

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 2021**

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)

285 Summer Street, Suite 101
Boston, MA
(Address of principal executive offices)

13-4196017
(I.R.S. Employer
Identification No.)

02210
(Zip Code)

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

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	ALRN	The Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<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 checked="" 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 November 9, 2021, the registrant had 90,573,597 shares of common stock, \$0.001 par value per share, outstanding.

Table of Contents

	<u>Page</u>
PART I.	
FINANCIAL INFORMATION	
Item 1.	5
Financial Statements (Unaudited)	5
Condensed Balance Sheets	5
Condensed Statements of Operations and Comprehensive Loss	6
Condensed Statement of Stockholders' Equity	7
Condensed Statements of Cash Flows	8
Notes to Financial Statements	9
Item 2.	20
Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3.	31
Quantitative and Qualitative Disclosures About Market Risk	31
Item 4.	31
Controls and Procedures	31
PART II.	
OTHER INFORMATION	
Item 1.	33
Legal Proceedings	33
Item 1A.	33
Risk Factors	33
Item 6.	72
Exhibits	72
Signatures	73

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

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

- our plans to develop and commercialize ALRN-6924, including the potential benefits thereof;
- our ongoing and future clinical trials for ALRN-6924, whether conducted by us or by any future collaborators, including the timing of initiation of these trials and of the anticipated results;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash, cash equivalents and investments;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the timing of and our ability to obtain and maintain marketing approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional product candidates with significant commercial potential;
- our plans to enter into collaborations for the development and commercialization of product candidates;
- potential benefits of any future collaboration;
- developments relating to our competitors and our industry;
- the impact of government laws and regulations;
- the impact the coronavirus pandemic may have on the timing of our clinical development and on our operations; and
- our ability to maintain our listing on the Nasdaq Capital Market.

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

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

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

SUMMARY RISK FACTORS

Our business is subject to a number of risks of which you should be aware in evaluating our company and our business. These risks are discussed more fully in the “Risk Factors” section of this Quarterly Report on Form 10-Q for the quarter ended September 30, 2021. These risks include the following:

- Our business depends entirely on the successful development and commercialization of our product candidate, ALRN-6924. Our clinical trials of ALRN-6924 may not be successful. If our trials prove unsuccessful or if we are unable to obtain approval for and commercialize ALRN-6924 or experience significant delays in doing so, our business will be materially harmed.
- We will need substantial additional funding to continue our operations. Our cash, cash equivalents and investments are not sufficient to enable us to complete the development of or commercialize ALRN-6924. If we are unable to raise capital when needed, we may be forced to delay, reduce and/or eliminate our research and drug development programs, reduce headcount, and future commercialization efforts, or take other actions that could adversely affect our business.
- We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability. Even if we are able to develop and commercialize ALRN-6924, we may never generate revenues that are significant or large enough to achieve profitability.
- The COVID-19 pandemic has affected and may continue to affect our ability to conduct our ongoing and planned clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, which could result in adverse effects on our business and operations.
- The approach we are taking to discover and develop novel drugs is unproven and may never lead to marketable products.
- We are pursuing the development of ALRN-6924 as a chemoprotective agent in combination with approved chemotherapeutics. If the U.S. Food and Drug Administration, or the FDA, revokes approval of any such chemotherapeutic, or if safety, efficacy, manufacturing or supply issues arise with any therapeutic that we use in combination with ALRN-6924 in the future, we may be unable to further develop and/or market ALRN-6924, or we may experience significant regulatory delays, and our business could be materially harmed.
- The outcome of preclinical testing and early clinical trials, such as the results of our Phase 1b trial of ALRN-6924 in patients with small cell lung cancer, may not be predictive of the success of later clinical trials, interim results of a clinical trial, do not necessarily predict final results and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities. In addition, results of clinical trials of ALRN-6924 when used with one chemotherapy or in one patient population may not be predictive of the results of other clinical trials of ALRN-6924 when used with a different chemotherapy or in a different patient population.
- Clinical drug development is a lengthy and expensive process, with an uncertain outcome. If clinical trials of ALRN-6924 or any other product candidate that we may develop fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs, experience delays in completing, or ultimately be unable to complete, the development of ALRN-6924 or any other product candidate that we may develop or be unable to obtain marketing approval.
- We are conducting clinical trials of ALRN-6924 and plan to conduct additional clinical trials of ALRN-6924 at sites outside the United States. The FDA’s acceptance of data from clinical trials outside of the United States is subject to conditions. Accordingly, the FDA may not accept data from trials conducted in such locations and the conduct of trials outside the United States could subject us to additional delays and expense.
- We may not be able to initiate or continue clinical trials for ALRN-6924 or any other product candidate that we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. We do not yet know exactly how many patients will have the genetic profile that ALRN-6924 or other future product candidates are designed to address. In particular, because our clinical trials are targeted at a subset of patients in indications with p53-mutated cancers, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.
- If serious adverse or unacceptable side effects are identified during the development of ALRN-6924 or any other product candidate that we may develop or we observe limited efficacy of ALRN-6924 or any other product candidate that we may develop, we may need to abandon or limit the development of ALRN-6924 or other product candidates that we may develop.
- The FDA or comparable foreign regulatory authorities may, under certain circumstances, require that a companion diagnostic be approved for use with ALRN-6924. If we are unable to successfully develop and obtain approval for such a diagnostic, either on our own or through a third party, or if we experience significant delays in doing so, we may not obtain marketing approval for ALRN-6924 in a timely manner, or at all.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

- We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.
- We contract with third parties for the manufacture of our ALRN-6924 for our ongoing clinical trials and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of ALRN-6924 or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- We may seek to enter into strategic collaborations for the development, marketing and commercialization of ALRN-6924 or other product candidates. If we are unable to enter into collaborations or those collaborations into which we enter are not successful, the development, marketing and/or commercialization of ALRN-6924 or such other product candidates that are the subject of such collaborations would be harmed.
- Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business.
- Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us, or any future collaborators, from obtaining approvals for the commercialization of ALRN-6924 or any other product candidate that we may develop. As a result, we cannot predict when or if, and in which territories or for which indications, we, or any future collaborators, will obtain marketing approval to commercialize ALRN-6924 or any other product candidate that we may develop.
- Even if ALRN-6924 receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AILERON THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS (UNAUDITED)

(In thousands, except share and per share data)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,603	\$ 7,046
Investments	44,629	6,759
Prepaid expenses and other current assets	2,166	1,928
Restricted cash	25	593
Total current assets	54,423	16,326
Operating lease, right-of-use asset	177	—
Other non-current assets	24	—
Property and equipment, net	144	15
Total assets	<u>\$ 54,768</u>	<u>\$ 16,341</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,035	\$ 1,596
Accrued expenses and other current liabilities	3,432	2,196
Paycheck Protection Program loan, current portion	—	168
Operating lease liability, current portion	93	—
Total current liabilities	4,560	3,960
Paycheck Protection Program loan, net of current portion	—	219
Operating lease liability, net of current portion	99	—
Total liabilities	<u>4,659</u>	<u>4,179</u>
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized and no shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.001 par value; 300,000,000 and 150,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 90,572,555 and 43,804,175 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	91	44
Additional paid-in capital	288,674	231,412
Accumulated other comprehensive gain/(loss)	1	(2)
Accumulated deficit	(238,657)	(219,292)
Total stockholders' equity	<u>50,109</u>	<u>12,162</u>
Total liabilities and stockholders' equity	<u>\$ 54,768</u>	<u>\$ 16,341</u>

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

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

(In thousands, except share and per share data)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	4,278	2,684	12,447	9,241
General and administrative	2,513	2,344	7,342	7,063
Total operating expenses	<u>6,791</u>	<u>5,028</u>	<u>19,789</u>	<u>16,304</u>
Loss from operations	(6,791)	(5,028)	(19,789)	(16,304)
Interest income	21	5	54	77
Other income, net	66	—	370	66
Net loss	<u>(6,704)</u>	<u>(5,023)</u>	<u>(19,365)</u>	<u>(16,161)</u>
Net loss per share — basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.13)</u>	<u>\$ (0.22)</u>	<u>\$ (0.49)</u>
Weighted average common shares outstanding—basic and diluted	<u>90,548,972</u>	<u>39,321,177</u>	<u>88,211,362</u>	<u>32,808,082</u>
Comprehensive loss:				
Net loss	\$ (6,704)	\$ (5,023)	\$ (19,365)	\$ (16,161)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net of tax of \$0	(5)	1	3	(8)
Total other comprehensive gain (loss)	<u>(5)</u>	<u>1</u>	<u>3</u>	<u>(8)</u>
Total comprehensive loss	<u>\$ (6,709)</u>	<u>\$ (5,022)</u>	<u>\$ (19,362)</u>	<u>\$ (16,169)</u>

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

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

(In thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balances at December 31, 2020	<u>43,804,175</u>	<u>\$ 44</u>	<u>\$ 231,412</u>	<u>\$ (2)</u>	<u>\$ (219,292)</u>	<u>\$ 12,162</u>
Issuance of common stock	46,406,382	46	59,042	—	—	59,088
Issuance costs	—	—	(3,482)	—	—	(3,482)
Stock-based compensation expense	—	—	631	—	—	631
Unrealized loss on investments	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(6,975)	(6,975)
Balances at March 31, 2021	<u>90,210,557</u>	<u>\$ 90</u>	<u>\$ 287,603</u>	<u>\$ (7)</u>	<u>\$ (226,267)</u>	<u>\$ 61,419</u>
Exercise of stock options	67,357	—	47	—	—	47
Issuance costs	—	—	(24)	—	—	(24)
RSU's vested	250,000	—	—	—	—	—
Stock-based compensation expense	—	—	361	—	—	361
Unrealized gain on investments	—	—	—	13	—	13
Net loss	—	—	—	—	(5,686)	(5,686)
Balances at June 30, 2021	<u>90,527,914</u>	<u>\$ 90</u>	<u>\$ 287,987</u>	<u>\$ 6</u>	<u>\$ (231,953)</u>	<u>\$ 56,130</u>
Exercise of stock options	44,641	1	26	—	—	27
Stock-based compensation expense	—	—	661	—	—	661
Unrealized loss on investments	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(6,704)	(6,704)
Balances at September 30, 2021	<u>90,572,555</u>	<u>\$ 91</u>	<u>\$ 288,674</u>	<u>\$ 1</u>	<u>\$ (238,657)</u>	<u>\$ 50,109</u>
Balances at December 31, 2019	<u>27,810,358</u>	<u>\$ 28</u>	<u>\$ 214,148</u>	<u>\$ 7</u>	<u>\$ (198,135)</u>	<u>\$ 16,048</u>
Issuance costs	—	—	(28)	—	—	(28)
Stock-based compensation expense	—	—	505	—	—	505
Unrealized loss on investments	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	(6,748)	(6,748)
Balances at March 31, 2020	<u>27,810,358</u>	<u>\$ 28</u>	<u>\$ 214,625</u>	<u>\$ (1)</u>	<u>\$ (204,883)</u>	<u>\$ 9,769</u>
Issuance costs	—	—	(1,186)	—	—	(1,186)
Issuance of common stock	11,425,118	11	11,904	—	—	11,915
RSU's vested, net of shares withheld	26,100	—	(13)	—	—	(13)
Stock-based compensation expense	—	—	560	—	—	560
Unrealized loss on investments	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	(4,390)	(4,390)
Balances at June 30, 2020	<u>39,261,576</u>	<u>\$ 39</u>	<u>\$ 225,890</u>	<u>\$ (2)</u>	<u>\$ (209,273)</u>	<u>\$ 16,654</u>
Issuance of common stock, net of issuance costs of \$159	606,747	1	363	—	—	364
RSUs vested, net of shares repurchased for tax	6,524	—	(3)	—	—	(3)
Stock-based compensation expense	—	—	465	—	—	465
Unrealized gain on investments	—	—	—	1	—	1
Net loss	—	—	—	—	(5,023)	(5,023)
Balances at September 30, 2020	<u>39,874,847</u>	<u>\$ 40</u>	<u>\$ 226,715</u>	<u>\$ (1)</u>	<u>\$ (214,296)</u>	<u>\$ 12,458</u>

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

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

(In thousands)

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (19,365)	\$ (16,161)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	81	153
Net amortization of premiums and discounts on investments	212	(19)
Stock-based compensation expense	1,653	1,530
Forgiveness of Paycheck Protection Program loan	(387)	—
Gain on sale of property and equipment	(66)	(66)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(238)	(580)
Other assets	(24)	510
Accounts payable	(564)	(451)
Operating lease liabilities	(36)	(325)
Accrued expenses and other current liabilities	1,235	(378)
Net cash used in operating activities	<u>(17,499)</u>	<u>(15,787)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(157)	(5)
Proceeds from sale of property and equipment	66	66
Purchases of investments	(70,828)	(8,035)
Proceeds from sales or maturities of investments	32,751	14,742
Net cash provided by (used in) investing activities	<u>(38,168)</u>	<u>6,768</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	55,583	11,174
Proceeds from Paycheck Protection Program loan	—	384
Proceeds from exercise of stock options	73	—
Net cash provided by financing activities	<u>55,656</u>	<u>11,558</u>
Net increase/(decrease) in cash, cash equivalents and restricted cash	(11)	2,539
Cash, cash equivalents and restricted cash at beginning of period	7,639	5,904
Cash, cash equivalents and restricted cash at end of period	<u>\$ 7,628</u>	<u>\$ 8,443</u>
Supplemental disclosure of non-cash financing activities:		
Common stock issuance costs included in accounts payable and accrued expenses	\$ —	\$ 127

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

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

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

1. Nature of the Business and Basis of Presentation

Aileron Therapeutics, Inc. (“Aileron” or the “Company”) is a clinical stage chemoprotection oncology company focused on fundamentally transforming the experience of chemotherapy for cancer patients. ALRN-6924, the Company’s first-in-class MDM2/MDMX dual inhibitor, is designed to activate p53, which in turn upregulates p21, a known inhibitor of the cell replication cycle. ALRN-6924 is the only reported chemoprotective agent in clinical development to employ a biomarker strategy, in which the Company exclusively focuses on treating patients with p53-mutated cancers. With this targeted strategy, ALRN-6924 is designed to selectively protect multiple healthy cell types throughout the body from chemotherapy without protecting cancer cells. As a result, healthy cells are spared from chemotherapeutic destruction while chemotherapy continues to kill cancer cells. By reducing or eliminating multiple chemotherapy-induced side effects, ALRN-6924 may improve patients’ quality of life and help them better tolerate chemotherapy. Enhanced tolerability may result in fewer dose reductions or delays of chemotherapy and the potential for improved efficacy.

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

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

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

Liquidity

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

The Company’s interim financial statements have been prepared on a going concern basis, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. Through September 30, 2021, the Company has financed operations primarily through \$145,467 in net proceeds from sales of common stock, \$131,211 from sales of preferred stock prior to its IPO, and \$34,910 from a collaboration agreement in 2010.

As of September 30, 2021, the Company had cash, cash equivalents and investments of \$52,232. The Company has incurred losses and negative cash flows from operations and had an accumulated deficit of \$238,657 as of September 30, 2021. The Company expects to continue to generate losses for the foreseeable future.

The Company believes that, based on its current operating plan, its cash, cash equivalents and investments of \$52,232 as of September 30, 2021 will enable the Company to fund its operating expenses for greater than twelve months from the date of issuance of these financial statements.

To execute its business plans beyond the next twelve months, the Company will need substantial funding to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through the sale of common stock in public offering and/or private placements, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing when needed, on acceptable terms or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its clinical programs, product portfolio expansion plans or commercialization efforts, which could adversely affect its business prospects. The interim financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Use of Estimates

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

Unaudited Interim Financial Information

The accompanying unaudited condensed financial statements as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020 have been prepared by the Company pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020 that was filed with the SEC on March 24, 2021.

The unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2021, the results of its operations for the three and nine months ended September 30, 2021 and 2020 and its cash flows for the nine months ended September 30, 2021 and 2020. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2021 and 2020 are unaudited. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period. The accompanying balance sheet as of December 31, 2020 has been derived from the Company's audited financial statements for the year ended December 31, 2020 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 24, 2021.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market accounts, corporate notes and commercial paper, are stated at fair value.

Restricted Cash

As of September 30, 2021 restricted cash consisted of \$25 deposited in a separate restricted bank account as a security deposit for the Company's corporate credit cards. As of December 31, 2020, restricted cash consisted of \$568 deposited in a separate restricted bank account as a security deposit for the lease of the Company's facility and \$25 deposited in a separate restricted bank account as a security deposit for the Company's corporate credit cards.

Investments

The Company classifies its available-for-sale debt security investments as current assets on the balance sheet if they mature within one year from the balance sheet date.

The Company's investments are measured and reported at fair value using quoted prices in active markets for similar securities or using other inputs that are observable or can be corroborated by observable market data. Unrealized gains and losses on available-for-sale securities are reported as accumulated other comprehensive income (loss), which is a separate component of stockholders' equity (deficit). The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense) within the statements of operations and comprehensive loss.

The Company evaluates its investments with unrealized losses for other-than-temporary impairment. When assessing investments for other-than-temporary declines in value, the Company considers such factors as, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general, among other factors. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary," the Company reduces the investment to fair value through a charge to the statements of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Concentration of Credit Risk and of Significant Suppliers

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

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including preclinical and clinical testing. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable.

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and investments are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. Diluted net loss is computed by adjusting basic loss per share to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share is computed by dividing the diluted net loss by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding options, restricted stock units and warrants to purchase common stock are considered potential dilutive common shares. In periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Risks and Uncertainties

In December 2019, an outbreak of respiratory illness caused by a strain of novel coronavirus, COVID-19, began in China. That outbreak has led to millions of confirmed cases worldwide, including in the United States and other countries where the Company is conducting clinical trials or activities in support thereof. The World Health Organization declared the outbreak a global pandemic on March 11, 2020. Recently, new variants of the virus that causes COVID-19 have been identified and are spreading in the United States and around the world, which may worsen or prolong the pandemic. In addition to those who have been directly affected, millions more have been affected by governmental efforts around the world to slow the spread of the virus. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce. The future progression of the pandemic and its effects on the Company's business and operations are uncertain.

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

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

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

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). This standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The standard also establishes additional disclosure requirements related to credit risks. This guidance was originally effective for annual reporting periods beginning after December 15, 2019, including interim periods within those annual reporting periods, and early adoption was permitted. In November 2019, the FASB subsequently issued ASU 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates, whereby the effective date of this standard for smaller reporting companies was deferred to annual reporting periods beginning after December 15, 2022, including interim periods within those annual reporting periods, and early adoption is still permitted. Accordingly, the Company will now adopt this standard effective January 1, 2023, and it is currently evaluating the potential impact that ASU 2016-13 may have on its condensed financial statements.

3. Fair Value of Financial Assets

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

	Fair Value Measurements as of September 30, 2021 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 5,174	\$ —	\$ —	\$ 5,174
Investments:				
Commercial paper	—	36,217	—	36,217
Corporate notes	—	6,409	—	6,409
Treasury bills	—	2,003	—	2,003
	<u>\$ 5,174</u>	<u>\$ 44,629</u>	<u>\$ —</u>	<u>\$ 49,803</u>

	Fair Value Measurements as of December 31, 2020 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 4,190	\$ —	\$ —	\$ 4,190
Commercial paper	—	1,001	—	1,001
Investments:				
Agency Bonds	—	3,511	—	3,511
Commercial paper	—	1,999	—	1,999
Treasury Bills	—	1,249	—	1,249
	<u>\$ 4,190</u>	<u>\$ 7,760</u>	<u>\$ —</u>	<u>\$ 11,950</u>

As of September 30, 2021 and December 31, 2020, the Company's cash equivalents and investments were valued based on Level 1 and Level 2 inputs. In determining the fair value of its corporate notes and commercial paper at each date presented above, the Company relied on quoted prices for similar securities in active markets or using other inputs that are observable or can be corroborated by observable market data. The Company's cash equivalents have original maturities of less than 90 days from the date of purchase. All available-for-sale investments have contractual maturities of less than one year. During the nine months ended September 30, 2021 and the year ended December 31, 2020, there were no transfers in or out of Level 3.

4. Investments

As of September 30, 2021 and December 31, 2020, the fair value of available-for-sale investments by type of security was as follows:

	September 30, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	\$ 36,215	\$ 2	\$ —	\$ 36,217
Corporate notes	6,410	—	(1)	6,409
Treasury Bills	2,003	—	—	2,003
	<u>\$ 44,628</u>	<u>\$ 2</u>	<u>\$ (1)</u>	<u>\$ 44,629</u>

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	\$ 1,999	\$ —	\$ —	\$ 1,999
Treasury bills	1,249	—	—	1,249
Agency bonds	3,511	—	—	3,511
	<u>\$ 6,759</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6,759</u>

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2021	December 31, 2020
Computer equipment and software	\$ 340	\$ 181
Less: Accumulated depreciation and amortization	(196)	(166)
	<u>\$ 144</u>	<u>\$ 15</u>

Depreciation and amortization expense for the three months ended September 30, 2021 and 2020 was \$15 and \$14 respectively. Depreciation and amortization expense for the nine months ended September 30, 2021 and 2020 was \$30 and \$153 respectively. During the nine months ended September 30, 2021, the Company received payment for disposed, fully depreciated assets, resulting in a gain on sale of \$66. During the nine months ended September 30, 2020, fully depreciated assets with a cost of \$45 were sold for \$66, resulting in a gain of \$66. During the year ended December 31, 2020, assets with a cost of \$640 were disposed of for \$208 in proceeds, resulting in a gain on sale of \$86.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2021	December 31, 2020
External research and development services	\$ 1,846	\$ 896
Payroll and payroll-related costs	1,150	922
Professional fees	420	135
Other	16	243
	<u>\$ 3,432</u>	<u>\$ 2,196</u>

7. Paycheck Protection Loan

On April 30, 2020, the Company received loan proceeds in the amount of approximately \$384 under the Paycheck Protection Program (“PPP”). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loan and accrued interest are forgivable after eight weeks if the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities. The amount of loan forgiveness may be reduced if the borrower terminates employees or reduces salaries during the eight-week period. The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1%, with a deferral of payments for the first six months. The Company used the proceeds for purposes consistent with the PPP. The Company has determined to account for the PPP loan as debt under Accounting Standards Update (“ASC 470”), “Debt”, and allocated and recorded the loan proceeds between current and non-current liabilities.

The Company further determined that loan forgiveness would become probable of occurring upon acceptance by the Small Business Association of the Company’s forgiveness application. On May 20, 2021 the Small Business Administration notified the Company that the PPP loan had been forgiven in full. During the nine months ended September 30, 2021 the Company recognized income for debt extinguishment pursuant to ASC 470-50-15-4 as other income.

8. Lease

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

The term of the Sublease (the “Term”) commenced on April 1, 2021 and terminates upon the earliest to occur of (i) March 31, 2023, (ii) early termination of the Prime Lease or (iii) termination of the Sublease pursuant to the terms thereof. The Company is obligated to pay monthly base rent under the Sublease to the Sublessor in an approximate amount of \$12 per month during the Term. The Company recorded a right of use asset of \$228 and operating lease liabilities of \$217 upon the inception of the Sublease.

9. Common Stock

On January 6, 2021, the Company entered into a securities purchase agreement (the “2021 Purchase Agreement”) with certain institutional investors, pursuant to which the Company issued and sold, in a registered direct offering (the “Offering”), an aggregate of 32,630,983 shares of common stock, \$0.001 par value per share, at a purchase price per share of \$1.10 (the “Shares”). The aggregate gross proceeds of the Offering were \$35,894, before deducting fees payable to the placement agent and other estimated offering expenses payable by the Company. The Offering closed on January 8, 2021. Between January 1, 2021 and January 28, 2021, the Company issued and sold an aggregate 7,174,993 shares of its common stock pursuant to its ATM Sales Agreement with JonesTrading Institutional Services LLC, resulting in net proceeds of \$9,368. The Company terminated its ATM Sales Agreement with Jones Trading in January 2021.

On January 29, 2021, the Company entered into a Capital on Demand™ Sales Agreement (the “ATM Sales Agreement”) with JonesTrading Institutional Services LLC (“JonesTrading”) and William Blair & Company, L.L.C. (“William Blair” and, collectively with JonesTrading, the “Agents”), pursuant to which the Company may offer and sell shares of its common stock having an aggregate offering price of up to \$30,000 from time to time through or to the Agents (the “ATM Offering”). On January 29, 2021, the Company filed a prospectus supplement with the SEC in connection with the ATM Offering under its Registration Statement. During the three and nine months ended September 30, 2021, the Company issued and sold an aggregate of 0 and 5,225,406 shares of its common stock, respectively, pursuant to the ATM Sales Agreement, resulting in net proceeds of \$0 and \$10,594, respectively.

During the three and nine months ended September 30, 2021, the Company issued and sold an aggregate of 0 and 1,375,000 shares of its common stock to Lincoln Park Capital, LLC pursuant to a purchase agreement entered into between Lincoln Park Capital, LLC and the Company in September 2020, resulting in gross proceeds of \$0 and \$2,614, respectively. During the three and nine months ended September 30, 2020, the Company issued and sold 588,235 shares to LPC under the Purchase Agreement for proceeds of \$500.

In June 2020, the Company issued and sold in an underwritten public offering an aggregate of 10,162,059 shares of common stock, including an additional 1,071,149 shares of common stock upon the partial exercise of an option of the underwriter to purchase additional shares, for a purchase price to the public of \$1.10 per share. The Company received aggregate gross proceeds from the public offering of approximately \$11,178, before deducting underwriting discounts and commissions and offering expenses of \$932.

10. Stock-Based Awards

2021 Stock Incentive Plan

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

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

The total number of shares of common stock that may be issued under the 2021 Plan was 12,756,267 as of September 30, 2021, of which 7,921,767 shares remained available for grant. The Company initially reserved 12,500,000 shares of common stock, plus the number of shares of common stock subject to outstanding awards under the Company’s 2017 Stock Incentive Plan (the “2017 Plan”), and the Company’s 2016 Stock Incentive Plan (“the 2016 Plan”) and the Company’s 2006 Stock Incentive Plan, as amended (the “2006 Plan”) that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right up to 6,280,135 shares.

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

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

2017 Stock Incentive Plan

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

Stock options granted under the 2017 Plan with service-based vesting conditions generally vest over four years and may not have a duration in excess of ten years, although options have been granted with vesting terms of less than four years.

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

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

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

2017 Employee Stock Purchase Plan

On June 16, 2017, the Company's stockholders approved the 2017 Employee Stock Purchase Plan (the "2017 ESPP"), which became effective on June 28, 2017. A total of 150,000 shares of common stock were initially reserved for issuance under this plan. Under the 2017 ESPP, the number of shares of common stock that may be issued under the 2017 ESPP will automatically increase on each January 1, beginning with the fiscal year ending December 31, 2018 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2027, equal to the least of (i) 622,408 shares, (ii) 1% of the outstanding shares of common stock on such date and (iii) an amount determined by the Company's board of directors. The compensation committee of the board of directors has determined that the number of shares of common stock that may be issued under the 2017 ESPP would not be increased on January 1, 2019 or January 1, 2020. The Company has not issued any shares under the 2017 ESPP.

Stock Option Valuation

The assumptions that the Company used to determine the grant-date fair value of the stock options granted to employees and directors during the nine months ended September 30, 2021 and 2020 were as follows, presented on a weighted average basis:

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Risk-free interest rate	0.96%	1.19%
Expected term (in years)	6.2	6.2
Expected volatility	91.0%	76.0%
Expected dividend yield	0%	0%

Stock Options

The following table summarizes the Company's stock option activity since January 1, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	4,665,586	\$ 2.39	8.1	\$ 622
Granted	5,371,900	1.30		
Exercised	(111,998)	0.62		
Canceled, forfeited or expired	(536,280)	2.27		
Outstanding at September 30, 2021	9,389,208	\$ 1.79	8.7	\$ 444
Options exercisable at September 30, 2021	2,787,647	\$ 2.97	7.1	\$ 223
Options vested and expected to vest at September 30, 2021	9,141,869	\$ 1.81	8.7	\$ 437
Options exercisable at December 31, 2020	2,377,533	\$ 3.28	7.6	\$ 197
Options vested and expected to vest at December 31, 2020	4,592,729	\$ 2.41	8.1	\$ 606

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2021 and 2020 was \$0.97 and \$0.48, respectively.

The aggregate fair value of stock options that vested during the nine months ended September 30, 2021 and 2020 was \$918 and \$1,694, respectively.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2021 and 2020 was \$66 and \$0, respectively.

Restricted Stock Units

The following table summarizes the Company's stock option activity since January 1, 2021:

	Units	Weighted-Average Grant Date per Unit
Outstanding, non-vested at December 31, 2020	—	\$ —
Issued	250,000	1.23
Vested	(250,000)	—
Canceled/forfeited	—	—
Outstanding, non-vested at September 30, 2021	—	—

Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development expenses	\$ 180	\$ 121	\$ 383	\$ 470
General and administrative expenses	481	344	1,270	1,060
	<u>\$ 661</u>	<u>\$ 465</u>	<u>\$ 1,653</u>	<u>\$ 1,530</u>

During the nine months ended September 30, 2021 and 2020 the Company recognized stock-based compensation expense of \$0 and \$160, respectively, included in the table above, related to performance-based awards for which achievement of such performance-based conditions were deemed probable.

As of September 30, 2021, the Company had an aggregate of \$5,505 of unrecognized stock-based compensation expense, which it expects to recognize over a weighted average period of 3.1 years.

11. Net Loss per Share

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Numerator:				
Net loss	\$ (6,704)	\$ (5,023)	\$ (19,365)	\$ (16,161)
Denominator:				
Weighted average common shares outstanding—basic and diluted	90,548,972	39,321,177	88,211,362	32,808,082
Net loss per share —basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.13)</u>	<u>\$ (0.22)</u>	<u>\$ (0.49)</u>

The Company's potential dilutive securities as of September 30, 2021 and 2020, which include stock options and warrants, have been excluded from the computation of diluted net loss per share whenever the effect of including them would be to reduce the net loss per share. In periods where there is a net loss, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The following potential shares of common stock, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>
Warrants to purchase common stock	12,935,323	12,935,323
Stock options to purchase common stock	9,389,208	4,628,687
Total	<u>22,324,531</u>	<u>17,564,010</u>

12. Commitments and Contingencies

Intellectual Property Licenses

Harvard and Dana-Farber Agreement

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

In February 2010, the agreement was amended and restated (the "Harvard/DFCI agreement") under which additional patent rights were added to the scope of the license agreement and the annual license maintenance fees were increased. Under the Harvard/DFCI agreement, the Company is obligated to make aggregate milestone payments of up to \$7,700 per licensed therapeutic product upon the Company's achievement of specified clinical, regulatory and sales milestones with respect to such product and up to \$700 per licensed diagnostic product upon the Company's achievement of specified regulatory and sales milestones with respect to such product. In addition, the Company is obligated to pay royalties of low single-digit percentages on annual net sales of licensed products sold by the Company, its affiliates or its sublicensees. The royalties are payable on a product-by-product and country-by-country basis, and may be reduced in specified circumstances. In addition, the 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 \$145. Any payments made in connection with the annual license maintenance fees will be credited against any royalties due.

The Company incurred license maintenance fees of \$0 and \$145 during each of the three and nine months ended September 30, 2021 and 2020 respectively. The Company did not make any milestone payments during the three and nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, no additional milestones had been achieved and no liabilities for additional milestone payments had been recorded in the Company's financial statements.

As of September 30, 2021, the Company had not developed a commercial product using the licensed technologies and no royalties under the agreement had been paid or were due.

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

Umicore Agreement

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

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

The Umicore agreement requires the Company to pay annual license fees of \$50. The Company incurred license fees of \$0 and \$50 during the three and nine months ended September 30, 2021 and 2020, respectively. The Company did not make any milestone payments during the three and nine months ended September 30, 2021 and 2020. As of September 30, 2021, no additional milestones had been achieved and no liabilities for additional milestone payments had been recorded in the Company's financial statements.

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

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims for indemnification that would have a material effect on its financial position, results of operations or cash flows, and it had not accrued any liabilities related to such obligations in its financial statements as of September 30, 2021 or December 31, 2020.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and related notes for the year ended December 31, 2020 included in our Annual Report on Form 10-K for the year ended December 31, 2020 that was filed with the Securities and Exchange Commission, or SEC, on March 24, 2021.

Some of the statements contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, constitute forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q particularly including those risks identified in Part II-Item 1A “Risk Factors” and our other filings with the SEC.

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

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

Overview

Aileron is a clinical stage chemoprotection oncology company focused on fundamentally transforming the experience of chemotherapy for cancer patients. ALRN-6924, our first-in-class MDM2/MDMX dual inhibitor, is designed to activate p53, which in turn upregulates p21, a known inhibitor of the cell replication cycle. ALRN-6924 is the only reported chemoprotective agent in clinical development to employ a biomarker strategy, in which we exclusively focus on treating patients with p53-mutated cancers. Our targeted strategy is designed to selectively protect multiple healthy cell types throughout the body from chemotherapy without protecting cancer cells. As a result, healthy cells are spared from chemotherapeutic destruction while chemotherapy continues to kill cancer cells. By reducing or eliminating multiple chemotherapy-induced side effects, ALRN-6924 may improve patients' quality of life and help them better tolerate chemotherapy. Enhanced tolerability may result in fewer dose reductions or delays of chemotherapy and the potential for improved efficacy. Our vision is to bring chemoprotection to patients with p53-mutated cancers, which represent approximately 50% of cancer patients, regardless of type of cancer or chemotherapy.

Our clinical development program for ALRN-6924 as a selective chemoprotective agent includes our completed Phase 1b open-label clinical trial evaluating ALRN-6924 as a chemoprotective agent in patients with p53-mutated small cell lung cancer, or SCLC being treated with chemotherapy; our ongoing study of ALRN-6924 in healthy volunteers; and our Phase 1b randomized, double-blind, placebo-controlled clinical trial evaluating ALRN-6924 as a chemoprotective agent in patients with p53-mutated non-small cell lung cancer, or NSCLC, being treated with chemotherapy or immuno-chemotherapy.

In September 2021, we presented final results from our Phase 1b study of ALRN-6924 in patients with SCLC undergoing treatment with second-line topotecan at the 2021 European Society for Medical Oncology (ESMO) Congress. A total of 39 patients were enrolled in the trial, 38 of whom were evaluable per the trial protocol. In the trial, topotecan (1.5 mg/m²) was administered to all patients on days 1 through 5 of every 21-day treatment cycle. Of these patients, 32 patients (31 evaluable) were treated with ALRN-6924 at 24 hours before each dose of topotecan at the following dose levels: 0.2 mg/kg (N=4), 0.3 mg/kg (N=16), 0.6 mg/kg (N=6; 5 evaluable) and 1.2 mg/kg (N=6). Seven patients were treated with 0.3 mg/kg of ALRN-6924 at 6 hours before each dose of topotecan. Per the final data, treatment with ALRN-6924 demonstrated a reduction of neutropenia, thrombocytopenia and anemia, as well as a reduction of platelet and red blood cell transfusions.

In the trial, toxicities were evaluated using the National Cancer Institute's (NCI) Common Terminology Criteria for Adverse Events (CTCAE). Per protocol, patients were not permitted to receive prophylactic granulocyte-colony stimulating factor (G-CSF) treatment in cycle 1. The median number of completed topotecan treatment cycles across all cohorts was 3. In addition, 13% of patients required topotecan dose reduction. No patients reported NCI CTCAE Grade 3 or greater events of nausea, vomiting or diarrhea; 5% had Grade 3 fatigue.

While chemoprotection effects were observed across all ALRN-6924 dose levels studied in the Phase 1b SCLC trial, the 0.3 mg/kg ALRN 6924 dose level given 24 hours prior to topotecan demonstrated the most robust chemoprotection results. None of the patients treated at the 0.3 mg/kg 24 hour ALRN-6924 dose level had a related serious adverse event. One patient (6%) at the 0.3 mg/kg 24 hour ALRN-6924 dose level required a red blood cell transfusion and a platelet transfusion.

These final data from the SCLC trial were in line with preliminary findings from this trial, which were presented in October 2020 at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics and with our belief that administering ALRN-6924 at 0.3mg/kg and 24 hours before topotecan remains the optimal dose and schedule in this patient population. The data from our SCLC trial have informed our choice of the recommended dose of ALRN-6924 (0.3 mg/kg) for subsequent clinical trials.

Biologically, we believe the same mechanism of action that leads to protection against chemotherapy-induced bone marrow toxicities has the potential to also protect healthy normal cells outside of the bone marrow, which may lead to protection against chemotherapy-induced side effects such as alopecia, mucositis, diarrhea and other chemotherapy-induced side effects. We aim to explore the chemoprotective effects of ALRN-6924 in other normal tissues and organs, such as the skin, hair follicles and the gastrointestinal tract in future clinical studies.

In the second quarter of 2021, we initiated a randomized, double-blind, placebo-controlled Phase 1b clinical trial of ALRN-6924 in patients with advanced NSCLC undergoing chemotherapy. We plan to enroll 60 patients with advanced p53-mutated NSCLC undergoing treatment with first-line carboplatin plus pemetrexed with or without immune checkpoint inhibitors. Patients enrolled in the NSCLC trial will be randomized 1:1 to receive carboplatin/pemetrexed plus 0.3 mg/kg ALRN-6924 or placebo for at least four 21-day treatment cycles. Components of the primary endpoint are the proportion of treatment cycles free of severe hematological and other toxicities, including Grade \geq 3 neutropenia, Grade \geq 3 thrombocytopenia, Grade \geq 3 anemia, Grade 4 neutropenia and febrile neutropenia, as well as duration of Grade 4 neutropenia. An additional component of the primary endpoint is the proportion of completed treatment cycles without chemotherapy dose reduction or without the use of growth factors or transfusions. Other endpoints include the proportion of patients with National Cancer Institute Common Terminology Criteria Adverse Events Grade 3/4 treatment-emergent adverse events, quality of life, overall response rate, and progression-free survival.

As of the date of this Quarterly Report on Form 10-Q, 12 trial sites are open for enrollment in the United States and Europe, and we anticipate opening additional sites. Due to the impact of the COVID-19 Delta variant in Eastern Europe, several sites in this region began screening two months later than planned. With those sites now activated, there has been an associated increase in patient enrollment. As a result of the delay in site activation and patient enrollment, we have updated our guidance for planned data readouts as follows: interim results on 20 patients with four cycles in the second quarter of 2022 and topline results on 60 patients with four cycles in the fourth quarter of 2022. We also plan to conduct a blinded safety evaluation on 10 patients after one cycle in the first quarter of 2022 to determine whether the safety and tolerability profile of ALRN-6924 in NSCLC patients is consistent with the safety and tolerability profile observed in previous clinical trials.

We are also conducting a trial of ALRN-6924 in healthy human volunteers designed to characterize the time to onset, and magnitude and duration of cell cycle arrest in human bone marrow relative to ALRN-6924 administration. The aim of the healthy volunteer study is to develop a universal dosing regimen for ALRN-6924 for use as a chemoprotective agent across a range of chemotherapies and tumor indications. We presented initial results from this ongoing trial at scientific conferences in the third quarter of 2021 and based on the initial results we believe that 0.3 mg/kg is the optimal dose for ALRN-6924 and confirmed the drug's novel p53 biomarker-driven mechanism of action, as well as its pharmacodynamic effects, including time to onset, magnitude and duration. The study is ongoing, including evaluating the effect of ALRN-6924 on epithelial cells, and we anticipate presenting additional findings at a later date.

In addition, we are making strategic investments in CMC development of ALRN-6924, and in the development of a p53 companion diagnostic to support late-stage clinical development in patients with NSCLC. We expect that these investments will also support future clinical programs of ALRN-6924 as a chemoprotective agent in other p53-mutated cancer indications. We are in discussions with the U.S. Food and Drug Administration, regarding the ALRN-6924 development program.

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.

Through September 30, 2021, we have financed operations primarily through \$145.5 in net proceeds from sales of common stock, \$131.2 from sales of preferred stock prior to its IPO, and \$34.9 from a collaboration agreement in 2010.

Since our inception, we have incurred significant losses on an aggregate basis. Our net losses were \$19.4 million and \$16.3 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of \$238.7 million. These losses have resulted primarily from costs incurred in connection with research and development activities, licensing and patent investment and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for at least the next several years.

As a result, we will need additional financing to support our continuing operations beyond the next twelve months. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity offerings, collaborations and licensing arrangements, or other sources of capital. Adequate additional financing may not be available to us on acceptable terms, if at all. Market conditions are volatile and may continue to be volatile for the foreseeable future, which may limit our ability to raise capital. In addition, while we may seek one or more collaborators for future development of our product candidates for one or more indications, we may not be able to enter into a collaboration for ALRN-6924 for such indications on suitable terms, on a timely basis or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate some or all of our clinical and drug development programs and future commercialization efforts. We may also be forced to take other actions that could adversely affect our business.

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

We believe, based on our current operating plan, that our cash, cash equivalents and investments of \$52.2 million as of September 30, 2021 will enable us to fund our operating expenses into the second half of 2023. Our funding estimates are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate. In any event, our cash, cash equivalents and investments will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development or commercialization of ALRN-6924, see "Liquidity and Capital Resources." Our future viability is dependent on our ability to raise additional capital to finance our operations.

COVID-19

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

In particular, the COVID-19 pandemic has impacted our ability to activate clinical trial sites and resulted in slower-than-anticipated enrollment in our Phase 1b clinical trial of ALRN-6924 in patients with advanced p53-mutated NSCLC undergoing chemotherapy. The ultimate impact of the COVID-19 pandemic on our operations is unknown and will depend on future developments. Such future events are highly uncertain and cannot be predicted with confidence, including the duration of the COVID-19 outbreak, new information which may emerge concerning the severity of the COVID-19 pandemic, including the new variants of the virus that causes COVID-19 that have been identified and are spreading in the United States and around the world, and any additional preventative and protective actions that governments or we may direct, which may result in an extended period of continued business disruption, reduced patient traffic and reduced operations. In particular, the continued spread of COVID-19 globally, and the magnitude of interventions to contain the spread of the virus, such as government-imposed quarantines, including shelter-in-place mandates, sweeping restrictions on travel, mandatory shutdowns for non-essential businesses, requirements regarding social distancing, vaccine mandates, and other public health safety measures, will determine the impact of the pandemic on our business, including our clinical trials. We are continuing to monitor the latest developments regarding the COVID-19 pandemic and its impact on our business, financial condition, results of operations and prospects.

Components of our Results of Operations

Revenue

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

Operating Expenses

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

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

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates, and include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufacture our product candidates for use in our preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- third-party license fees;
- costs related to compliance with regulatory requirements; and

- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

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

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

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect to incur significant research and development expenses in the foreseeable future as we continue our ongoing clinical trials of ALRN-6924, initiate additional clinical trials of ALRN-6924 and pursue later stages of clinical development of ALRN-6924.

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

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

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

General and Administrative Expenses

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

Interest Income

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

Other Income, net

Other income, net consists of gains or losses recognized from non-routine items such as debt forgiveness under the Paycheck Protection Program and gains or losses recognized from the disposal of fixed assets.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Increase (Decrease)
	2021	2020	
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	4,278	2,684	1,594
General and administrative	2,513	2,344	169
Total operating expenses	6,791	5,028	1,763
Loss from operations	(6,791)	(5,028)	(1,763)
Interest income	21	5	16
Other income, net	66	—	66
Net loss	\$ (6,704)	\$ (5,023)	\$ (1,681)

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2021 were \$4.3 million, compared to \$2.7 million for the three months ended September 30, 2020. The increase of \$1.6 million primarily resulted from increased spending of (a) \$0.5 million related to clinical development of ALRN-6924 for our Phase 1b clinical trial in patients with advanced NSCLC and our trial of ALRN-6924 in healthy human volunteers, (b) \$0.7 million of ALRN-6924 manufacturing costs, (c) \$0.3 million of higher employee-related costs, and (d) \$0.2 million in non-clinical research costs, all partially offset by lower facility costs.

General and Administrative Expenses

General and administrative expenses were \$2.5 million for the three months ended September 30, 2021, compared to \$2.3 million for the three months ended September 30, 2020. The increase in general and administrative expense was the result of higher employee related cost partially offset by lower facility costs in the three months ended September 30, 2021 as compared to 2020 resulting from the relocation of the Company's corporate headquarters in November 2020.

Interest Income

Interest income for the three months ended September 30, 2021 and 2020 was less than \$0.1 million. We anticipate that our interest income will fluctuate in the future in response to our then current cash, cash equivalents and investments, and then current interest rates.

Other Income, net

Other income, net for the three months ended September 30, 2021 was \$0.1 million, compared to \$0 for the three months ended September 30, 2020. The increase of \$0.1 million was primarily a result of payment received for equipment sold in 2020.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		Increase (Decrease)
	2021	2020	
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	12,447	9,241	3,206
General and administrative	7,342	7,063	279
Total operating expenses	19,789	16,304	3,485
Loss from operations	(19,789)	(16,304)	(3,485)
Interest income	54	77	(23)
Other income, net	370	66	304
Net loss	\$ (19,365)	\$ (16,161)	\$ (3,204)

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2021 were \$12.4 million, compared to \$9.2 million for the nine months ended September 30, 2020. The increase of \$3.2 million primarily resulted from increased spending of \$4.8 million related to clinical development of ALRN-6924 for the purpose of chemoprotection, partially offset by \$1.3 million of decreased clinical development expense resulting from the completion of our Phase 2a expansion cohort of the combination of ALRN-6924 and palbociclib (Ibrance), and lower drug development, research, and facility costs during the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020.

General and Administrative Expenses

General and administrative expenses were \$7.3 million for the nine months ended September 30, 2021, compared to \$7.1 million for the nine months ended September 30, 2020. Increased professional fees during the nine months ended September 30, 2021, as compared to September 30, 2020 of approximately \$0.4 million and higher employee related costs of \$0.3 million were partially offset by lower facility costs resulting from the relocation of the Company's corporate headquarters in November 2020.

Interest Income

Interest income for the nine months ended September 30, 2021 and 2020 was less than \$0.1 million. We anticipate that our interest income will fluctuate in the future in response to our then current cash, cash equivalents and investments, and then current interest rates.

Other Income, net

Other income, net for the nine months ended September 30, 2021, was \$0.4 million, compared to \$0.1 million for the nine months ended September 30, 2020. The increase of \$0.3 million is primarily a result of Paycheck Protection Program loan forgiveness.

Liquidity and Capital Resources

Since our inception, we have incurred significant losses on an aggregate basis. We have not yet commercialized any product candidate, including ALRN-6924, which is in clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. We have financed our operations through sales of common stock in our initial public offering and follow-on public offerings, sales of common stock and warrants in a private placement, sales of common stock in "at-the-market" offerings under the Capital on Demand Sales Agreements, sales of common stock under our equity line with LPC, sales of preferred stock prior to our initial public offering and payments received under a collaboration agreement. As of September 30, 2021, we had cash, cash equivalents and investments of \$52.2 million.

Public Offerings

In June 2020, we issued and sold in an underwritten public offering an aggregate of 10,162,059 shares of common stock, including an additional 1,071,149 shares of common stock upon the partial exercise of the option of the underwriter to purchase additional shares of common stock, for a purchase price to the public of \$1.10 per share. We received aggregate gross proceeds from the public offering of approximately \$11.2 million, before deducting underwriting discounts and commissions and offering expenses of \$0.9 million.

In January 2021, we issued and sold an aggregate of 32,630,983 shares of common stock in a registered direct offering at a purchase price per share of \$1.10. The aggregate gross proceeds of the registered direct offering were \$35.9 million, before deducting fees payable to the placement agent and other estimated offering expenses payable by us of approximately \$2.9 million.

At-the-Market Offering

In July 2019, we entered into a Sales Agreement with JonesTrading Institutional Services LLC, or JonesTrading, under which we currently may issue and sell shares of common stock, having an aggregate offering price of up to \$15.0 million. Sales of common stock through JonesTrading may be made by any method that is deemed an “at the market” offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. We are not obligated to make any sales of common stock under the Sales Agreement. During the year ended December 31, 2020, we issued and sold an aggregate of 4,160,899 shares of common stock pursuant to the Sales Agreement for gross proceeds of \$4.0 million, before deducting commissions and fees. Between January 1, 2021 and January 28, 2021, we sold an additional 7,174,993 shares of common stock pursuant to the Sales Agreement for gross proceeds of \$9.7 million, before deducting commissions and fees. We terminated the Sales Agreement in January 2021.

In January 2021, we entered into a Capital on Demand Sales Agreement, or the ATM Sales Agreement, with JonesTrading and William Blair & Company, L.L.C., or William Blair, as agents, under which we may issue and sell shares of common stock, having an aggregate offering price to up to \$30.0 million. Sales of common stock through JonesTrading and William Blair may be made by any method that is deemed an “at the market” offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. We are not obligated to make any sales of common stock under the ATM Sales Agreement. Between January 29, 2021 and March 31, 2021, we issued and sold an aggregate of 5,225,406 shares of common stock pursuant to the ATM Sales Agreement for proceeds of \$10.6 million, after deducting commissions and fees. There were no sales under the ATM Sales Agreement during the three months ended September 30, 2021.

Equity Line Financing

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

Upon entering into the LPC Purchase Agreement, we issued and sold 367,647 shares of common stock, or the Initial Purchase Shares, to LPC at a price per share of \$1.36, or \$0.5 million, which is part of the \$15.0 million of shares of common stock that we may sell to LPC under the Purchase Agreement. Additionally, we issued to LPC as a commitment fee 220,588 shares of common stock as consideration for LPC entering into the Purchase Agreement.

Under the Purchase Agreement, we may, at our discretion, direct LPC to purchase on any single business day, or a Regular Purchase, up to (i) 250,000 shares of common stock if the closing sale price of our common stock is not below \$1.50 per share on Nasdaq, (ii) 200,000 shares of common stock if the closing sale price of our common stock is not below \$1.00 per share on Nasdaq or (iii) 150,000 shares of common stock if the closing sale price of our common stock is below \$1.00 per share on Nasdaq. In any case, LPC’s commitment in any single Regular Purchase may not exceed \$1,000,000.

The purchase price per share for each such Regular Purchase will be based on prevailing market prices of our common stock immediately preceding the time of sale as computed under the LPC Purchase Agreement. Under the LPC Purchase Agreement, we may not effect any sales of shares of common stock on any purchase date that the closing sale price of our common stock on Nasdaq is less than the floor price of \$0.30 per share.

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

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

The LPC Purchase Agreement contains customary representations, warranties, covenants, indemnification and termination provisions. LPC has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our common stock. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings (other than restrictions on our ability to enter into additional “equity line” or a substantially similar transaction whereby a specific investor is irrevocably bound pursuant to an agreement with us to purchase securities over a period of time from us at a price based on the market price of the common stock at the time of such purchase), rights of first refusal, participation rights, penalties or liquidated damages in the LPC Purchase Agreement. The LPC Purchase Agreement may be terminated by us at any time, at our sole discretion, without any cost or penalty. During any “event of default” under the LPC Purchase Agreement, LPC does not have the right to terminate the LPC Purchase Agreement; however, we may not initiate any purchase of shares by LPC until such event of default is cured. Through December 31, 2020, we issued and sold an aggregate of 1,417,647 shares of common stock to LPC for gross proceeds of \$1,801 million. Between January 1, 2021 and March 31, 2021, we issued and sold an aggregate of 1,375,000 shares of common stock to LPC for gross proceeds of \$2.6 million. There were no sales under the LPC Purchase Agreement during the three months ended September 30, 2021.

Private Placement

On April 2, 2019, we issued and sold in a private placement an aggregate of (i) 11,838,582 units, consisting of 11,838,582 shares of our common stock and associated warrants, or the common warrants, to purchase an aggregate of 11,838,582 shares of common stock, for a combined price of \$2.01 per unit and (ii) 1,096,741 units, consisting of (a) pre-funded warrants to purchase 1,096,741 shares of our common stock and (b) associated common warrants to purchase 1,096,741 shares of common stock, for a combined price of \$2.01 per unit. The pre-funded warrants had an exercise price of \$0.01 per share and had no expiration. The common warrants are exercisable at an exercise price of \$2.00 per share and expire five years from the date of issuance. The securities were sold pursuant to a securities purchase agreement entered into with accredited investors on March 28, 2019. We received aggregate gross proceeds from the private placement of approximately \$26.0 million before deducting placement agent fees and offering expenses of approximately \$2.2 million and excluding the exercise of any warrants. In July 2019, all outstanding pre-funded warrants were exercised for 1,096,741 shares of common stock.

Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Cash used in operating activities	\$ (17,499)	\$ (15,787)
Cash provided by/(used in) investing activities	(38,168)	6,768
Cash provided by financing activities	55,656	11,558
Net increase/(decrease) in cash, cash equivalents and restricted cash	<u>\$ (11)</u>	<u>\$ 2,539</u>

Operating Activities. During the nine months ended September 30, 2021, operating activities used \$17.5 million of cash, resulting primarily from our net loss of \$19.4 million, partially offset by \$1.5 million in non-cash expenses. Net cash provided by changes in our operating assets and liabilities during the nine months ended September 30, 2021 consisted primarily of an increase of \$1.2 million in accrued expenses partially offset by a decrease of \$0.6 million in accounts payable and an increase of \$0.2 million in prepaid expenses and other current assets from December 31, 2020. The increase in accrued expenses is due to increased clinical trial activity.

During the nine months ended September 30, 2020, operating activities used \$15.8 million of cash, resulting primarily from our net loss of \$16.2 million, offset by \$1.5 million in non-cash stock-based compensation expense. Net cash used by changes in our operating assets and liabilities during the nine months ended September 30, 2020 consisted primarily of a decrease of \$0.4 million in accrued expenses and other current liabilities as well as a decrease of \$0.5 million in accounts payable from December 31, 2019. The decrease in accrued expenses and other current liabilities was primarily due to a decrease in payroll-related accruals.

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

During the nine months ended September 30, 2020, investing activities provided \$6.8 million of cash resulting from \$14.7 million of proceeds from the sale of investments and \$0.1 million of proceeds from the sale of property and equipment offset by \$8.0 million of purchases of investments.

Financing Activities. During the nine months ended September 30, 2021, net cash provided by financing activities was \$55.7 million due to the proceeds received from the sale of common stock during the first quarter of 2021. During the nine months ended September 30, 2020, net cash provided by financing activities was \$11.6 million due to the proceeds received from the sale of common stock in our public offering in June 2020, sales under our Sales Agreement with JonesTrading, funds received from sales of common stock to LPC in September 2020 and the proceeds from the Paycheck Protection Program loan.

Funding Requirements

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

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

We believe, based on our current operating plan, that our cash, cash equivalents and investments of \$52.2 million as of September 30, 2021 will enable us to fund our operating expenses into the second half of 2023. Our funding estimates are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate. In any event, our cash, cash equivalents and investments will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development or commercialization of ALRN-6924. Our future viability is dependent on our ability to raise additional capital to finance our operations.

Accordingly, we will be required to obtain further funding through public or private equity offerings, collaborations and licensing arrangements, or other sources of capital. Adequate additional financing may not be available to us on acceptable terms, if at all. In addition, while we may seek one or more collaborators for future development of ALRN-6924 or other product candidates that we may develop, we may not be able to enter into a collaboration for ALRN-6924 or other product candidates that we may develop on suitable terms, on a timely basis or at all.

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

- the scope, progress, results and costs of our ongoing, planned and future clinical trials of ALRN-6924;
- the impact of the COVID-19 pandemic on our business and operations;
- the scope, progress, results and costs of drug discovery, preclinical research and clinical trials for any other product candidates that we may develop;
- the number of future product candidates that we pursue and their development requirements;

- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the success of any collaborations that we may enter into with third parties;
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates, although we currently have no commitments or agreements to complete any such transactions;
- the costs and timing of future commercialization activities, including drug sales, marketing, manufacturing and distribution, for any product candidate for which we receive marketing approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator that we may have at such time;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any product candidate receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs, as we expand our business operations and our research and development activities; and
- the costs of operating as a public company.

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

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

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Use of Estimates

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

During the three and nine months ended September 30, 2021, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Use of Estimates” in our Annual Report on Form 10-K and the notes to the unaudited condensed financial statements included in Item 1, “Unaudited Financial Statements,” of this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve judgment and complexity:

- Accrued research and development expenses; and
- Stock-based compensation.

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

Emerging Growth Company Status

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

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, for this reporting period and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2021.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) has occurred during the quarter ended September 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the SEC, in evaluating our company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position

We will need substantial additional funding to continue our operations. If we are unable to raise capital when needed, we may be forced to delay, reduce and/or eliminate our research and drug development programs, reduce headcount, and future commercialization efforts, or take other actions that could adversely affect our business.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We will be required to expend significant funds in order to advance the development of, conduct clinical trials of, and seek marketing approval for, our product candidate, ALRN-6924, as well as any other product candidates we may develop. If we are able to obtain marketing approval for ALRN-6924 or for any other product candidate in the future, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator that we may have at such time for any such product candidate. We also expect to continue to incur additional costs associated with operating as a public company.

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

- the scope, progress, results and costs of our ongoing, planned and future clinical trials of ALRN-6924;
- the impact of the COVID-19 pandemic on our business and operations;
- the scope, progress, results and costs of drug discovery, preclinical research and clinical trials for other product candidates we may develop;
- the number of future product candidates that we pursue and their development requirements;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations with third parties on favorable terms, if at all;
- the success of any collaborations that we may enter into with third parties;
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates, although we currently have no commitments or agreements to complete any such transactions;
- the costs and timing of future commercialization activities, including drug sales, marketing, manufacturing and distribution, for any product candidate for which we receive marketing approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator that we may have at such time;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any product candidate receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and our research and development activities; and
- the costs of operating as a public company.

We believe, based on our current operating plan, that our cash, cash equivalents and investments as of September 30, 2021 will enable us to fund our operating expenses into the second half of 2023. Our funding estimates are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate. In any event, our cash, cash equivalents and investments will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development or commercialization of ALRN-6924.

Accordingly, we will need to obtain further funding through public or private equity offerings, collaborations and licensing arrangements, or other sources of capital. Adequate additional financing may not be available to us on acceptable terms, if at all. Market conditions are volatile and may continue to be volatile for the foreseeable future, which may limit our ability to raise capital. In addition, while we may seek one or more collaborators for future development of our product candidates for one or more indications, we may not be able to enter into a collaboration for ALRN-6924 for such indications on suitable terms, on a timely basis or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate some or all of our clinical and drug development programs and future commercialization efforts. We may also be forced to take other actions that could adversely affect our business.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.

We expect our expenses to increase as we will incur significant research and development expenses as we continue our ongoing clinical trials of ALRN-6924, continue our non-clinical research with ALRN-6924, initiate additional clinical trials of ALRN-6924 and pursue later stages of clinical development of ALRN-6924. Until such time, if ever, as we can generate substantial revenues from the sale of our products, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our then existing stockholders may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholders. In addition, debt financing, if available, would result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. Securing financing may also require a substantial amount of time and attention from our management team and could divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

We may seek one or more collaborators for future development of ALRN-6924 for one or more indications. However, we may not be able to enter into such collaborations on suitable terms, on a timely basis, or at all. Even if we are able to raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds when needed, we may be required to delay, reduce and/or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we might otherwise prefer to develop and market ourselves.

Our limited operating history may make it difficult for our stockholders to evaluate the success of our business to date and to assess our future viability.

We are an early-stage company, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our stabilized cell-permeating peptide platform, identifying potential product candidates, conducting preclinical studies of our product candidates and conducting clinical trials of our product candidates. Our product candidates other than ALRN-6924 have not advanced beyond the preclinical research stage. In March 2020, we determined to focus our efforts on the development of ALRN-6924 as a chemoprotective agent, and do not plan to advance any development of ALRN-6924 for any other purpose at this time. We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical trials, including large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale drug or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful drug commercialization. Typically, it takes about six to ten years to develop a new drug from the time it is first evaluated in Phase 1 clinical trials to when it is approved for treating patients, but in many cases, it may take longer. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

As a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. In the future, we may need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition. Our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. If we are unable to obtain product approvals or generate significant commercial revenues, our business will be materially harmed.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, stockholders should not rely upon the results of any particular quarterly or annual periods as indications of future operating performance.

We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant losses on an aggregate basis. Our net loss was \$19.4 million and \$16.2 million for the nine months ended September 30, 2021 and 2020, respectively. We have not generated any revenue to date from sales of any drugs and have financed our operations principally through sales of our common stock, through private placements of our preferred stock prior to our initial public offering, and, to a lesser extent, through a collaboration agreement. We have devoted substantially all of our efforts to research and development. Our product candidate, ALRN-6924, is in clinical development and we expect that it will be several years, if ever, before it is ready for commercialization. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

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

To become and remain profitable, we must develop, obtain approval for and eventually commercialize a product or products with significant market potential, either on our own or with a collaborator. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and establishing and managing any collaborations for the development, marketing and/or commercialization of our product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business and/or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

Risks Related to the Discovery, Development and Commercialization of Product Candidates

We are dependent on the success of our product candidate, ALRN-6924. Our clinical trials of ALRN-6924 may not be successful. If our trials prove unsuccessful or if we are unable to obtain approval for and commercialize ALRN-6924 or experience significant delays in doing so, our business will be materially harmed.

Our future success is substantially dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, ALRN-6924, our product candidate. We are investing a substantial portion of our efforts and financial resources in the research and development of ALRN-6924 as a chemoprotective agent. Our business depends entirely on the successful development and commercialization of ALRN-6924. We currently generate no revenues from sales of any products, and we may never be able to develop a marketable product. We have not identified any other product candidates for development and are not currently conducting any preclinical research to discover and identify new product candidates.

ALRN-6924 will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote ALRN-6924, or any other product candidates, before we receive marketing approval from the U.S. Food and Drug Administration, or the FDA, and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of ALRN-6924 will depend on several factors, including the following:

- successful and timely patient enrollment and completion of our ongoing and planned clinical trials of ALRN-6924;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals for both ALRN-6924 and any required companion diagnostic from applicable regulatory authorities;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials and drug product suppliers and manufacturers;
- establishment of scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator.

The COVID-19 pandemic has affected and may continue to affect our ability to conduct our ongoing clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, which could result in adverse effects on our business and operations.

Significant outbreaks of contagious diseases, and other adverse public health developments, could have a material impact on our business operations and operating results. In December 2019, an outbreak of respiratory illness caused by a strain of novel coronavirus, COVID-19, began in China. That outbreak has led to numerous confirmed cases worldwide, including in the United States and other countries where we are conducting clinical trials or activities in support thereof. The World Health Organization declared the outbreak a global pandemic on March 11, 2020. Recently, new variants of the virus that causes COVID-19, such as the delta variant, have been identified and are spreading in the United States and around the world, which may worsen or prolong the outbreak. In addition to those who have been directly affected, millions more have been affected by governmental efforts around the world to slow the spread of the outbreak. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on

businesses and commerce, including supply chains. The future progression of the outbreak and its effects on our business and operations are uncertain.

We and our third-party contract manufacturers, contract research organizations and clinical sites may experience disruptions in supply of product candidates and/or procuring items that are essential for our research and development activities, including, for example, raw materials used in the manufacturing of ALRN-6924, medical and laboratory supplies used in our clinical trials or preclinical studies or animals that are used for preclinical testing, in each case, for which there may be shortages because of ongoing efforts to address the COVID-19 pandemic and resulting disruptions to global supply chains. While we believe that we currently have sufficient supply of ALRN-6924 to continue our ongoing and planned clinical trials, ALRN-6924 and materials contained therein, come from facilities located in areas impacted by the COVID-19 pandemic. There is no guarantee that the ongoing COVID-19 outbreak, or any potential future outbreak, will not impact our future supply chain, which could have a material adverse impact on our clinical trial plans and business operations.

Additionally, we have enrolled, and are seeking to enroll, cancer patients in our clinical trials at sites located in areas being impacted the COVID-19 pandemic. In the event that clinical trial sites close to enrollment in our trials or shift resources to address COVID-19, this could have a material adverse impact on our clinical trial plans and timelines. We may face difficulties recruiting or retaining patients in our ongoing and planned clinical trials if patients are affected by the virus or are fearful of visiting or traveling to our clinical trial sites because of the COVID-19 pandemic. For instance, the initiation of, and expected timing of reporting data from, our ongoing healthy volunteer study was delayed due to the impact of the COVID-19 pandemic and we experienced a higher than anticipated screen failure rate during our recently completed Phase 1b SCLC trial due to COVID-19 related complications in the patient population that was targeted for enrollment. Additionally, the COVID-19 pandemic has impacted our ability to activate clinical trial sites and accordingly resulted in slower-than-anticipated enrollment in our Phase 1b clinical trial of ALRN-6924 in patients with advanced p53-mutated NSCLC undergoing chemotherapy

Any negative impact that the COVID-19 pandemic has on the ability of our suppliers to provide materials for ALRN-6924 or in the conduct of our clinical trials could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize ALRN-6924, increase our operating expenses, affect our ability to raise additional capital, and have a material adverse effect on our financial results.

The response to the COVID-19 pandemic may cause governments to redirect resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to progress regulatory approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and approvals due to measures intended to limit in-person interactions.

The COVID-19 pandemic has significantly impacted economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business. It has the potential to adversely affect our business, financial condition, results of operations, and prospects.

The approach we are taking to discover and develop novel drugs is unproven and may never lead to marketable products.

We have concentrated our efforts and therapeutic product research on stabilized cell-permeating alpha-helical peptide technology, and our future success depends on the successful development of this technology and products based on our proprietary peptide technology. Neither we nor any other company has received marketing approval to market therapeutics utilizing cell-permeating peptides. The scientific discoveries that form the basis for our efforts to discover and develop new drugs are relatively new. The scientific evidence to support the feasibility of developing drugs based on these discoveries is both preliminary and limited. Very few drug candidates based on these discoveries have ever been tested in animals, and development of an earlier stabilized cell-permeating peptide product candidate by us was suspended following a clinical trial due to the anticipated costs of required reformulation. Peptides, the class of molecule we are trying to develop into drugs, do not naturally possess the inherent molecular properties typically required of drugs, such as the ability to be stable in the body long enough to reach the tissues in which their effects are required, nor the ability to enter cells within these tissues in order to exert their effects. We currently have only limited data to suggest that we can introduce these properties into peptides. We may spend large amounts of money trying to introduce these properties, and never succeed in doing so. In addition, our stabilized cell-permeating peptide product candidates may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory studies, and they may interact with human biological systems in unforeseen, ineffective or harmful ways. As a result, we may never succeed in developing a marketable product. If we do not successfully develop and commercialize products based upon our technological approach, we will not become profitable and the value of our common stock will decline. Further, our focus on stabilized cell-permeating peptide technology as opposed to multiple technologies increases the risks associated with the ownership of our common stock. If our approach is not successful, we may be required to change the scope and direction of our product development activities. In that case, we may not be able to successfully identify and implement an alternative product development strategy.

Moreover, we believe our product candidate, ALRN-6924, reactivates p53 by disrupting the interactions between p53 and its endogenous inhibitors, MDM2 and MDMX, thereby freeing p53 to transit to its DNA target in the nucleus and initiate cell cycle arrest in healthy cells and/or apoptosis in cancerous cells. We believe that ALRN-6924 is the first and only product candidate in clinical

development that can bind to and disrupt the interaction of MDM2 and MDMX with p53 with equivalent effectiveness, or equipotently. Although we have evaluated ALRN-6924 in preclinical studies and early-stage clinical trials, and are aware of published literature supporting the role of MDM2 and MDMX in reactivating non-mutated or wild type, or WT, p53 as well as clinical results for small molecule inhibitors that act to disrupt the interaction of p53 and MDM2, we believe that we are the first to clinically test a molecule that binds directly to both MDM2 and MDMX. As such, the effect of binding to and simultaneously disrupting the interactions of MDM2 and MDMX with WT p53 in cancer patients has not been established in clinical trials. In addition, the role of factors other than MDM2 and MDMX in circumventing the p53 mechanism is still the subject of continued research.

The use of a dual inhibitor of MDM2 and MDMX to reduce chemotherapy-related toxicities in the bone marrow and healthy normal cells outside of the bone marrow is a novel approach and we believe that we are the only company currently developing in clinical trials a MDM2 and MDMX inhibitor for this purpose. The scientific evidence to support the feasibility of developing this product candidate for this purpose is both preliminary and limited. Even though ALRN-6924 has demonstrated positive results in preclinical and clinical studies, we may not succeed in demonstrating safety and efficacy of ALRN-6924 as a chemoprotective agent in additional or later-stage clinical trials.

As a result, we do not know whether the mechanism of action of ALRN-6924 will have the expected effect on patients receiving chemotherapy in any cancer indications and whether ALRN-6924 will succeed in demonstrating the safety and efficacy needed to advance in clinical development and obtain marketing approval.

We are pursuing the development of ALRN-6924 in combination with other approved therapeutics. If the FDA revokes approval of any such therapeutic, or if safety, efficacy, manufacturing or supply issues arise with any therapeutic that we use in combination with ALRN-6924 in the future, we may be unable to further develop and/or market ALRN-6924, or we may experience significant regulatory delays, and our business could be materially harmed.

We are pursuing the development of ALRN-6924 in combination with other approved therapeutics. In the future, we may commence additional clinical trials of ALRN-6924 in combination with other approved therapeutics, including, if our ongoing trials are successful, later stage clinical trials of ALRN-6924 in combination with approved therapeutics.

We did not develop or obtain regulatory approval for, and we do not manufacture or sell, any of these approved therapeutics. In addition, these combinations have not been tested before and may, among other things, fail to demonstrate synergistic activity, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, may exacerbate adverse events associated with one of our product candidates when used as a single agent, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy.

If the FDA revokes its approval of any of these therapeutics, we will not be able to continue clinical development of or market ALRN-6924 or any other product candidate in combination with such revoked therapeutic. If safety or efficacy issues arise with these or any other therapeutics that we seek to combine with our product candidates in the future, we may experience significant regulatory delays, and the FDA may require us to redesign or terminate the applicable clinical trials. Moreover, if these therapeutics were to receive regulatory approval in combination with a different therapeutic in any indication for which we are pursuing approval, such approval could impact the feasibility and design of any subsequent clinical trials that we may seek to conduct evaluating ALRN-6924, or any other product candidate, in combination with such therapeutic. If manufacturing, cost or other issues result in a supply shortage of these therapeutics or any other combination therapeutics, we may not be able to complete clinical development of ALRN-6924 on our current timeline or at all, or any other product candidate we may develop in the future.

In addition, we may need, for supply, data referencing or other purposes, to collaborate or otherwise engage with the companies who market these approved therapeutics. If we are unable to do so on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate or indication, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities.

Even if ALRN-6924 or any other product candidate were to receive regulatory approval and be commercialized for use in combination with an approved therapeutic, we would continue to be subject to the risk that the FDA could revoke its approval of such therapeutic, that safety, efficacy, manufacturing, cost or supply issues could arise with one of these therapeutic agents, or that the current standard of care may be replaced. This could result in ALRN-6924 or any such other product candidate, if approved, being removed from the market or being less successful commercially.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, interim results of a clinical trial do not necessarily predict final results and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

We currently have no drugs approved for sale and we cannot guarantee that we will ever have marketable drugs. Clinical failure can occur at any stage of clinical development. For instance, our first clinical trial of one of our earlier cell-permeating peptide product candidates did not generate the desired results, and we suspended the development program. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Product candidates that have shown promising results in preclinical studies and early-stage clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Additionally, the outcome of preclinical studies and early-stage clinical trials, such as the results of our Phase 1b trial of ALRN-6924 in patients with small cell lung cancer, may not be predictive of the success of later-stage clinical trials.

We may publish or report interim or preliminary data from our clinical trials, such as preliminary data from our Phase 1 pharmacology study in healthy volunteers to evaluate the pharmacokinetics and pharmacodynamics of ALRN-6924. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available.

In addition, the design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and conduct a clinical trial to support marketing approval. Further, if our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain marketing approval for them and our business would be harmed. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in preclinical studies and earlier clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. We may also determine to discontinue development of our product candidates for certain indications for a variety of other strategic reasons.

In the event that an adverse safety issue, clinical hold or other adverse finding occurs in one or more of our clinical trials of ALRN-6924, such event could adversely affect our other clinical trials of ALRN-6924. Moreover, there is a relatively limited safety data set for product candidates utilizing stabilized cell-permeating peptides or that are designed to reactivate p53. An adverse safety issue or other adverse finding in a clinical trial conducted by a third party with a product candidate utilizing stabilized cell-permeating peptides or that is designed to reactivate p53, such as the small molecules in development that target the p53-MDM2 interaction, could adversely affect our clinical trials of ALRN-6924.

Further, ALRN-6924 or any other product candidate we may develop may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA or non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or another regulatory authority. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. In addition, the FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Before obtaining marketing approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and well-controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication. There is no assurance that the FDA or non-U.S. regulatory authorities will consider our future clinical trials to be sufficient to serve as the basis for approval of one of our product candidates for any indication. The FDA and non-U.S. regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that a product candidate is

safe and effective. If we are required to conduct additional clinical trials of a product candidate than we expect prior to its approval, we will need substantial additional funds and there is no assurance that the results of any such additional clinical trials will be sufficient for approval.

Clinical drug development is a lengthy and expensive process, with an uncertain outcome. If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs, experience delays in completing, or ultimately be unable to complete, the development of our product candidates or be unable to obtain marketing approval.

Before obtaining marketing approval from regulatory authorities for the sale of ALRN-6924 or any other product candidate we may develop, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early-stage clinical trials, such as results of our Phase 1b clinical trial of ALRN-6924 in patients with p53-mutated SCLC that we announced in September 2021, may not be predictive of the success of later clinical trials in the same or different indications, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We do not know whether our ongoing clinical trials will be completed on schedule or at all, or whether future clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Moreover, due to the continuing COVID-19 pandemic, the activation of trial sites and enrollment in our clinical trials has been and may continue to be adversely affected, delayed or interrupted. For instance, the initiation of, and expected timing of reporting data from, our ongoing human volunteer study was delayed due to the impact of the COVID-19 pandemic. Patients may choose to withdraw from our studies or we may choose to or be required to pause enrollment and or patient dosing in our ongoing clinical trials in order to preserve health resources and protect trial participants.

Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining marketing approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board approval at each clinical trial site;
- recruiting suitable patients to participate in a trial;
- developing and validating any companion diagnostic to be used in the trial, to the extent we are required to do so;
- patients failing to comply with trial protocol or dropping out of a trial;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the need to add new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side

effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the drug removed from the market after obtaining marketing approval.

Our drug development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Furthermore, we rely on third-party CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring drugs to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We are conducting a clinical trial of ALRN-6924 and plan to conduct additional trials of ALRN-6924 at sites outside the United States. The FDA may not accept data from trials conducted in such locations and the conduct of trials outside the United States could subject us to additional delays and expense.

We are conducting clinical trials of ALRN-6924 and plan to conduct additional trials of ALRN-6924 at one or more trial sites that are located outside the United States. The FDA's acceptance of data from clinical trials outside of the United States is subject to certain conditions. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practice. The FDA must be able to validate the data from the trial through an onsite inspection if necessary. The trial population must also have a similar profile to the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically occur in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. We do not yet know exactly how many patients will have the genetic profile that ALRN-6924 or other future product candidates are designed to address. In particular, because our clinical trials are targeted at a subset of patients in indications with p53-mutated cancers, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Due to the ongoing COVID-19 pandemic, the opening of trial sites and patient recruitment and enrollment in our clinical trials has been and may continue to be adversely affected, delayed or interrupted. Patients may choose to withdraw from our studies or we may choose to or be required to pause enrollment and or patient dosing in our ongoing clinical trials in order to preserve health resources and protect trial participants. It is unknown how long these pauses or disruptions could continue.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse or unacceptable side effects are identified during the development of our product candidates or we observe limited efficacy of our product candidates, we may need to abandon or limit the development of one or more of our product candidates.

Adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, any future collaborators, an institutional review board, or IRB, or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities or a more restrictive label, if approved.

In general, our clinical trials of ALRN-6924 include cancer patients who are very sick and whose health is deteriorating, and we expect that additional clinical trials of ALRN-6924 and any other product candidates that we may develop will include similar patients with deteriorating health. It is possible that some of these patients might die prior to their completion of our clinical trial. For example, in our Phase 1 trial of single agent ALRN-6924 for the treatment of AML and MDS a patient that was receiving a 3.8 mg/kg dose of ALRN-6924 under our three times per week dosing regimen died of tumor lysis syndrome related to treatment with ALRN-6924. Such deaths may be caused by the cancers from which such patients are suffering, or other causes, unrelated to ALRN-6924 or the other product candidates that may be the subject of the clinical trial. Even if the deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidate.

If ALRN-6924 is associated with adverse events or undesirable side effects or has properties that are unexpected such as the aforementioned death we observed in our Phase 1 trial of single agent ALRN-6924 for the treatment of AML and MDS, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. We, or any future collaborators, may abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, results of operations, financial condition and prospects significantly.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any new drug applications, or NDAs, that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for our product candidates, it may require that we conduct additional clinical, nonclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

The FDA or comparable foreign regulatory authorities may, under certain circumstances, require that a companion diagnostic be approved for use with ALRN-6924. If we are unable to successfully develop and obtain approval for such a diagnostic, either on our own or through a third party, or if we experience significant delays in doing so, we may not obtain marketing approval for ALRN-6924 in a timely manner, or at all.

We expect that the FDA will, under certain circumstances, require us to have a companion *in vitro* diagnostic approved for use with ALRN-6924 in order to identify patients with mutated p53. We expect that we will also be required to obtain similar approvals from comparable foreign regulatory authorities. We are in the process of evaluating third party supply of a commercially available diagnostic to identify patients' p53 status, which diagnostic would require approval by applicable regulatory authorities. We are currently evaluating the likelihood of such a requirement, given recent FDA actions, as well as the risks and benefits of each approach. We currently rely upon commercially available third-party assays and employ a central laboratory to test both archived tumor tissue samples and fresh biopsy samples from patients taken prior to enrollment in clinical trials of ALRN-6924 to identify p53 status. We do not have experience or capabilities in developing or commercializing companion diagnostics.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate marketing approval prior to commercialization. We or any third party upon which we decide to rely may encounter difficulties in developing and obtaining approval for a companion diagnostic for ALRN-6924, including issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. The process of complying with the requirements of the FDA and comparable foreign regulatory authorities to support marketing authorization of a companion diagnostic is costly, time-consuming and burdensome. Any delay or failure to develop or obtain marketing approval of the companion diagnostic could delay or prevent approval of ALRN-6924.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable drugs. For instance, we have conducted clinical trials of ALRN-6924 for the treatment of peripheral T-cell lymphoma, acute myeloid leukemia and advanced high-risk myelodysplastic syndrome, SCLC and MDM2-amplified advanced solid tumors in combination with palbociclib (Ibrance) and, in part, due to commercial developments, have ceased clinical development of ALRN-6924 for those indications. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may not be successful in our efforts to identify or discover additional potential product candidates.

One element of our strategy is to leverage our proprietary stabilized cell-permeating peptide platform to develop additional product candidates across oncology and other diseases with unmet medical need. We may not be successful in doing so. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and/or achieve market acceptance; and
- potential product candidates may not be effective in treating their targeted diseases.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, our business would be harmed.

If ALRN-6924 or any of our future product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any future collaborators, to market the drug could be compromised.

Clinical trials of our product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives marketing approval and we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the drug may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

Even if ALRN-6924 or any of our future product candidates receives marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If ALRN-6924 or any of our future product candidates receives marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well-established in the medical community, and doctors may not be willing to utilize chemoprotective agents in combination with effective anti-cancer therapies. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenues from sales of drugs and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;

- the prevalence and severity of any side effects;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale or marketing of pharmaceutical drugs. We are not currently a party to a strategic collaboration that provides us with access to a collaborator's resources in selling or marketing drugs. To achieve commercial success for any approved drug for which sales and marketing is not the responsibility of any strategic collaborator that we may have in the future, we must either develop a sales and marketing organization or outsource these functions to other third parties. In the future, we may choose to build a sales and marketing infrastructure to market or co-promote some of our product candidates if and when they are approved or enter into collaborations with respect to the sale and marketing of our product candidates.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any commercial launch of a product candidate. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our drugs on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive drug lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

If we enter into arrangements with third parties to perform sales and marketing services, our revenues from the sale of drugs or the profitability of these revenues to us are likely to be lower than if we were to market and sell any drugs that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drugs effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The pharmaceutical and biotechnology industries generally, and the cancer drug sector targeted at treating and reducing chemotherapy-induced toxicity specifically, are highly competitive and characterized by rapidly advancing technologies, evolving understanding of disease etiology and a strong emphasis on proprietary drugs. We face competition with respect to ALRN-6924, our product candidate, and will face competition with respect to any product candidates that we may seek to discover and develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies. There are a number of major pharmaceutical, specialty pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of cancer and for prevention of chemotherapy-induced toxicities. Potential competitors also include academic institutions and governmental agencies and public and private research institutions.

There are a large number of companies developing or marketing treatments for cancer and chemotherapy-induced toxicities, including the indications for which we may develop product candidates. Many of the companies that we compete or may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Small 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 that may be necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs 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. The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

The most common methods of treating patients with cancer are surgery, chemotherapy, radiation and drug therapy. There are a variety of available drug therapies marketed for cancer and chemotherapy-induced toxicities. In many cases, these drugs are administered in combination to enhance efficacy. Some of the currently-approved drug therapies are branded and subject to patent protection and may be established as the standard of care for the treatment of indications and toxicities for which we may choose to seek regulatory approvals. Many of these approved drugs are well-established therapies and are widely accepted by physicians, patients and third-party payors, and, even if our product candidate was to be approved, there can be no assurance that our drug would displace these therapies. In addition to currently marketed therapies, there are also a number of drugs in late-stage clinical development to treat cancer and chemotherapy-induced toxicity. These clinical-stage drug candidates may provide efficacy, safety, convenience and other benefits that are not provided by currently-marketed therapies. As a result, they may provide significant competition for ALRN-6924 any of our future product candidates for which we obtain regulatory approval.

We are aware of another company that is actively developing agents to reduce chemotherapy-induced toxicities, G1 Therapeutics, Inc. In addition, ALRN-6924 may compete with multiple approved drugs or drugs that may be approved in the future, such as plinabulin which is being developed by BeyondSpring Inc. for the treatment of chemotherapy-induced neutropenia in late-stage clinical trials in multiple tumor types.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our drugs that receive marketing approval, or such authorities do not grant our drugs appropriate periods of data or market exclusivity before approving generic versions of our drugs, the sales of our drugs could be adversely affected.

Once an NDA is approved, the drug covered thereby becomes a “reference-listed drug” in the FDA’s publication, “Approved Drug Products with Therapeutic Equivalence Evaluations.” Manufacturers may seek approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials demonstrating safety and efficacy. Rather, the applicant generally must show that its drug has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic drugs may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic drugs are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug is typically lost to the generic drug.

The FDA may not approve an ANDA for a generic drug until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent

exclusivity for a new drug containing a new chemical entity, or NCE. Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA and the FDA may not approve the application until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference-listed drug is either invalid or will not be infringed by the generic drug, in which case the applicant may submit its application four years following approval of the reference-listed drug. Manufacturers may seek to launch these generic drugs following the expiration of the marketing exclusivity period, even if we still have patent protection for our drug.

Competition that our drugs may face from generic versions of our drugs could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those drug candidates. Our future revenues, profitability and cash flows could also be materially and adversely affected and our ability to obtain a return on the investments we have made in those drug candidates may be substantially limited if our drugs, if and when approved, are not afforded the appropriate periods of non-patent exclusivity.

Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations, third-party coverage and reimbursement policies or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approval, pricing, coverage and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement and coverage for these products and related treatments will be available from government authorities, private health insurers and other organizations, and if reimbursement and coverage is available, the level of reimbursement and coverage. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the healthcare industry in the United States and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for medical products. We cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, we cannot be sure as to the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new products that we develop and for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any drugs that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any drugs that we may develop.

We currently hold clinical trial liability insurance coverage for up to \$5.0 million, but that coverage may not be adequate to cover any and all liabilities that we may incur. We would need to increase our insurance coverage when we begin the commercialization of our product candidates, if ever. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues from the sales of our products, if any.

In some countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we, or our future collaborators, may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials of ALRN-6924 and expect to continue to rely upon third parties to conduct additional clinical trials of ALRN-6924 and any other product candidates that we may develop. We currently rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical studies. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our drug development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practice, or GCP, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The European Medicines Agency, or EMA, also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurances that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. Furthermore, we conduct clinical trials in foreign countries, subjecting us to additional risks and challenges, including additional regulatory compliance. We also contract with foreign CROs that may be less experienced with respect to regulatory matters applicable to us. In addition, our clinical trials must be conducted with product produced under current Good Manufacturing Practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials

on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of such third parties could delay clinical development or marketing approval of our product candidates or commercialization of our drugs, producing additional losses and depriving us of potential revenue from sales of drugs.

We contract with third parties for the manufacture of ALRN-6924 for our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of ALRN-6924 for clinical trials under the guidance of members of our organization. To date, we have obtained the active pharmaceutical ingredient, or API, of ALRN-6924 from one third-party manufacturer. We have engaged a separate third-party manufacturer to conduct fill-and-finish and labeling services, as well as for the storage and distribution of ALRN-6924 to clinical sites. We do not have a long-term supply agreement with either of these third-party manufacturers, and we purchase our required drug supplies on a purchase order basis.

We expect to rely on third-party manufacturers or third-party collaborators for the manufacture of our product candidates for commercial supply of ALRN-6924 or any of our future product candidates for which we or any of our future collaborators obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible failure of the third party to manufacture our product candidate according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the possible termination or nonrenewal of agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the possible breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the possible failure of the third party to manufacture our product candidates according to our specifications;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have complete control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drugs and harm our business and results of operations.

Any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply of the API of ALRN-6924 and we only currently use a different single third-party manufacturer for fill-and-finish services for ALRN-6924. If our current contract manufacturers cannot perform as agreed, we may be required to replace those manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

We may enter into strategic collaborations for the development, marketing and commercialization of ALRN-6924. If those collaborations are not successful, the development, marketing and/or commercialization of our product candidates that are the subject of such collaborations would be harmed.

As we further develop ALRN-6924, we may build a commercial infrastructure with the capability to directly market it to a variety of markets and geographies. Although we currently plan to retain all commercial rights to ALRN-6924, we may enter into strategic collaborations for the development, marketing and commercialization of ALRN-6924 and any other product candidates that we may develop. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development, marketing and/or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development, marketing and/or commercialization of our product candidates or may elect not to continue or renew development, marketing or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or product candidates;
- a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to the marketing and distribution of such drug or drugs;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- we may lose certain valuable rights under circumstances identified in any collaboration arrangement that we enter into, such as if we undergo a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development, marketing and/or commercialization of the applicable product candidates;
- collaborators may learn about our discoveries, data, proprietary information, trade secrets or compounds and use this knowledge to compete with us in the future; and
- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all.

If we decide to seek to establish collaborations, but are not able to establish those collaborations, we may have to alter our development and commercialization plans.

Our development of ALRN-6924 and the potential commercialization of ALRN-6924 will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties.

We would face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

We may also be restricted under then-existing collaboration agreements from entering into future agreements on certain terms with potential collaborators.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all, if and when we seek to enter into collaborations. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue from sales of drugs.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, which include ALRN-6924 and others, their respective components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our pending and future patent applications may not result in issued patents that protect our technology or products, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies.

We currently in-license certain intellectual property from President and Fellows of Harvard College, or Harvard, and Dana-Farber Cancer Institute, or DFCl, and others. In the future we may in-license intellectual property from other licensors. We rely on certain of these licensors to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. These pharmaceutical compounds may be covered by intellectual property rights held by others. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors access to the same technologies licensed to us.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

During the course of business we have decided not to pursue certain products or processes and have terminated certain corresponding intellectual property license agreements or removed certain intellectual property from current license agreements, and we may do so again in the future. If it is later determined that our activities or product candidates infringe this intellectual property,

then we may be liable for damages, enhanced damages or subjected to an injunction, any of which could have a material adverse effect on our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the U.S. Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In March 2013, under the Leahy-Smith America Invents Act, or America Invents Act, the United States moved from a “first to invent” to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the “first-to-file” provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. We may become involved in opposition, interference, derivation, *inter partes* review or other proceedings challenging our patent rights or the patent rights of others, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the patent claims of our owned or in-licensed patents being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the pharmaceutical compounds used in our product candidates but that are not covered by the claims of our patents;
- the active pharmaceutical ingredients in our current product candidates will eventually become commercially available in generic drug products, and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;

- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope or may be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents or become hostile to us or the patents or patent applications on which they are named as inventors;
- we have engaged in scientific collaborations in the past, such as with Roche, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors or use such information to compete with us. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and this would have a material adverse effect on our business.

If any of our owned or in-licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. Our current owned and in-licensed patents covering our proprietary technologies and our product candidates are expected to expire on various dates from 2021 through 2033, including a composition of matter patent that we own covering our product candidate, ALRN-6924, which expires in the United States in 2033, without taking into account any possible patent term adjustments or extensions. Our earliest in-licensed patents were only filed in the United States and may expire before, or soon after, our first product achieves marketing approval in the United States. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We own or in-license pending patent applications covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2021 through 2037, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of these patent applications.

If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business.

We are a party to license agreements with Harvard, DFCI, Umicore Precious Metals Chemistry USA, LLC and others, pursuant to which we in-license key patent and patent applications for our product candidates. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

In early 2016, Harvard communicated a claim to us that we had not achieved one or more of the diligence milestones set forth in our license agreement with Harvard and DFCI and that we were in material breach of the license agreement. We provided Harvard with a response stating our position that we had fully satisfied the diligence milestones required under the license agreement. Since that time, Harvard has never re-asserted its claim or sought to terminate the license agreement. In making its assertion, Harvard did not seek to terminate the license agreement or interfere with our ongoing p53 program, but instead proposed to convert our exclusive license with

respect to certain of the patent families licensed under the license agreement to a non-exclusive license. In any event, Harvard's proposal would not have impeded our development of ALRN-6924 or our other ongoing programs. DFCI did not join Harvard in making this assertion or proposal and has not expressed a similar position to us. We have continued to communicate with Harvard in the ordinary course, including providing periodic reports, and have paid applicable licensing and milestone payments to Harvard pursuant to the terms of the license agreement, and we believe we remain in full compliance with the agreement.

We continue to monitor our compliance with our obligations under our license agreements on an ongoing basis. However, if in the future Harvard or DFCI were to successfully assert a material breach and if we were to lose some or all of our rights under the license agreement, our business would be adversely affected, and it may be difficult to commercialize ALRN-6924 until the applicable patents covered by the license agreement with Harvard and DFCI expired, unless we were able to negotiate a new license arrangement with those parties.

We may incur substantial costs as a result of litigation or other proceedings relating to patents, and we may be unable to protect our rights to our products and technology.

If we or our licensors choose to go to court to stop a third party from using the inventions claimed in our owned or in-licensed patents, that third party may ask the court to rule that the patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we or they, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the third party on the ground that such third party's activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court has recently changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria which could also make it more difficult to obtain patents.

We, or our licensors, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors, later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third party.

If another party questions the patentability of any of our claims in our owned or in-licensed U.S. patents, the third party can request that the USPTO review the patent claims such as in an *inter partes* review, *ex parte* re-exam or post-grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in the European Patent Office, or EPO, or similar proceedings in other foreign patent offices, where either our owned or in-licensed foreign patents are challenged. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

We may incur substantial costs as a result of litigation or other proceedings relating to intellectual property rights other than patents, and we may be unable to protect our rights to our products and technology.

We may rely on trade secrets and confidentiality agreements to protect our technology and know-how, especially where we do not believe patent protection is appropriate or obtainable. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful.

If we are sued for infringing patents or other intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications

filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us on or before March 15, 2013, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding initiated by such other party to determine priority of invention in the United States. If another party has filed such patent application after March 15, 2013, a derivation proceeding in the United States can be initiated by such other party to determine whether our, or in the case of in-licensed technology, the licensor's invention was derived from such party's invention. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

We may not be able to protect our intellectual property rights with patents throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technology in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Obtaining and maintaining our patent protection depends upon compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent prosecution process and following the issuance of a patent. Our failure to comply with such requirements could result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case if our patent were in force, which would have a material adverse effect on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

Risks Related to Marketing Approval and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us, or any future collaborators, from obtaining approvals for the commercialization of some of our product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of drugs are subject to extensive regulation by the FDA and comparable foreign regulatory authorities, whose laws and regulations may differ from country to country. We, and any future collaborators, are not permitted to market our product candidates in the United States or in other countries until we or they receive approval of an NDA from the FDA or marketing approval from comparable foreign regulatory authorities. Our product candidates are in early stages of development and are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for ALRN-6924 any of our future product candidates in the United States or in any other jurisdiction. We have limited experience in conducting and managing the clinical trials necessary to obtain marketing approvals, including FDA approval of an NDA.

The process of obtaining marketing approvals, both in the United States and abroad, is a lengthy, expensive and uncertain process. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities have substantial discretion and may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Our product candidates could fail to receive marketing approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain marketing approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve any companion diagnostics that may be required in connection with approval of our therapeutic product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain marketing approval to market ALRN-6924, which would significantly harm our business, results of operations and prospects.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted drug application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical studies, clinical trials or other studies and testing. In addition, varying interpretations of the data obtained from preclinical studies and clinical trials could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or any collaborators we may have in the future, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or that of any collaborators we may have to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we are granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions.

In order to market and sell our products in the European Union and many other foreign jurisdictions, we or our potential third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our potential third-party collaborators may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products candidates in any market.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the recent withdrawal of the United Kingdom from the European Union. The United Kingdom and the European Union, the United Kingdom withdrew from the European Union, effective December 31, 2020. On December 24, 2020, the United Kingdom and European Union entered into a Trade and Cooperation Agreement, which set out certain procedures for approval and recognition of medical products in each jurisdiction. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of the Trade and Cooperation Agreement, could prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for any product candidates, which could significantly and materially harm our business.

We, or any future collaborators, may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. We may also seek orphan drug designations for ALRN-6924 for other indications, or for other of our product candidates. There can be no assurances that we will be able to obtain such designations.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate as we have obtained for ALRN-6924 for AML, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition.

Even after an orphan drug is approved, the FDA can subsequently approve a different product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. The FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business.

Even if we, or any collaborators we may have in the future, obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our drugs could require substantial expenditure of resources and may limit how we, or they, manufacture and market our drugs, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved drug and its manufacturer and marketer are subject to ongoing review and extensive regulation. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. We, and any collaborators we may have in the future, must also comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the drug's approved labeling. Thus, we, and any collaborators we may have in the future, may not be able to promote any drugs we develop for indications or uses for which they are not approved.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a drug. For example, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a Risk Evaluation and Mitigation Strategy, which could include requirements for a restricted distribution system. Manufacturers of approved drugs and those manufacturers' facilities are also required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, our future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or our future collaborators, receive marketing approval for one or more of our product candidates, we, and our future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, and our future collaborators, are not able to comply with post-approval regulatory requirements, we, and our future collaborators, could have the marketing approvals for our drugs withdrawn by regulatory authorities and our, or our future collaborators', ability to market any future drugs could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current administration may impact our business and industry. Namely, the current administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications.

ALRN-6924 and any of our future product candidates for which we, or our future collaborators, obtain marketing approval in the future will be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our drugs following approval.

ALRN-6924 and any of our future product candidates for which we, or our future collaborators, obtain marketing approval in the future, will be subject to continual review by the FDA and other regulatory authorities.

The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or our future collaborators, do not market any of our product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our drugs or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- litigation involving patients taking our drug;
- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a drug;
- restrictions on drug distribution or use;

- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of drugs;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- restrictions on coverage by third-party payors;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of drugs;
- drug seizure; or
- injunctions or the imposition of civil or criminal penalties.

Recently enacted and future legislation may increase the difficulty and cost for us and our future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain for any products that are approved in the United States or foreign jurisdictions.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any product candidates for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we, or any future collaborators, may receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This legislation resulted in aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through 2030 under the CARES Act. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the TCJA, which was signed by President Trump on December 22, 2017, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019.

On November 10, 2020, the Supreme Court heard oral arguments to a case challenging the ACA. On February 10, 2021, the Biden Administration withdrew the federal government’s support for overturning the ACA. On June 17, 2021, the Supreme Court rejected this challenge to the ACA.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. This Executive Order also directs the U.S. Department of Health and Human Services to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic. We cannot predict how federal agencies will respond to such Executive Orders.

Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The costs of prescription pharmaceuticals in the United States and foreign jurisdictions is subject to considerable legislative and executive actions and could impact the prices we obtain for our drug products, if and when approved.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. To those ends, President Trump issued several executive orders intended to lower the costs of prescription drug products. Certain of these orders are reflected in recently promulgated regulations, including an interim final rule implementing President Trump's most favored nation model, but such final rule is currently subject to a nationwide preliminary injunction. The Biden Administration has frozen certain of the previous administration's measures to reform drug prices, pending further review. It remains to be seen how the Biden Administration will address this issue but, under Medicare Part D, the new administration may seek to establish a ceiling for the launch prices of all branded, biologic, and certain generic drugs by referencing the average price of these drugs in other developed countries. At the same time, the administration may seek to limit Medicare Part D and public option drug prices through a tax penalty on manufacturers for increases in the cost of drugs and biologics above the general inflation rate. The American Rescue Plan Act of 2021, comprehensive COVID-19 relief legislation recently enacted under the Biden administration, includes a number of healthcare-related provisions, such as support to rural health care providers, increased tax subsidies for health insurance purchased through insurance exchange marketplaces, financial incentives to states to expand Medicaid programs and elimination of the Medicaid drug rebate cap effective in 2024.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

We may seek to obtain certain regulatory designations for ALRN-6924. We may not receive such designations, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek to obtain breakthrough therapy designation, fast track designation, or priority review designation for ALRN-6924. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. FDA fast track designation is possible for drugs intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition. In addition, if the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA.

Such regulatory designations are within the discretion of the FDA, and the FDA may not approve any application that we submit. Even if we were to obtain breakthrough designation or fast track designation, the FDA may subsequently withdraw such designation if the FDA determines that the designation no longer meets the conditions for qualification or is no longer supported by data from our clinical development program. In addition, receipt of any such designations may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures, and does not assure ultimate approval by the FDA of any drug candidates so designated.

Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Our relationships with healthcare providers, physicians and third-party payors will subject us to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Our future arrangements with healthcare providers, physicians and third-party payors and patients may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- *Anti-Kickback Statute*—the federal anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing any remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good, facility, item or service, for which payment may be made, in whole or in part, by a federal healthcare program, such as Medicare and Medicaid.
- *False Claims Act*—the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- *HIPAA*—the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- *HIPAA Privacy Provisions*—as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information
- *Transparency Requirements*—the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- *Analogous State and Foreign Laws*—analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to sales or marketing arrangements and claims involving healthcare items or services and are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management’s attention from the operation of our business, even if our defense is successful. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be costly to us in terms of money, time and resources, and they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The Securities and Exchange Commission, or SEC, is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or €20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act, which went into effect on January 1, 2020, is creating similar risks and obligations as those created by the GDPR, though the California Consumer Privacy Act does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and

increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our Chief Executive Officer and other key executives, and to attract, retain and motivate qualified personnel.

We are highly dependent on Manuel Aivado, M.D., Ph.D., our Chief Executive Officer, as well as the other principal members of our management and scientific teams. Our agreements with Dr. Aivado and other key employees do not prevent them from terminating their employment with us at any time. Replacing our executives or other key employees may be extremely difficult, and may take an extended period of time due to the intense competition for qualified personnel in our industry and the limited number of individuals who have the breadth of skills and experience required to develop, gain regulatory approval of, and commercialize products successfully. We do not maintain “key person” insurance for any of our executives or other employees. Accordingly, the loss of the services of Dr. Aivado or any other senior member of our management and scientific teams could impede the achievement of our research, development and commercialization objectives, and harm our business.

Recruiting and retaining qualified personnel in the scientific and clinical fields is also critical to our success. The pool of qualified candidates is limited, and competition in the life sciences industry, particularly in the Greater Boston area, is intense. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. We may be unable to hire, train, retain or motivate additional key personnel on acceptable terms given the degree of competition for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our development and regulatory capabilities and potentially our sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

In order to conduct later stage clinical trials and prepare for commercialization, we would need to expand our organization significantly through the hiring of a number of additional employees, particularly in the areas of drug development, clinical operations, regulatory affairs and, potentially, sales and marketing. To manage this future growth, we must continue to implement and improve our managerial, operational and financial systems, periodically assess the adequacy of our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our leadership team in managing a company’s growth, we may not be able to effectively manage an expansion of our operations or recruit and train additional qualified personnel. In addition, a physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs or overall business operations.

Despite our security measures, our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed or halted. In addition, we may not have adequate insurance coverage to provide compensation for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in our information systems and networks, including personal information of our employees. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our employees or employees of our vendors to disclose sensitive information to gain access to our data. Like other companies, we may experience threats to our data and systems, including malicious codes and viruses, and other cyber-attacks. The number and complexity of these

threats continue to increase over time. If a material breach of our security or that of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed, we could lose business and our reputation and credibility could be damaged. We could also be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

Risks Related to Our Common Stock

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for shares of common stock. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on The Nasdaq Global Market June 29, 2017 and transferred to The Nasdaq Capital Market, effective December 30, 2019. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of stockholders to sell their shares. An inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If few analysts commence, or if analysts discontinue, coverage of us, the trading price of our stock would likely decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

The price of our common stock is volatile and may fluctuate substantially, which could result in substantial losses for our stockholders.

Our stock price is volatile. During the period from June 28, 2017 to November 9, 2021, the closing price of our common stock ranged from a high of \$14.91 per share to a low of \$0.29 per share. The stock market in general and the market for pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their shares at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including:

- the timing and results of clinical trials of ALRN-6924 and any of our other product candidates that may develop;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- the effect of the COVID-19 pandemic on both the healthcare system and the patient population;
- the success of existing or new competitive products or technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- establishment or termination of collaborations for our product candidates or development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to ALRN-6924 or development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

We are an "emerging growth company," and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an emerging growth company until December 31, 2022, or until such earlier time as we have more than \$1.07 billion in annual revenue, the market value of our stock held by non-affiliates is more than \$700 million or we issue more than \$1 billion of non-convertible debt over a three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, not being required to comply with any requirement that may be adopted by the Public

Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than \$250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than \$100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than \$700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404 and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We have elected to take advantage of certain of the reduced reporting obligations. Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Our management is required to devote substantial time to new compliance initiatives. Any failure to maintain effective internal control over our financial reporting could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

As a public company, we incur, and particularly after we are no longer an "emerging growth company" or a "smaller reporting company" we will incur, significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have had to hire additional accounting, finance, and other personnel in connection with our becoming a public company, and our efforts to comply with the requirements of being a public company, and our management and other personnel devote a substantial amount of time towards maintaining compliance with these requirements. These requirements increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

In addition, Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls. To maintain compliance with Section 404, we are required to document and evaluate our internal control over financial reporting, which is both costly and challenging. We will need to continue to dedicate internal resources, continue to engage outside consultants, and follow a detailed work plan to continue to assess and document the adequacy of internal control over financial reporting, continue to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. There is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted the TCJA, which significantly reformed the U.S. Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits.

As part of Congress' response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted on March 27, 2020 and COVID-19 relief provisions were included in the Consolidated Appropriations Act, 2021, or CAA, which was enacted on December 27, 2020. All contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of net operating losses, which was enacted as part of the TCJA. It also provides that net operating losses arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30 to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act, the CARES Act and the CAA is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. It is also likely that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act, the CARES Act and the CAA.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2020, we had federal net operating loss carryforwards of \$203.5 million, of which \$129.6 million will, if not utilized, begin to expire in 2029. As of December 31, 2020, we had state net operating carryforwards of \$197.7 million, which will, if not utilized, begin to expire in 2030. Our federal and state research and development tax credit carryforwards of \$2.6 million and \$1.8 million, respectively, will, if not utilized, begin to expire in 2025. We also have federal orphan drug tax credit carryforwards of \$1.0 million which begin to expire in 2039. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities.

We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future; thus, we do not know whether or when we will generate taxable income necessary to utilize our net operating losses or research and development tax credit carryforwards.

In addition, under Section 382 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not conducted a study to assess whether we have experienced Section 382 ownership changes in the past and if a portion of our net operating loss and tax credit carryforwards are subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If we determine that an ownership change has occurred at any time since our inception and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

There is also a risk that due to regulatory changes, such as suspensions on the use of net operating losses, or other unforeseen reasons, our existing net operating losses could expire or otherwise become unavailable to offset future income tax liabilities. In addition, state net operating losses generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our net operating losses and other tax attributes.

Because we do not anticipate paying any cash dividends on our capital stock for the foreseeable future, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

A significant portion of our total outstanding shares may be sold into the market at any time, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of November 9, 2021, we had 90,573,597 shares of common stock outstanding.

We have filed several registration statements covering the resale of shares of our common stock held by several stockholders. In connection with our April 2019 private placement, we filed a registration statement covering the resale of shares purchased by the purchasers in the private placement and shares issuable upon exercise of warrants issued in the private placement. In August 2020 and February 2021, we filed registration statements on Form S-3 covering the resale of an aggregate of 12,700,000 shares of our common stock held by Satter Medical Technology Partners, L.P., or SMTP, and entities affiliated with SMTP. Dr. Nolan Sigal, a partner at Satter Management Co., L.P., an affiliate of SMTP, is a member of our board of directors.

On September 21, 2020, we entered into the Purchase Agreement with LPC pursuant to which LPC has committed to purchase up to \$15.0 million of shares of our common stock. We filed a registration statement on Form S-1 covering the sale of shares of common stock that are issued to LPC under the Purchase Agreement, which was declared effective on October 15, 2020. We generally have the right to control the timing and amount of any future sales of shares of our common stock to LPC. Sales of shares of our common stock, if any, to LPC will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to LPC all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. Therefore, sales to LPC by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to LPC, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. If and when we do sell shares of our common stock to LPC, after LPC has acquired the shares of common stock, LPC may resell all, some or none of those shares of common stock at any time or in its discretion.

We have also registered all shares of common stock that we may issue under our equity compensation plans, including upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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

On July 12, 2019, we received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on the Nasdaq Global Market, or the Bid Price Rule. On December 20, 2019, we applied to transfer the listing of our stock from the Nasdaq Global Market to the Nasdaq Capital Market. The Nasdaq Capital Market is a continuous trading market that operates in substantially the same manner as the Nasdaq Global Market and listed companies must meet certain financial requirements and comply with Nasdaq's corporate governance requirements.

On December 27, 2019, Nasdaq approved our transfer application. This transfer became effective at the opening of business on December 30, 2019. On June 11, 2020, after our common stock had a closing bid price of at least \$1.00 per share for 10 consecutive trading days, Nasdaq provided written notification to us that we had regained compliance with the Bid Price Rule. We have remained in compliance with the Bid Price Rule since June 2020. However, there can be no assurance that we will continue to maintain compliance with the Bid Price Rule in the future.

Our certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors, officers and employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws, or any action asserting a claim against us governed by the internal affairs doctrine. We do not expect this choice of forum provision will apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act of 1934, as amended, or any other claim for which federal courts have exclusive jurisdiction. This exclusive forum provision may limit the ability

of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees.

Item 6. Exhibits.

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

Exhibit Number	Description
31.1	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1	<u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2	<u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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

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

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

Aileron Therapeutics, Inc.

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

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

Dated: November 12, 2021

**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, Richard J. Wanstall certify that:

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

Aileron Therapeutics, Inc.

/s/ Richard J. Wanstall

Richard J. Wanstall

Chief Financial Officer and Treasurer

Dated: November 12, 2021

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

In connection with the Quarterly Report on Form 10-Q of Aileron Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Manuel C. Alves Aivado, M.D., Ph.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that to his knowledge:

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

Dated: November 12, 2021

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

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

President and Chief Executive Officer

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

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

In connection with the Quarterly Report on Form 10-Q of Aileron Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard J. Wanstall, Chief Financial Officer and Treasurer of the Company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that to his knowledge:

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

Dated: November 12, 2021

/s/ Richard J. Wanstall

Richard J. Wanstall
Chief Financial Officer and Treasurer

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