exercisable for Lung common stock immediately outstanding prior to the closing of the Lung Acquisition, each subject to adjustment pursuant to the terms of the Lung Acquisition Agreement.

Immediately following the closing of the Lung Acquisition, on October 31, 2023, Aileron entered into a Stock and Warrant Purchase Agreement (the “Purchase Agreement”) with a group of accredited investors, pursuant to which Aileron issued and sold (i) an aggregate of 4,707 shares of Series X Preferred Stock, and (ii) warrants (the “PIPE Warrants”) to purchase up to an aggregate of 2,353,500 shares of Aileron common stock (the “PIPE Warrant Shares”), for an aggregate purchase price of approximately \$18,429, which included the conversion of certain convertible promissory notes in the aggregate principal amount of \$1,553 issued by Lung to Bios Partners, the majority stockholder of Lung prior to the closing of the Lung Acquisition, at a 10% discount to the per share price of the Series X Preferred Stock (collectively, the “PIPE Financing”). The PIPE Financing closed on November 2, 2023. Each share of Series X Preferred Stock is convertible into 1,000 shares of common stock.

At the 2023 annual meeting of stockholders (the “2023 Annual Meeting”), the Company’s stockholders approved the issuance, in accordance with Nasdaq Listing Rule 5635(a), of shares of common stock, upon conversion of the Company’s outstanding Series X Preferred Stock. On March 5, 2024, based upon existing beneficial ownership limitations, 11,957 shares of Series X Preferred Stock were automatically converted into 11,957,000 shares of common stock.

The Lung Acquisition was accounted for under the acquisition method of accounting under ASC 805, Business Combinations. Under the acquisition method, the total purchase price of the acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on the fair values as of the date of the acquisition. Consideration transferred is the sum of the acquisition-date fair values of the assets transferred, the liabilities incurred by the acquirer to the former owners of the acquiree, and the

equity interests issued by the acquirer to the former owners of the acquiree (except for the measurement of share-based payment awards). The Company recorded the assets acquired and liabilities assumed as of the date of the Lung Acquisition based on the information available at that date.

#### 4. 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:

	June 30, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 11,444	\$ —	\$ —	\$ 11,444
Treasury bills	\$ 10,006	\$ —	\$ —	\$ 10,006
	<u>\$ 21,450</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 21,450</u>
	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 10,322	\$ —	\$ —	\$ 10,322
	<u>\$ 10,322</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,322</u>

During the six months ended June 30, 2024 and the year ended December 31, 2023, there were no transfers between levels.

#### 5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	June 30, 2024	December 31, 2023
Prepaid research and development	\$ 913	\$ 207
Other current assets	304	675
Total prepaid expenses and other current assets	<u>\$ 1,217</u>	<u>\$ 882</u>

#### 6. Goodwill and Indefinite-Lived Intangible Assets

\$6,330 of goodwill and \$79,200 of indefinite-lived intangible assets acquired in the Lung Acquisition were recorded at fair value on the Lung Acquisition date. The Company performed a qualitative assessment of goodwill and indefinite-lived intangible assets for potential impairment as of June 30, 2024, and concluded that there was no goodwill or intangible assets impairment as of June 30, 2024.

#### 7. Other Assets

Other assets consisted of the following:

	June 30, 2024	December 31, 2023
Non-current prepaid research and development	\$ 707	\$ 2,140
Other assets	2	53
Total other non-current assets	<u>\$ 709</u>	<u>\$ 2,193</u>

#### 8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2024	December 31, 2023
External research and development services	\$ 1,907	\$ 1,110
Payroll and payroll-related costs	1,434	1,178
Professional fees	559	653
Other	255	206
Total accrued expenses and other current liabilities	<u>\$ 4,155</u>	<u>\$ 3,147</u>

## **9. Preferred Stock**

The Company is authorized to issue 5,000,000 shares of preferred stock, par value \$0.001 per share. As of June 30, 2024, the Company had issued 24,610 shares of Series X Preferred Stock, of which 12,232 shares of Series X Preferred Stock remained outstanding. As of December 31, 2023, 24,610 shares of Series X Preferred Stock were issued and outstanding.

On October 31, 2023, under the terms of the Lung Acquisition Agreement, at the closing of the Lung Acquisition, Aileron issued to the stockholders of Lung 344,345 shares of common stock, and 19,903 shares of Series X Preferred Stock.

Immediately following the closing of the Lung Acquisition, on October 31, 2023, Aileron entered into the Purchase Agreement with a group of accredited investors, pursuant to which Aileron issued and sold an aggregate of 4,707 shares of Series X Preferred Stock and PIPE Warrants to purchase up to an aggregate of 2,353,500 shares of Aileron common stock. Refer to Note 3 for more details on the PIPE Financing in connection with the Purchase Agreement. Since the Series X Preferred Stock was sold as a unit with the PIPE Warrants according to the Purchase Agreement, the proceeds received were allocated to each instrument on a relative fair value basis. Total gross proceeds of \$18,429, less \$893 of issuance costs were allocated as follows: \$16,795 to the Series X Preferred Stock and \$741 to the PIPE Warrants. The Series X Preferred Stock and the PIPE Warrants issued in the PIPE Financing were recorded at par value of \$0.001.

At the 2023 Annual Meeting, the Company's stockholders approved the issuance, in accordance with Nasdaq Listing Rule 5635(a), of shares of common stock, upon conversion of the Company's outstanding Series X Preferred Stock. On March 5, 2024, based upon existing beneficial ownership limitations, 11,957 shares of Series X Preferred Stock were automatically converted into 11,957,000 shares of common stock. On May 8, 2024, the Bios Entities (as defined below) provided notice to the Company and converted 421 shares of Series X Preferred Stock held by them into 421,000 shares of common stock. As of June 30, 2024, 12,232 shares of Series X Preferred Stock (which are convertible into 12,232,000 shares of common stock) remained convertible at the option of the holder thereof, subject to certain beneficial ownership limitations (as described below).

The Company evaluated the Series X Preferred Stock for liability classification in accordance with the provisions of ASC 480, Distinguishing Liabilities from Equity ("ASC 480"), and determined that equity treatment was appropriate because the Series X Preferred Stock did not meet the definition of the liability instruments. Specifically, the Series X Preferred Stock is not mandatorily redeemable and does not embody an obligation to buy back the shares outside of the Company's control in a manner that could require the transfer of assets. The Company determined that the Series X Preferred Stock would be recorded as temporary equity, based on the guidance of ASC 480, given that it is contingently redeemable.

Each share of Series X Preferred Stock is convertible into 1,000 shares of Common Stock. The preferences, rights, and limitations initially applicable to the Series X Preferred Stock are set forth in the Certificate of Designation.

The Series X Preferred Stock has the following characteristics:

### ***Voting***

Except as otherwise required by law, the Series X Preferred Stock does not have voting rights. However, as long as any shares of Series X Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series X Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series X Preferred Stock or alter or amend the Certificate of Designation, amend or repeal any provision of, or add any provision to, the Certificate of Incorporation or by-laws of the Company, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series X Preferred Stock, (ii) issue further shares of Series X Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series X Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing.

### ***Dividends***

Holders of Series X Preferred Stock are entitled to receive dividends on shares of Series X Preferred Stock equal, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of the common stock. Such dividends are not cumulative. Since the Company's inception, no dividends have been declared or paid.

### ***Liquidation, dissolution or winding up***

The Series X Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company.

Upon liquidation, dissolution or winding up of the Company, the Series X preferred stockholders shall be entitled to receive an equivalent amount of distributions as would be paid on the common stock underlying the Series X Preferred Stock, determined on an as-converted basis, pari passu with any distributions to the common stock shareholders.

### ***Conversion***

The Series X Preferred Stock is convertible into common stock at a rate of 1,000 shares of common stock for every one share of Series X Preferred Stock that is converted. The Series X Preferred Stock is subject to certain beneficial ownership limitations, including that a holder of Series X Preferred Stock is prohibited from converting shares of Series X Preferred Stock into shares of common stock if, as a result of such conversion, such holder (together with its affiliates and any other persons acting as a group together with the holder or any of its affiliates) would beneficially own more than a specified percentage (to be initially set at 19.99% and thereafter adjusted by the holder to a number not to exceed 19.99%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion.

### ***Redemption***

Shares of the Series X Preferred Stock are not redeemable at the election of the holder.

### ***Maturity***

The Series X Preferred Stock shall be perpetual unless converted.

## **10. Common Stock**

On February 28, 2024, the Company held the 2023 Annual Meeting, at which the Company's stockholders approved an amendment to the Company's Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock of the Company from 45,000,000 to 100,000,000 shares. The Company filed the Certificate of Amendment to implement the increase in the number of authorized shares, which was effective upon filing, with the Secretary of State of the State of Delaware on February 28, 2024. The additional shares of common stock authorized by the Certificate of Amendment have rights identical to the Company's currently outstanding common stock. As of June 30, 2024 and December 31, 2023, the Company was authorized to issue 100,000,000 and 45,000,000 shares of common stock, respectively, par value \$0.001 per share.

As of June 30, 2024, the Company had 21,625,085 shares of common stock issued and outstanding. As of December 31, 2023, the Company had 4,885,512 shares of common stock issued and outstanding.

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 (the "Board"), if any. As of June 30, 2024 and December 31, 2023, no dividends had been declared.

In the event of liquidation or dissolution, the holders of the common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

### ***Issuance of Common Stock and Warrants***

In May 2024, the Company completed an underwritten follow-on public offering, pursuant to which the Company issued and sold 4,273,505 shares of the Company's common stock and accompanying warrants to purchase 4,273,505 shares of common stock. All of the Offering Shares and Offering Warrants were sold by the Company. Each Offering Share was offered and sold together with an accompanying Offering Warrant at a combined offering price of \$4.68, and the underwriter purchased each Offering Share and accompanying Offering Warrant at a combined price of \$4.35. Net proceeds from the Offering were approximately \$18,162, after deducting underwriting discounts and commissions and offering expenses, and excluding any proceeds that may be received from exercise of the Offering Warrants. The Offering closed on May 3, 2024.

Each Offering Warrant has an exercise price per share of common stock equal to \$4.68. Each Offering Warrant may be exercised until May 1, 2027. Each Offering Warrant is exercisable solely by means of a cash exercise, except that an Offering Warrant is exercisable via cashless exercise if at the time of exercise, a registration statement registering the issuance of Offering Warrant Shares is not then effective or the prospectus contained therein is not available for the issuance of Offering Warrant Shares.

The Offering Warrants include certain rights upon "fundamental transactions" as described in the Offering Warrants, including the right of the holders thereof to receive from the Company or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of common stock in such fundamental transaction (as described in such Offering Warrants) of the unexercised portion of the applicable Warrants immediately prior to such fundamental transaction. A holder of Offering Warrants (together with its affiliates) may not exercise any portion of an Offering Warrant to the extent that the holder would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the Company's outstanding common stock immediately after exercise.

The Company has assessed the Offering Warrants for appropriate equity or liability classification and determined the Offering 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, Derivatives and Hedging ("ASC 815"). The Offering 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 Offering Warrants

are classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. The Offering Warrants were initially recognized at their relative fair value in the amount of \$8.0 million at the time of issuance determined using Black-Scholes option-pricing model and will not be remeasured.

The following assumptions were used to perform the Offering Warrants valuation:

	<u>May 3,</u>	
	<u>2024</u>	
Risk-free interest rate		4.6%
Expected term (in years)		3.0
Expected volatility		113.5%
Expected dividend yield		0%
Stock price	\$	3.76
Exercise price	\$	4.68

At the 2023 Annual Meeting, the Company's stockholders also approved the issuance, in accordance with Nasdaq Listing Rule 5635(a), of shares of common stock, upon conversion of the Company's outstanding Series X Preferred Stock. On March 5, 2024, based upon existing beneficial ownership limitations, 11,957 shares of Series X Preferred Stock were automatically converted into 11,957,000 shares of common stock.

On October 31, 2023, Aileron acquired Lung. Under the terms of the Lung Acquisition Agreement, at the closing of the Lung Acquisition, Aileron issued to the stockholders of Lung 344,345 shares of common stock and 19,903 shares of Series X Preferred Stock.

Immediately following the closing of the Lung Acquisition, on October 31, 2023, Aileron entered into the Purchase Agreement with a group of accredited investors, pursuant to which Aileron issued and sold an aggregate of 4,707 shares of Series X Preferred Stock and PIPE Warrants to purchase up to an aggregate of 2,353,500 shares of Aileron common stock. Refer to Note 3 for more details on the PIPE Financing in connection with the Purchase Agreement. The exercise price of the PIPE Warrants is \$4.89 per share, subject to certain price and share adjustments, including for stock splits, stock dividends, recapitalizations, subdivisions, combinations, reclassifications, noncash distributions, and cash dividends. The PIPE Warrants are exercisable on or prior to May 2, 2027. Payment for the PIPE Warrant Shares upon exercise of the PIPE Warrants may be (i) in cash or (ii) in the event that there is no registration statement available for the resale of the PIPE Warrant Shares, by cashless exercise.

Under the terms of the PIPE Warrants, the Company shall not effect the exercise of any portion of any PIPE Warrant, and a holder shall not have the right to exercise any portion of any PIPE Warrant, to the extent that after giving effect to such exercise, the holder (together with its affiliates and any other persons acting as a group together with the holder or any of its affiliates), would beneficially own in excess of a percentage elected by the holder up to 19.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the PIPE Warrants. However, any holder may, upon written notice to the Company, increase or decrease such percentage to any other percentage not in excess of 19.99%; provided that any increase or decrease in such percentage will not be effective until 61 days after such notice is delivered to the Company.

The Company has assessed the PIPE Warrants for appropriate equity or liability classification and determined the PIPE 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 PIPE 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 PIPE Warrants are classified as equity and accounted for as a component of additional paid-in capital at the time of issuance. The PIPE Warrants were initially recognized at their relative fair value in the amount of \$741 at the time of issuance determined using Black-Scholes option-pricing model and will not be remeasured.

As of June 30, 2024, 21,625,085 shares of common stock were issued and outstanding, no shares were held in treasury, and 24,610 shares of Series X Preferred Stock had been issued, of which 12,232 shares of Series X Preferred Stock remained outstanding. In addition, as of June 30, 2024, there were:

- 12,469,000 shares of common stock reserved for issuance upon conversion of the Series X Preferred Stock;
- 2,196,327 shares of common stock issuable upon the exercise of options under existing equity incentive plans;
- 3,212,623 and 7,500 shares of common stock reserved for issuance under the 2021 Plan (as defined below) and 2017 ESPP (as defined below), respectively, as well as any automatic increases in the number of shares of the common stock reserved under these plans; and
- 7,353,442 shares of common stock reserved for issuance upon exercise of outstanding warrants. The warrants consist of (i) warrants to purchase 726,437 shares of the Company's common stock, with an exercise price of \$5.66, which expire on May 20, 2029, which were assumed in connection with the Lung Acquisition, (ii) warrants to purchase 2,353,500 shares of the Company's common stock, with an exercise price of \$4.89 per share, which were issued and sold in the PIPE Financing

as described above and expire on May 2, 2027, and (iii) warrants to purchase 4,273,505 shares of the Company's common stock, with an exercise price of \$4.68 per share, which were issued and sold in the Offering as described above and expire on May 3, 2027.

Accordingly, as of June 30, 2024, out of the 100,000,000 shares of common stock presently authorized, 46,863,977 shares are issued and outstanding or reserved for issuance and 53,136,023 shares of common stock remain available for future issuance.

## **11. Stock-Based Awards**

As of June 30, 2024, the Company had five equity compensation plans, each of which was approved by its stockholders: 2006 Equity Incentive Plan, as amended (the "2006 Plan"), 2016 Stock Incentive Plan (the "2016 Plan"), 2017 Stock Incentive Plan (the "2017 Plan"), 2021 Stock Incentive Plan (the "2021 Plan"), and 2017 Employee Stock Purchase Plan (the "2017 ESPP"). The Company also assumed Lung's 2013 Long-Term Incentive Plan (the "2013 Plan") as a result of the Lung Acquisition.

As of June 30, 2024, the Company had 6,693 shares issuable upon exercise of outstanding options under the 2006 Plan; 8,404 shares to be issued upon exercise of outstanding options under the 2016 Plan, 98,528 shares to be issued upon exercise of outstanding options under the 2017 Plan, and 462,279 shares to be issued upon exercise of outstanding options under the 2021 Plan. No shares remained available for future awards under the 2006 Plan, the 2016 Plan, or the 2017 Plan as of June 30, 2024.

Under the 2021 Plan, 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.

### ***2021 Stock Incentive Plan***

The Company's 2021 Plan was approved by the Company's stockholders on June 15, 2021 and became effective on June 16, 2021. At the 2023 Annual Meeting, the stockholders of the Company approved an amendment (the "Plan Amendment") to the 2021 Plan to increase the number of shares of common stock issuable under the 2021 Plan by 3,000,000 shares to 3,840,254. Other than increasing the number of shares issuable under the 2021 Plan, the Plan Amendment does not make any changes to the 2021 Plan.

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 or, at the discretion of the Board, 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, 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 3,841,710 as of June 30, 2024, of which 3,212,623 shares remained available for grant. The Company initially reserved 625,000 shares of common stock, plus the number of shares of common stock subject to outstanding awards under the 2017 Plan, the 2016 Plan and the 2006 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right up to 314,006 shares. As of June 30, 2024, the Company had 462,279 shares to be issued upon exercise of outstanding options under the 2021 Plan.

### ***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 or, at the discretion of the Board, 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, 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 determined to grant no further awards under the 2017 Plan.



Shares that are expired, terminated, surrendered or canceled without having been fully exercised under the 2017 Plan 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 ESPP, which became effective on June 28, 2017. 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 ended December 31, 2018 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2027, equal to the least of (i) 31,120 shares, (ii) 1% of the outstanding shares of common stock on such date and (iii) an amount determined by the Company's Board. On January 1, 2023 and January 1, 2024, no additional shares were reserved for issuance under the 2017 ESPP pursuant to this provision. 7,500 shares remained available for future issuance under the 2017 ESPP as of June 30, 2024.

### 2013 Stock Incentive Plan

The Company assumed the 2013 Plan as a result of the Lung Acquisition. In October 2013, Lung's Board of Directors ("Lung Board") approved the 2013 Plan to provide long-term incentives for its employees, non-employee directors and certain consultants. As of June 30, 2024, 1,620,423 shares were reserved to be issued upon exercise of options outstanding under the 2013 Plan. These options were assumed by the Company in connection with the Lung Acquisition.

Before the Lung Acquisition, the 2013 Plan was administered by the Lung Board or, at the discretion of the Lung Board, by a committee of the Lung Board. The exercise prices, vesting and other restrictions were determined at the discretion of the Lung Board, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The contractual term for stock option awards is ten years. The vesting periods for equity awards were determined by the Lung Board, but generally were four years. The contractual term for stock option awards is ten years. Following the closing of the Lung Acquisition on October 31, 2023, no further awards can be granted under the 2013 Plan.

### 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 six months ended June 30, 2024 were as follows, presented on a weighted average basis:

	<u>Six Months Ended June 30,</u> <u>2024</u>
Risk-free interest rate	4.3 %
Expected term (in years)	5.5
Expected volatility	105.7 %
Expected dividend yield	0 %

### Stock Options

The following table summarizes the Company's stock option activity since January 1, 2024:

	<u>Number of</u> <u>Shares</u>	<u>Weighted</u> <u>Average</u> <u>Exercise</u> <u>Price Per Share</u>	<u>Weighted</u> <u>Average</u> <u>Remaining</u> <u>Contractual</u> <u>Term</u>	<u>Aggregate</u> <u>Intrinsic</u> <u>Value</u>
Outstanding at December 31, 2023	2,212,102	\$ 7.42	6.0	\$ 2,905
Granted	205,450	3.12	—	—
Exercised	(88,068)	1.16	—	—
Forfeited/Canceled	(49,246)	3.28	—	—
Expired	(83,911)	29.86	—	—
Outstanding at June 30, 2024	<u>2,196,327</u>	<u>6.51</u>	<u>6.1</u>	<u>2,305</u>
Options exercisable at June 30, 2024	1,902,866	\$ 6.55	5.8	\$ 2,175
Options vested and expected to vest at June 30, 2024	2,089,774	\$ 6.68	5.9	\$ 2,297
Options exercisable at December 31, 2023	1,882,191	\$ 7.46	5.8	\$ 2,631
Options vested and expected to vest at December 31, 2023	2,209,420	\$ 7.41	6.0	\$ 2,904

The weighted average grant-date fair value of stock options granted during the six months ended June 30, 2024 was \$2.47. There were no options granted to employees or directors during the six months ended June 30, 2023. The aggregate fair value of stock options that vested during the six months ended June 30, 2024 and 2023, was \$689 and \$796, 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 six months ended June 30, 2024 was \$144. There were no stock options exercised during the six months ended June 30, 2023.

### Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development expenses	\$ 37	\$ 71	\$ 76	\$ 190
General and administrative expenses	289	229	400	501
	<u>\$ 326</u>	<u>\$ 300</u>	<u>\$ 476</u>	<u>\$ 691</u>

As of June 30, 2024, the Company had an aggregate of \$639 of unrecognized stock-based compensation expense, which it expects to recognize over a weighted average period of 0.94 years.

On March 11, 2024, the Company and Manuel C. Alves-Aivado, M.D., Ph.D., agreed that his employment with the Company would cease and he would resign from his position as Chief Executive Officer ("CEO") of the Company, effective as of March 11, 2024. Dr. Aivado remains a member of the Company's Board. Dr. Aivado's resignation from the Company was not the result of any disagreement with the Company on any matter relating to its operations, policies or practices. As a non-employee director, following the separation date, Dr. Aivado will be compensated in accordance with the terms of the Company's non-employee director compensation program. In addition, Dr. Aivado will continue to vest in all unvested stock option awards pursuant to the original vesting terms. The resignation of Dr. Aivado as CEO was considered a significant reduction in service and his original awards were deemed to have been modified and accounted for as a Type III modification with no material effect on these condensed consolidated financial statements.

## 12. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	\$ (8,942)	\$ (1,787)	\$ (16,055)	\$ (6,566)
Denominator:				
Weighted average common shares outstanding—basic and diluted	19,911,462	4,541,167	14,172,326	4,541,167
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.45)</u>	<u>\$ (0.39)</u>	<u>\$ (1.13)</u>	<u>\$ (1.45)</u>

The Company's potential dilutive securities, which include stock options as of June 30, 2024 and 2023, have been excluded from the computation of diluted net loss per share attributable to common stockholders 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 attributable to common stockholders 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 attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Six Months Ended June 30,	
	2024	2023
Options to purchase common stock	2,196,327	485,985
Warrants to issue shares of common stock	7,353,442	646,759
Series X Preferred Stock issued and outstanding, as converted	12,232,000	—
Total	<u>21,781,769</u>	<u>1,132,744</u>

## 13. Income Taxes

As of June 30, 2024, the Company has not recorded any U.S. federal or state income tax benefits for either the net losses it has incurred or its earned research and orphan drug credits, due to the uncertainty of realizing a benefit from those items in the future.

#### **14. Related Party Transactions**

On May 8, 2024, entities and individuals affiliated with Bios Partners (collectively, the “Bios Entities”) converted 421 shares of the Company’s Series X Preferred Stock into 421,000 shares of common stock. After the conversion, as of June 30, 2024, the Bios Entities owned 2,094,305 shares of the Company’s common stock resulting in a beneficial ownership of 9.9% of the Company’s outstanding common stock.

The Company also has several license agreements with University of Texas System and its affiliates, as disclosed in Note 15.

#### **15. Commitments and Contingencies**

##### ***Operating Leases***

On August 16, 2021, Lung entered into an operating lease agreement to rent approximately 6,455 square feet of office space for its corporate headquarters in Austin, Texas, beginning on October 1, 2021. The lease expired March 31, 2024, and the Company did not renew the lease. Following expiration of the lease, the Company is operating virtually, and expects to do so for the foreseeable future.

##### ***Legal Proceedings***

The Company may from time to time be party to litigation arising in the ordinary course of business. As of June 30, 2024, the Company was not party to any legal proceedings and no material legal proceedings are currently pending or, to the best of the Company’s knowledge, threatened.

##### ***Intellectual Property Licenses***

###### ***Harvard and Dana-Farber Agreement***

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

In February 2010, the agreement was amended and restated (the “Harvard/DFCI agreement”) under which additional patent rights were added to the scope of the license agreement and the annual license maintenance fees were increased. Under the Harvard/DFCI agreement, the Company is obligated to make aggregate milestone payments of up to \$7,700 per licensed therapeutic product upon the Company’s achievement of specified clinical, regulatory and sales milestones with respect to such product and up to \$700 per licensed diagnostic product upon the Company’s achievement of specified regulatory and sales milestones with respect to such product. In addition, the Company is obligated to pay royalties of low single-digit percentages on annual net sales of licensed products sold by the Company, its affiliates or its sublicensees. The royalties are payable on a product-by-product and country-by-country basis and may be reduced in specified circumstances. In addition, the 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 Harvard/DFCI agreement requires the Company to pay annual license maintenance fees of \$110 each year, which was reduced to \$35 starting in 2023. Any payments made in connection with the annual license maintenance fees will be credited against any royalties due.

As of June 30, 2024, 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. The Company incurred \$18 in license maintenance fees in the six months ended June 30, 2024. No license maintenance fees were incurred by the Company in the six months ended June 30, 2023.

###### ***Agreement with the University of Texas Health Science Center at Tyler***

In June 2013, Lung entered into a patent and technology license agreement with UT System, on behalf of UTHSCT. The patent and technology license agreement with UT System (the “UTHSCT Agreement”) provides Lung access to patents and technology related to the development of LTI-01 and LTI-03. As part of the UTHSCT Agreement, Lung has (i) a royalty-bearing, exclusive license under the patent rights to manufacture, distribute, and sell certain intellectual property; (ii) a non-exclusive license under the technology rights

to manufacture, distribute and sell the licensed product; and (iii) a sublicensing right that allows Lung to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the UTHSCT Agreement. In December 2013, the UTHSCT Agreement was amended and restated to include certain patents in all fields worldwide. In May 2017, the UTHSCT Agreement was amended and restated to modify the specific milestone criteria.

In consideration of the UTHSCT Agreement, Lung granted UT System (via UTHSCT and UT Horizon Fund affiliates) (i) 2,000,000 shares of Lung common stock and (ii) 400,000 shares of Lung non-convertible preferred stock. On February 6, 2015, UT System exchanged the 400,000 shares of Lung non-convertible preferred stock for 4,000,000 shares of Lung common stock. In addition, Lung agreed to pay past and ongoing patent expenses, and Lung owes UTHSCT sublicensing fees, assignment fees, and single digit royalties on worldwide net product sales, with fixed minimum royalty payments that started in 2015.

Pursuant to the UTHSCT Agreement, Lung is required to use diligent efforts to commercialize the licensed technology as soon as commercially practicable, including maintaining active research and development, regulatory, marketing and sales program, all as commercially reasonable.

The Company may terminate the UTHSCT Agreement for convenience with 90 days' notice. UTHSCT may also terminate the UTHSCT Agreement, but only if the Company breaches the terms of the agreement. The Company did not incur any expenses under the UTHSCT Agreement in the six months ended June 30, 2024 and 2023.

#### *Agreement with the University of Texas at Austin*

In May 2015, Lung entered into a patent license agreement with UT Austin on behalf of UT System. This license agreement with UT Austin (the "UT Austin 6607 Agreement") relates to the patent rights to polypeptide therapeutics and uses thereof. Pursuant to the UT Austin 6607 Agreement Lung has (i) a royalty-bearing, exclusive license under the patent rights to manufacture, distribute, and sell the licensed product; and (ii) a sublicensing right that allows Lung to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the agreement. The UT Austin 6607 Agreement was amended and restated in January 2017, November 2018, and June 2019. The amendments related to extension of milestone payment dates and specific terminology around the milestone achievement criteria.

In consideration of the UT Austin 6607 Agreement, Lung agreed to pay past and ongoing patent expenses, milestone fees upon certain development and regulatory milestone events, annual license fees, tiered sublicense fees, assignment fees, low single digit royalties on net sales and a Food and Drug Administration ("FDA") Priority Review Voucher fee if Lung sells or transfers this voucher.

Pursuant to the UT Austin 6607 Agreement, Lung is required to use diligent efforts to commercialize the licensed products, including maintaining active research and development, regulatory, marketing and sales program. Moreover, Lung is required to meet certain development and regulatory milestones by specific dates.

The Company may terminate the UT Austin 6607 Agreement for convenience with 90 days' notice. UT Austin may also terminate the UT Austin 6607 Agreement, but only if the Company breaches the terms of the agreement. The Company did not incur any expenses under the UT Austin 6607 Agreement in the six months ended June 30, 2024 and 2023.

#### *Agreement with Medical University of South Carolina*

In March 2016, Lung entered into a license agreement with Medical University of South Carolina Foundation for Research Development ("MUSC"). Pursuant to this license agreement with MUSC (the "MUSC Agreement") Lung has patent rights related to protecting against lung fibrosis by up regulating Cav1. The MUSC Agreement granted (i) a royalty-bearing, exclusive license under the patent rights to make, use and sell the license product; and (ii) a sublicensing right that allows Lung to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the agreement. In September 2018, the agreement was amended and restated to include definitions of related methods, related products and related rights.

In consideration of the MUSC Agreement, Lung agreed to pay a non-refundable license fee, patent expenses, milestone fees upon certain development, regulatory and commercial milestone events, sublicense fees, assignment fees and low single digit royalties on net sales, with a fixed minimum royalty payment starting in 2019 and a transaction fee upon Lung's liquidation.

Pursuant to the MUSC Agreement, Lung is required to use diligent efforts to develop, manufacture and sell the licensed products.

The Company may terminate the MUSC Agreement for convenience by providing a written notice to MUSC effective 90 days following the receipt of notice, and either party may terminate the agreement for a breach of contract. The Company incurred \$25 in license fee in the six months ended June 30, 2024. No license fee was incurred by the Company in the six months ended June 30, 2023.

#### *Agreement with Vivarta Therapeutics LLC*

In March 2018, Lung entered into a license agreement with Vivarta Therapeutics, LLC, or Vivarta. This license agreement with Vivarta (the "Vivarta Agreement") relates to intellectual property relating to epithelial sodium channel inhibitors and methods to treat pulmonary disease. Pursuant to the Vivarta Agreement Lung has (i) a royalty-bearing, exclusive license under the intellectual property

rights to make, use and sell the licensed product, and (ii) a sublicensing right that allows Lung to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the agreement.

In consideration for the Vivarta Agreement, Lung agreed to grant Vivarta a warrant to purchase an aggregate of 75,000 shares of Lung common stock for \$0.12 per share, to pay a license fee of \$10,000 upon the Vivarta Agreement effective date and \$40,000 within 30 days of the receipt of a positive freedom to operate analysis from legal counsel. Lung also agreed to pay patent expenses, milestone fees upon certain development and regulatory milestone events, sublicense fees, assignment fees and low single digit royalties on net sales.

Pursuant to the Vivarta Agreement, Lung is required to use diligent efforts to develop, manufacture and sell the licensed products.

The Company may terminate the Vivarta Agreement for convenience by providing a written notice to Vivarta effective 90 days following the receipt of notice, and either party may terminate the agreement for a breach of contract. The Company did not incur any expenses under the Vivarta Agreement in the six months ended June 30, 2024 and 2023.

### ***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 does not believe that the outcome of any claims under indemnification arrangements will 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 consolidated financial statements as of June 30, 2024 or December 31, 2023.

### **16. Subsequent Event**

On July 26, 2024, the Company entered into an Equity Distribution Agreement with Citizens JMP Securities, LLC (“Citizens JMP”), as agent and/or principal, under which the Company may offer and sell up to \$50,000 of shares of its common stock from time to time through or to Citizens JMP. Sales of common stock through or to Citizens JMP 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, including sales made directly on or through the Nasdaq Capital Market.

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

The following discussion and analysis are meant to provide material information relevant to an assessment of the financial condition and results of operations of our Company, including an evaluation of the amounts and certainty of cash flows from operations and from outside sources, so as to allow investors to better view our Company from management's perspective. You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements for the quarter ended June 30, 2024, included elsewhere in this Quarterly Report on Form 10-Q. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "Form 10-K").

### Overview and Recent Developments

We are a clinical stage biopharmaceutical company focused on developing novel therapies for the treatment of orphan pulmonary and fibrosis indications with no approved or limited effective treatments. We currently have two product candidates in clinical development, LTI-03 and LTI-01, and multiple candidates in preclinical development focused on fibrosis indications. Our pipeline includes:

- LTI-03, a peptide, for which we are currently recruiting patients for a Phase 1b dose-ranging, placebo-controlled safety, tolerability, and pharmacodynamic biomarker activity trial in development for the treatment of Idiopathic Pulmonary Fibrosis, or IPF, that has demonstrated the ability in both preclinical studies and clinical trials to protect healthy lung epithelial cells and reduce pro-fibrotic signaling;
- LTI-01, a proenzyme that completed a Phase 2a dose-ranging, placebo-controlled trial and a Phase 1b safety, tolerability and proof of mechanism trial in loculated pleural effusion, or LPE, patients, an indication that has no approved drug treatment; and
- preclinical programs targeting cystic fibrosis and a peptide program focused on the Cav1 protein for systemic fibrosis indications.

In June 2024, we decided to temporarily delay clinical development of LTI-01 in an effort to focus our resources on clinical development of LTI-03 and until additional funds are raised.

Prior to the termination of development of our main product candidate in February 2023 and the Lung Acquisition (as described below), our focus was the development of our main product candidate, ALRN-6924, a MDM2/MDMX dual inhibitor that leveraged our proprietary peptide drug technology. 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.

### Data from Cohort 1 of Phase 1b Clinical Trial of LTI-03

On May 1, 2024, we announced positive data from Cohort 1 of the ongoing Phase 1b clinical trial evaluating the safety and tolerability of inhaled LTI-03 in patients diagnosed with IPF.

The Phase 1b trial of LTI-03 is a randomized, double-blind, placebo-controlled, Phase 1b clinical trial of LTI-03 in IPF patients, which is being conducted at 11 centers in the United States, the United Kingdom, Belgium, Germany and Australia. We plan to enroll a total of 24 patients. In the trial, these patients have a bronchoscopy at a baseline screening followed by either LTI-03 or placebo twice a day for 14 days. On day 14, shortly after the final dose, patients receive a second bronchoscopy and are monitored thereafter for seven days. In Cohort 1, patients in the active arm inhaled a single 2.5 mg capsule of LTI-03 twice daily. In Cohort 2, patients will receive two 2.5 mg capsules of LTI-03 for inhalation twice daily.

Of the 12 patients enrolled in Cohort 1 of the trial, three were randomized to the placebo arm and nine to the active arm. In addition to the safety and tolerability of LTI-03, in the trial, various biomarkers relating to epithelial damage, fibrosis and inflammation in blood cells were assessed. The eight biomarkers that we evaluated in Cohort 1 included: thymic stromal lymphopoietin (TSLP), galectin-7 (GAL-7), interleukin-11 (IL-11), collagen 1 alpha chain (Col-1 $\alpha$ 1), phosphorylated SMAD2/3 (pSMAD2/3/tSMAD2/3), phosphorylated AKT kinase (pAKT), soluble (sol) receptor for advanced glycation end-products (solRAGE), and CXC chemokine 7 (CXCL7).

In Cohort 1, a positive trend was observed in seven out of the eight biomarkers with data from three biomarkers being statistically significant (based on a one-tailed t-test). The findings from Cohort 1 include:

- LTI-03 reduced expression of multiple profibrotic proteins in both pathologic basal-like cells and fibroblasts, with statistically significant decreases observed in three biomarkers - GAL-7 (p=0.0014, SEM 0.901), TSLP (p=0.0223, SEM

5.163) and Col-1 $\alpha$ 1 (p=0.0489, SEM 0.7102) - supporting the potential of LTI-03 to reduce fibrosis, inflammation and associated changes in the lung.

- LTI-03 stimulated production of solRAGE (p=0.1407, SEM 0.3269), a factor indicative of type I epithelial cell health that is a critically important aspect of IPF and has gone largely unaddressed.
- LTI-03 did not induce inflammation in peripheral blood mononuclear cells as measured by pAKT (p=0.358, SEM 11.32).
- LTI-03 was generally well-tolerated with no serious adverse events reported.

The Phase 1b trial is ongoing, with topline results from the high-dose Cohort 2 expected in the third quarter of 2024.

### ***The Lung Acquisition***

On October 31, 2023, we acquired Lung Therapeutics, Inc., or Lung, pursuant to an Agreement and Plan of Merger (the “Lung Acquisition Agreement”). Following our acquisition of Lung (the “Lung Acquisition”), Lung became a wholly-owned subsidiary of the Company. In addition, following the Lung Acquisition, the business conducted by Lung became the business primarily conducted by the Company and we shifted our operating disease focus to advancing a pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications.

Under the terms of the Lung Acquisition Agreement, at the closing of the Lung Acquisition, we issued to the stockholders of Lung 344,345 shares of our common stock and 19,903 shares of our newly designated Series X non-voting convertible preferred stock, or the Series X Preferred Stock. Each share of Series X Preferred Stock is convertible into 1,000 shares of common stock. In addition, we assumed all Lung stock options and all warrants exercisable for Lung common stock immediately outstanding prior to the closing of the Lung Acquisition, each subject to adjustment pursuant to the terms of the Lung Acquisition Agreement.

Immediately following the closing of the Lung Acquisition, we entered into a Stock and Warrant Purchase Agreement (the “Purchase Agreement”) with a group of accredited investors led by Bios Partners, the majority stockholder of Lung prior to the closing of the Lung Acquisition, and including Nantahala Capital, as well as additional undisclosed investors, pursuant to which we issued and sold (i) an aggregate of 4,707 shares of Series X Preferred Stock, and (ii) warrants to purchase up to an aggregate of 2,353,500 shares of common stock (the “PIPE Warrant Shares”) for an aggregate purchase price of approximately \$18.4 million, which included the conversion of certain convertible promissory notes in the aggregate principal amount of approximately \$1.6 million issued by Lung to Bios Partners prior to the closing of the Lung Acquisition at a 10% discount to the per share price of the Series X Preferred Stock (the “PIPE Financing”). The PIPE Financing closed on November 2, 2023.

On February 28, 2024, we held our 2023 annual meeting of stockholders in which our stockholders approved the issuance, in accordance with Nasdaq Listing Rule 5635(a), of shares of common stock, upon conversion of our outstanding Series X Preferred Stock. Following approval of the conversion of outstanding Series X Preferred Stock, the Company had approximately 29,495,512 shares of common stock issued and outstanding on a pro forma basis, which gives effect to the full conversion of the Series X Preferred Stock as of the date of our 2023 annual meeting of stockholders, without regard to beneficial ownership limitations that may limit the ability of certain holders of Series X Preferred Stock to convert such shares to common stock as such time. On March 5, 2024, based upon existing beneficial ownership limitations, 11,957 shares of Series X Preferred Stock were automatically converted into 11,957,000 shares of common stock.

### **Components of our Results of Operations**

#### ***Revenue***

We have not generated any revenue from product sales and we do not expect to generate any revenue from the sale of products in the foreseeable future.

#### ***Operating Expenses***

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

##### ***Research and Development Expenses***

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

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred in connection with the clinical development of our product candidates, including under agreements with third parties, such as consultants and contract research organizations, or CROs;

- the cost of manufacturing product candidates for use in our clinical trials and preclinical studies, including under agreements with third parties, such as consultants and contract manufacturing organizations, or CMOs;
- expenses incurred in connection with the preclinical development of our product candidates, including outsourced professional scientific development services, consulting research fees and payments made under sponsored research arrangements with third parties;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- third-party license fees;
- costs related to compliance with regulatory requirements; and
- facility-related expenses, which included direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses.

In addition, we typically 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 because these costs are deployed across multiple programs and, as such, are not separately classified.

Research and development activities are central to our business model. The duration, costs and timing of clinical trials and development of a product candidate depend on a variety of factors, including:

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

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate would 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 could 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 the SEC requirements, director and officer insurance costs; and both public and investor relations costs. General and administrative expenses also include legal fees relating to patent and corporate matters; legal and other professional fees relating to our strategic process; other insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

#### *Restructuring Costs*

Restructuring-related charges are comprised of one-time termination costs in connection with our reduction-in-workforce in 2023, including severance, benefits, and related costs.

### ***Other Income, net***

#### *Interest and Other Income*



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

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

## Results of Operations

### Comparison of the Three Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Increase (Decrease)
	2024	2023	
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	3,741	187	3,554
General and administrative	5,298	1,893	3,405
Restructuring and Other Costs	—	(88)	88
Total operating expenses	9,039	1,992	7,047
Loss from operations	(9,039)	(1,992)	(7,047)
Other income, net	97	205	(108)
Net loss	\$ (8,942)	\$ (1,787)	\$ (7,155)

#### Research and Development Expenses

Research and development expenses for the three months ended June 30, 2024 were \$3.7 million, compared to \$0.2 million for the three months ended June 30, 2023. The increase of \$3.5 million was primarily a result of the clinical programs acquired as part of the Lung Acquisition in October 2023. During the three months ended June 30, 2024, we incurred expenses of \$1.1 million on clinical trials, \$2.0 million on manufacturing including \$1.8 million write-offs due to the expiration of clinical materials, and \$0.1 million on regulatory and development consulting as well as \$0.5 million on employee and related expenses associated with clinical programs acquired in the Lung Acquisition. These programs and related activities did not exist during the three months ended June 30, 2023 and were offset by the termination of ALRN-6924 activities during the three months ended June 30, 2023.

#### General and Administrative Expenses

General and administrative expenses were \$5.3 million for the three months ended June 30, 2024, compared to \$1.9 million for the three months ended June 30, 2023. The increase of \$3.4 million was primarily due to increased professional fees of \$1.0 million and increased employee and related expenses of \$1.8 million as a result of increased business activity, headcount associated with the Lung Acquisition and severance expense recognized due to departure of former employees, and increased facilities and other expenses of \$0.5 million during the three months ended June 30, 2024 as compared to the three months ended June 30, 2023.

#### Restructuring and Other Costs

There were no restructuring-related expenses incurred in the three months ended June 30, 2024. In February 2023, our Board of Directors determined to reduce the Company's workforce at that time from nine to three full-time employees. We incurred restructuring-related charges of less than \$0.1 million for the three months ended June 30, 2023. Restructuring-related charges were comprised of one-time termination costs in connection with the reduction-in-workforce, including severance, benefits, and related costs. All restructuring-related expenses were incurred and paid in 2023.

#### Other Income, net

Other income, net for the three months ended June 30, 2024 was less than \$0.1 million and it was primarily driven by fluctuations in foreign currency exchange rates and interest of our money market funds.

### Comparison of the Six Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,		Increase (Decrease)
	2024	2023 (in thousands)	
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	7,204	1,997	5,207
General and administrative	9,040	4,072	4,968
Restructuring and Other Costs	—	934	(934)
Total operating expenses	16,244	7,003	9,241
Loss from operations	(16,244)	(7,003)	(9,241)
Other income, net	189	437	(248)
Net loss	<u>\$ (16,055)</u>	<u>\$ (6,566)</u>	<u>\$ (9,489)</u>

#### Research and Development Expenses

Research and development expenses for the six months ended June 30, 2024 were \$7.2 million, compared to \$2.0 million for the six months ended June 30, 2023. The increase of \$5.2 million was primarily a result of the clinical programs acquired as part of the Lung Acquisition in October 2023. During the six months ended June 30, 2024, we incurred expenses of \$2.2 million on clinical trials, \$3.6 million on manufacturing including \$2.4 million write-offs due to the expiration of clinical materials, and \$0.3 million on regulatory and development consulting as well as \$1.1 million on employee and related expenses associated with clinical programs acquired in the Lung Acquisition. These programs and related activities did not exist during the six months ended June 30, 2023 and were offset by the termination of ALRN-6924 activities during the six months ended June 30, 2023.

#### General and Administrative Expenses

General and administrative expenses were \$9.0 million for the six months ended June 30, 2024, compared to \$4.1 million for the six months ended June 30, 2023. The increase of \$4.9 million was primarily due to increased professional fees of \$2.0 million and increased employee and related expenses of \$2.1 million as a result of increased business activity, headcount associated with the Lung Acquisition and severance expense recognized due to departure of former employees, and increased facilities and other expenses of \$0.8 million during the six months ended June 30, 2024 as compared to the six months ended June 30, 2023.

#### Restructuring and Other Costs

There were no restructuring-related expenses incurred in the six months ended June 30, 2024. We incurred restructuring-related charges of \$0.9 million for the six months ended June 30, 2023 in connection with our February 2023 restructuring. Restructuring-related charges were comprised of one-time termination costs in connection with the reduction-in-workforce, including severance, benefits, and related costs. All restructuring-related expenses were incurred and paid in 2023.

#### Other Income, net

Other income, net for the six months ended June 30, 2024 was less than \$0.2 million and it was primarily driven by fluctuations in foreign currency exchange rates and interest of our money market funds.

### Liquidity and Capital Resources

Since inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our lead candidates, LTI-03 and LTI-01, or any future product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing for our lead product candidates or any future product candidates to support potential future commercialization and providing general and administrative support for our operations, including the costs associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. See the section titled “Risk Factors” found elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on April 15, 2024 for additional risks associated with our substantial capital requirements.

To date, we have funded our operations through sales of common stock in our initial public offering, sales of common stock and warrants in 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 now terminated equity line with Lincoln Park Capital LLC, sales of preferred stock prior to our initial public offering, payments received under a collaboration agreement, sales of common stock, preferred stock and

warrants in connection with the Lung Acquisition and the PIPE Financing and sales of common stock upon option exercises. As of June 30, 2024, we had cash and cash equivalents of \$21.9 million.

In May 2024, we completed an underwritten follow-on public offering (the “Offering”) of 4,273,505 shares of our common stock and accompanying warrants to purchase 4,273,505 shares of our common stock. All of the shares and accompanying warrants sold in the Offering were sold by the Company. Each share was offered and sold together with an accompanying warrant at a combined offering price of \$4.68, and the underwriter purchased each share and accompanying warrant at a combined price of \$4.35. Net proceeds from the Offering were approximately \$18.2 million, after deducting underwriting discounts and commissions and offering expenses, and excluding any proceeds that may be received from exercise of the warrants.

In July 2024, we entered into an Equity Distribution Agreement with Citizens JMP Securities, LLC, or Citizens JMP, as agent and/or principal, under which we may offer and sell up to \$50.0 million of our common stock from time to time through or to Citizens JMP. Sales of common stock through or to Citizens JMP 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, including sales made directly on or through the Nasdaq Capital Market.

### Cash Flows

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

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
Cash used in operating activities	\$ (13,660)	\$ (7,777)
Cash provided by investing activities	—	15,750
Cash provided by financing activities	18,263	—
Effect of exchange rate changes on cash and cash equivalents	1	—
Net increase in cash, cash equivalents and restricted cash	\$ 4,604	\$ 7,973

#### Operating Activities.

During the six months ended June 30, 2024, net cash used in operating activities was \$13.7 million primarily due to our net loss of \$16.1 million, offset by cash provided by the change in operating assets and liabilities of \$1.8 million and non-cash charges of \$0.6 million. Non-cash charges resulted primarily from stock-based compensation expense of \$0.5 million. Changes in our operating assets and liabilities during the six months ended June 30, 2024 consisted primarily of a decrease of \$1.5 million in other assets due to the recognition of a prepaid expense, and an increase of \$1.0 million in accrued expenses and other current liabilities, offset by an increase of \$0.3 million in prepaid expenses and other current assets and a decrease of \$0.4 million in accounts payable. During the six months ended June 30, 2023, net cash used in operating activities was \$7.8 million primarily due to our net loss of \$6.6 million and \$1.8 million of decreased net operating assets and liabilities, offset by \$0.6 million in non-cash expenses.

#### Investing Activities.

During the six months ended June 30, 2024, there were no cash provided by investing activities. During the six months ended June 30, 2023, net cash provided by investing activities was \$15.8 million primarily resulting from proceeds from the sale of investments.

#### Financing Activities.

During the six months ended June 30, 2024, net cash provided by financing activities was \$18.3 million primarily due to the Offering in May 2024. During the six months ended June 30, 2023, there were no cash provided by financing activities.

### Funding Requirements

Our plan of operation is to continue implementing our business strategy, continue research and development of LTI-03 and any other product candidates we may acquire or develop and continue to expand our research pipeline and our internal research and development capabilities. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our current and future product candidates. In addition, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or terminate our research and development programs or future commercialization efforts. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current and future product candidates;
- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current and future product candidates;

- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain, skilled personnel;
- the costs of operating as a public company;
- if our product candidates are approved, our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in businesses, products, and technologies; and
- unfavorable global economic conditions, which may exacerbate the magnitude of the factors discussed above.

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 the product candidates. As of June 30, 2024, we had cash and cash equivalents of \$21.9 million. Based on our current operating plan, we believe that our existing cash and cash equivalents as of June 30, 2024 will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of issuance of these condensed consolidated financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations from the sale of additional equity or debt financings, or other capital which comes in the form of strategic collaborations, licensing, or other arrangements. In the event that additional financing is required, we may not be able to raise it on terms acceptable to us, or at all. If we raise additional funds through the issuance of equity or convertible preferred stock, it may result in dilution to our existing stockholders. Debt financing or preferred equity financing, if available, may result in increased fixed payment obligations, and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations.

If we raise funds through strategic collaborations, licensing or other arrangements, we may relinquish significant rights or grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

### **Critical Accounting Estimates**

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements to this Report on Form 10-Q, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated 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 consolidated 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 six months ended June 30, 2024, there were no material changes to the items that we disclosed as our critical accounting estimates in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2023 as filed with the SEC on April 15, 2024.

### **Recent Accounting Pronouncements**

See Note 2 to our unaudited condensed consolidated financial statements to this Report on Form 10-Q for a discussion of recent accounting pronouncements.

### **Smaller Reporting Company Status**

We are a “smaller reporting company” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than \$250.0 million or (ii) our annual revenue was less than \$100.0 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700.0 million. For so long as we continue to be a smaller reporting company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

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

### **Item 4. Controls and Procedures.**

#### **Limitations on Effectiveness of Controls and Procedures**

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

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

#### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and principal 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 our principal financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of June 30, 2024, because of the identified material weaknesses in our internal control over financial reporting described below.

#### **Material Weaknesses**

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Management identified material weaknesses related to (i) lack of sufficient accounting and supervisory personnel to maintain appropriate segregation of duties relating to user access of the financial accounting system and who have the appropriate level of technical accounting experience and training, (ii) lack of evidence over reviews of account reconciliations and supporting schedules, and (iii) lack of adequate procedures and controls to ensure that accurate financial statements could have been prepared and reviewed on a timely basis for annual reporting purposes. In the year ended December 31, 2023, management identified material weaknesses related to the accounting for our acquisition of Lung, including a lack of sufficient precision in the performance of reviews supporting the purchase price allocation accounting, and a lack of timely oversight over third-party specialists and the reports they produced to support the accounting for the Lung Acquisition. These material weaknesses continue to exist as of June 30, 2024.

#### **Management’s Plan to Remediate the Material Weaknesses**

We have implemented and are continuing to implement procedures to remediate these material weaknesses, including the hiring of a Controller with the requisite supervisory background and knowledge in financial reporting, integration into one accounting system, engaging third party accounting specialists and building a more streamlined process in order to prepare and review financial information,

however, our control environment needs improvement, and as a result we may be exposed to errors. Our remediation plan also includes the hiring of additional accounting employees and/or consultants with the specific technical accounting experience necessary to assist with complex, non-routine transactions and to support the timely completion of financial close procedures, the implementation of robust processes, and to assist with the preparation of financial statements and our compliance with SEC reporting obligations. Management has engaged an external advisor to assist in evaluating and documenting the design and operating effectiveness of our internal control over financial reporting, and their work is ongoing. With the help of third-party consultants, we have nearly completed the integration of the acquired systems from the Lung Acquisition into our financial and accounting systems. Additionally, we intend to develop and implement consistent accounting policies and internal control procedures and provide additional training to our accounting and financial reporting personnel.

We are taking actions to remediate the deficiencies in our internal control over financial reporting and are implementing additional processes and controls designed to address the underlying causes associated with the above-mentioned material weaknesses. Our internal control remediation efforts include the following:

- Enhanced the execution of our risk assessment activities by evaluating whether the design of our internal controls appropriately addresses changes in the business (including changes to people, processes and systems) that could impact our system of internal controls.
- Substantially completed the integration of the acquired systems from the Lung Acquisition into our financial and accounting systems to allow for systematic segregation of duties, and to enhance the accurate and timely preparation and review of financial statements and supporting schedules.

In addition to implementing and executing the aforementioned activities, the following activities are expected to be completed in fiscal year 2024:

- Continue to reassess staffing and add additional resources, as required, with the requisite technical accounting experience and training, to further allow for segregation of duties and to support our system of internal control.
- As needed, we will also supplement our internal resources with third-party resources and enhance our corporate oversight and monitoring over these resources, process-level controls and structures to ensure that there is appropriate assignment of authority, responsibility, and accountability.
- Engage a third-party to assist in redesigning, documenting, and testing the internal control activities that support the Company's timely preparation and review of account reconciliations, financial statements and supporting schedules.
- Continue to report regularly to the audit committee on the progress and results of the remediation plan, including the identification, status and resolution of internal control deficiencies.

The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. Management believes that the remediation measures described above will be implemented in a manner such that the controls can be tested, and the identified material weaknesses can be determined to be remediated, however, no assurance can be made that such remediation will occur or that additional material weaknesses will not be identified.

#### **Changes in Internal Control Over Financial Reporting**

Except for the above noted and previously reported material weaknesses and the related ongoing remediation activities described above, 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 June 30, 2024 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 a party to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, litigation can have a material adverse impact on us because of defense and settlement, costs, diversion of management resources, and other factors.

### Item 1A. Risk Factors.

Other than as described below, there have been no material changes to our risk factors discussed in “Part I, Item 1A-Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023.

You should carefully consider the risks included in our Annual Report on Form 10-K and in this Quarterly Report on Form 10-Q, together with all of the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated 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 may not achieve our publicly announced milestones according to schedule, or at all.***

From time to time, we may announce the timing of certain events that we expect to occur, such as the anticipated timing of results from our clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical trial, the announcement of the results of a clinical trial, or the filing of an application to obtain regulatory approval may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical trial or during a research phase, timing of the completion of clinical trials, or any other event having the effect of delaying the publicly announced timeline. We undertake no obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on our business plan, financial condition or operating results and the trading price of our common stock.

***Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business.***

We have limited financial and human resources and intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. This approach may cause us to commit significant resources to prepare for and conduct later-stage trials for one or more product candidates that subsequently fail earlier-stage clinical testing. Therefore, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities, or expend resources on product candidates that are not viable. For instance, in June 2024, we decided to temporarily delay clinical development of LTI-01 in an effort to focus our resources on clinical development of LTI-03 for the treatment of IPF and until additional funds are raised. .

There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient, or less expensive than any products that we may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of IPF and LPE as well, which could give such products significant regulatory and market timing advantages over LTI-03 and LTI-01 or other product candidates that we may identify. Currently, off-label use of fibrinolytics is utilized in many hospitals for the treatment of LPE. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. If competitors obtain patent protection or market exclusivity for their products before any of our products are approved, they could significantly delay the approval, and even review (in some cases), of our marketing application. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors. The availability of competitive products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

The Company made no unregistered sales of equity securities during the quarter covered by this report.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

During the second quarter of 2024, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K.

**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
3.1	<a href="#"><u>Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 11, 2021.)</u></a>
3.2	<a href="#"><u>Certificate of Amendment of Restated Certificate of Incorporation of the Registrant, dated as of November 10, 2022 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 10, 2022.)</u></a>
3.3	<a href="#"><u>Certificate of Amendment of Restated Certificate of Incorporation of the Registrant, dated February 28, 2024 (incorporated by reference to Exhibit 3.3 of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 15, 2024.)</u></a>
3.4	<a href="#"><u>Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 5, 2017.)</u></a>
4.1	<a href="#"><u>Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 1, 2024.)</u></a>
31.1	<a href="#"><u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
31.2	<a href="#"><u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
32.1	<a href="#"><u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
32.2	<a href="#"><u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
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 With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)





**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, Brian Windsor, 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.
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Dated: August 14, 2024

**AILERON THERAPEUTICS, INC.**

/s/ Brian Windsor, Ph.D.

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Brian Windsor, Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

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**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, Timothy M. Cunningham, 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.
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Dated: August 14, 2024

**AILERON THERAPEUTICS, INC.**

/s/ Timothy M. Cunningham

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Timothy M. Cunningham  
Interim Chief Financial Officer  
(Principal Financial Officer)

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**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 June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Windsor, Ph.D., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my 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: August 14, 2024

**AILERON THERAPEUTICS, INC.**

/s/ Brian Windsor, Ph.D.

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Brian Windsor, Ph.D.

President and Chief Executive Officer  
(Principal Executive Officer)

**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 June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Timothy M. Cunningham, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my 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: August 14, 2024

**AILERON THERAPEUTICS, INC.**

/s/ Timothy M. Cunningham

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Timothy M. Cunningham  
Interim Chief Financial Officer  
(Principal Financial Officer)

