UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from___ to
Commission File Number: 001-40315

ONKURE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-2309515**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
6707 Winchester Circle, Suite 400 **Boulder, Colorado** **(Address of Principal Executive Offices)**	**80301** **(Zip Code)**

(Registrant's telephone number, including area code): (720) 307-2892

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

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Class A Common Stock, par value $0.0001 per share	**OKUR**	**The Nasdaq Stock Market LLC**

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

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

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

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

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

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

As of November 4, 2024, the registrant had 12,652,890 shares of Class A common stock, $0.0001 par value per share, and 686,527 shares of Class B common stock, $0.0001 par value per share, outstanding.

Explanatory Note

On October 4, 2024 (the Closing Date), the Delaware corporation formerly known as "Reneo Pharmaceuticals, Inc." (Reneo) completed its previously announced merger transaction pursuant to the terms of the Agreement and Plan of Merger, dated as of May 10, 2024 (the Merger Agreement), by and among Reneo, Radiate Merger Sub I, Inc., a Delaware corporation and a direct, wholly-owned subsidiary of Reneo (Merger Sub I), Radiate Merger Sub II, LLC, a Delaware limited liability company and a direct, wholly-owned subsidiary of Reneo (Merger Sub II), and OnKure, Inc., a Delaware corporation (Legacy OnKure).

Pursuant to the Merger Agreement, on the Closing Date, (i) Reneo effected a reverse stock split of Reneo's issued common stock at a ratio of 1:10 (the Reverse Stock Split), (ii) Reneo changed its name to "OnKure Therapeutics, Inc.", (iii) Reneo reclassified all of its common stock as Class A Common Stock, and (iv) Merger Sub I merged with and into Legacy OnKure (the Merger), with Legacy OnKure as the surviving company in the Merger and, after giving effect to such Merger, Legacy OnKure became a wholly-owned subsidiary of OnKure Therapeutics, Inc. (together, the Combined Company). Pursuant to the terms of the Merger Agreement, OnKure determined that the Merger would qualify for the intended tax treatment even if only the merger with Merger Sub I was consummated, and therefore the parties determined not to consummate the second merger with Merger Sub II contemplated by the Merger Agreement.

Because the Merger was completed after the period covered by the financial statements included in this Quarterly Report on Form 10-Q, this Quarterly Report on Form 10-Q includes historical financial information, including as of and for the nine months ended September 30, 2024, of Reneo, unless otherwise indicated or as the context otherwise requires. In addition, except where otherwise indicated, the information in this Quarterly Report on Form 10-Q as of and for the periods prior to the effective time of the Merger gives effect to the Reverse Stock Split.

Unless the context otherwise requires, "OnKure," "we," "us," "our," and the "Company" refer to the Combined Company. All references herein to the "Board" refer to the board of directors of the Combined Company.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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 future results of operations and financial position, business strategy, development plans, planned preclinical studies and clinical trials, future results of clinical trials, expected research and development costs, regulatory strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our future results of operations and financial position;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our current and future product candidates, subject to regulatory approvals;
- our cash runway and our ability to extend our operating capital;
- the initiation, timing, progress and results of our preclinical and clinical activities, including the suspension of development activity for mavodelpar;
- the potential of our technologies and our ability to execute on our corporate strategy;
- our ability to obtain and adequately protect intellectual property rights for our product candidates;
- our ability to obtain regulatory approval for our product candidates and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- existing regulations and regulatory developments in the United States and other jurisdictions; and
- our ability to realize some or all of the anticipated benefits of the Merger.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

In addition, statements such as "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

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Part I. Financial Information

ONKURE THERAPEUTICS, INC.

(Formerly Reneo Pharmaceuticals, Inc.)
Consolidated Balance Sheets
(In thousands, except share and par value data)

	September 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 60,689	$ 27,632
Short-term investments	15,979	75,331
Prepaid expenses and other current assets	331	3,659
Total current assets	76,999	106,622
Property and equipment, net	59	134
Right-of-use assets	440	599
Other non-current assets	147	81
Total assets	$ 77,645	$ 107,436
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 237	$ 8,717
Accrued expenses	725	9,129
Private placement deposit	2,000	—
Operating lease liabilities, current portion	286	331
Total current liabilities	3,248	18,177
Operating lease liabilities, less current portion	379	642
Performance award	—	7
Total liabilities	3,627	18,826
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized at September 30, 2024 and December 31, 2023; 3,343,525 shares issued and outstanding at September 30, 2024 and 3,342,034 shares issued and outstanding at December 31, 2023, respectively	—	—
Additional paid-in capital	309,969	307,076
Accumulated deficit	(235,953)	(218,474)
Accumulated other comprehensive income	2	8
Total stockholders' equity	74,018	88,610
Total liabilities and stockholders' equity	$ 77,645	$ 107,436

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

ONKURE THERAPEUTICS, INC.
(Formerly Reneo Pharmaceuticals, Inc.)

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 904	$ 13,622	$ 6,436	$ 39,009
General and administrative	3,760	7,266	14,155	19,038
Total operating expenses	4,664	20,888	20,591	58,047
Loss from operations	(4,664)	(20,888)	(20,591)	(58,047)
Other income	972	1,692	3,112	4,213
Net loss	(3,692)	(19,196)	(17,479)	(53,834)
Unrealized gain (loss) on short-term investments	15	10	(6)	22
Comprehensive loss	$ (3,677)	$ (19,186)	$ (17,485)	$ (53,812)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.10)	$ (5.68)	$ (5.23)	$ (18.11)
Weighted-average shares used in computing net loss per share, basic and diluted	3,342,824	3,380,794	3,343,287	2,971,868

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

ONKURE THERAPEUTICS, INC.
(Formerly Reneo Pharmaceuticals, Inc.)

Consolidated Statements of Changes in Stockholders' Equity
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances, December 31, 2023	**3,342,034**	**$ —**	**$ 307,076**	**$ 8**	**$ (218,474)**	**$ 88,610**
Stock-based compensation	—	—	1,078	—	—	1,078
Other comprehensive loss	—	—	—	(20)	—	(20)
Net loss	—	—	—	—	(8,426)	(8,426)
Balances, March 31, 2024	**3,342,034**	**$ —**	**$ 308,154**	**$ (12)**	**$ (226,900)**	**$ 81,242**
Stock-based compensation	—	—	989	—	—	989
Other comprehensive loss	—	—	—	(1)		(1)
Net loss	—	—	—	—	(5,361)	(5,361)
Balances, June 30, 2024	**3,342,034**	**$ —**	**$ 309,143**	**$ (13)**	**$ (232,261)**	**$ 76,869**
Stock-based compensation	—	—	826	—	—	826
Issuance of common stock in connection with equity plans	1,491	—	—	—	—	—
Other comprehensive income	—	—	—	15	—	15
Net loss	—	—	—	—	(3,692)	(3,692)
Balances, September 30, 2024	**3,343,525**	**$ —**	**$ 309,969**	**$ 2**	**$ (235,953)**	**$ 74,018**

ONKURE THERAPEUTICS, INC.
(Formerly Reneo Pharmaceuticals, Inc.)

Consolidated Statements of Changes in Stockholders' Equity
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances, December 31, 2022	**2,469,955**	**$ —**	**$ 236,696**	**$ (43)**	**$ (136,683)**	**$ 99,970**
Stock-based compensation	—	—	1,157	—	—	1,157
Issuance of common stock in connection with at-the-market facility, net of issuance costs	40,787	—	1,009	—	—	1,009
Other comprehensive income	—	—	—	55	—	55
Net loss	—	—	—	—	(15,107)	(15,107)
Balances, March 31, 2023	**2,510,742**	**$ —**	**$ 238,862**	**$ 12**	**$ (151,790)**	**$ 87,084**
Issuance of common stock in public offering, net of offering costs	790,625	—	58,862	—	—	58,862
Issuance of common stock in private placement, net of offering costs	62,500	—	4,667	—	—	4,667
Stock-based compensation	—	—	1,207	—	—	1,207
Issuance of common stock in connection with equity plans	16,210	—	282	—	—	282
Other comprehensive loss	—	—	—	(43)	—	(43)
Net loss	—	—	—	—	(19,531)	(19,531)
Balances, June 30, 2023	**3,380,077**	**$ —**	**$ 303,880**	**$ (31)**	**$ (171,321)**	**$ 132,528**
Stock-based compensation	—	—	1,429	—	—	1,429
Issuance of common stock in connection with equity plans	7,137	—	173	—	—	173
Other comprehensive income	—	—	—	10	—	10
Net loss	—	—	—	—	(19,196)	(19,196)
Balances, September 30, 2023	**3,387,214**	**$ —**	**$ 305,482**	**$ (21)**	**$ (190,517)**	**$ 114,944**

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

ONKURE THERAPEUTICS, INC.
(Formerly Reneo Pharmaceuticals, Inc.)

Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (17,479)	$ (53,834)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,893	3,793
Depreciation and amortization	40	126
Amortization/accretion on short-term investments	(1,904)	(3,551)
Changes in the fair value of performance award	(7)	1,040
Non-cash lease expense	128	354
Loss on disposal of fixed asset	37	5
Changes in operating assets and liabilities:		
Prepaid and other assets	3,351	2,025
Accounts payable and accrued expenses	(16,884)	6,507
Operating lease liabilities	(277)	(394)
Net cash used in operating activities	(30,102)	(43,929)
Cash flows from investing activities		
Purchases of property and equipment	(2)	(196)
Purchase of available-for-sale short-term investments	(67,750)	(190,058)
Proceeds from maturities of available-for-sale short-term investments	129,000	161,000
Net cash provided by (used in) investing activities	61,248	(29,254)
Cash flows from financing activities		
Private placement deposit in advance of the closing	2,000	—
Payments of deferred costs in connection with private placement transaction	(89)	—
Proceeds from public offering of common stock, net of offering costs	—	58,862
Proceeds from private placement of common stock, net of offering costs	—	4,667
Proceeds from issuance of common stock under the at-the-market facility, net of offering costs	—	1,009
Proceeds from issuance of common stock in connection with equity plans	—	455
Net cash provided by financing activities	1,911	64,993
Net increase (decrease) in cash and cash equivalents	33,057	(8,190)
Cash and cash equivalents, beginning of period	27,632	19,927
Cash and cash equivalents, end of period	$ 60,689	$ 11,737
Noncash investing and financing activities:		
Property and equipment in accounts payable	$ —	$ 11

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

ONKURE THERAPEUTICS, INC.
(Formerly Reneo Pharmaceuticals, Inc.)

Notes to Consolidated Financial Statements
(Unaudited)

1. Organization and Business

On October 4, 2024 (the Closing Date), Reneo Pharmaceuticals, Inc., a Delaware corporation and our predecessor company (Reneo), consummated the previously announced merger pursuant to the terms of the Agreement and Plan of Merger, dated as of May 10, 2024 (the Merger Agreement), by and among Reneo, Radiate Merger Sub I, Inc., a Delaware corporation and a direct, wholly-owned subsidiary of Reneo (Merger Sub I), Radiate Merger Sub II, LLC, a Delaware limited liability company and a direct, wholly-owned subsidiary of Reneo (Merger Sub II), and OnKure, Inc., a Delaware corporation (Legacy OnKure). Pursuant to the Merger Agreement, on the Closing Date, (i) Reneo effected a reverse stock split of Reneo's issued common stock at a ratio of 1:10 (the Reverse Stock Split), (ii) Reneo changed its name to "OnKure Therapeutics, Inc.", (iii) Reneo reclassified all of its common stock as Class A Common Stock, and (iv) Merger Sub I merged with and into Legacy OnKure (the Merger), with Legacy OnKure as the surviving company in the Merger and, after giving effect to such Merger, Legacy OnKure became a wholly-owned subsidiary of OnKure Therapeutics, Inc. (together, the Combined Company). Pursuant to the terms of the Merger Agreement, OnKure determined that the Merger would qualify for the intended tax treatment even if only the merger with Merger Sub I was consummated, and therefore the parties determined not to consummate the second merger with Merger Sub II contemplated by the Merger Agreement.

Concurrently with the closing of the Merger, Reneo completed a private placement with certain investors (the PIPE Investors) to purchase 2,839,005 shares of Class A Common Stock at a price per share of approximately $22.895 per share for an aggregate purchase price of approximately $65.0 million, including the conversion of outstanding convertible notes and accrued but unpaid interest thereon held by certain Legacy OnKure investors (the Concurrent PIPE Investments). As of September 30, 2024, the Company recorded $2 million in liabilities as a result of cash received from investors prior to closing of the PIPE. In connection with the Concurrent PIPE Investments, Reneo entered into a registration rights agreement with the PIPE Investors, pursuant to which Reneo agreed to use commercially reasonable efforts to prepare and file a registration statement with the SEC within 45 calendar days after the Closing Date, registering the resale of the shares of Class A Common Stock issued pursuant to the Concurrent PIPE Investments. Immediately after the effective time of the Merger, following the consummation of the Concurrent PIPE Investments, Legacy OnKure stockholders owned approximately 53.6%, pre-Merger Reneo stockholders owned approximately 25.1%, and the PIPE Investors owned approximately 21.3% of the Combined Company's outstanding common stock.

As of the open of trading on October 7, 2024, the Class A Common Stock of the Combined Company began trading on the Nasdaq Global Market (Nasdaq) under the symbol "OKUR."

OnKure Therapeutics, Inc. (OnKure or the Company) is a clinical-stage biopharmaceutical company focused on the discovery and development of precision medicines designed to target biologically validated drivers of cancers underserved by available therapies. Using a structure- and computational chemistry-driven drug design platform, the Company is committed to improving clinical outcomes for patients by building a robust pipeline of small molecule drugs designed to selectively target specific mutations thought to be key drivers of cancer. The Company's lead product candidate, OKI-219, is a highly selective inhibitor of 3 kinase alpha (PI3Kα), a key mediator in cancer growth signaling, harboring the H1047R mutation (PI3KαH1047R) that has a much smaller impact on non-mutated (or wild-type) PI3Kα (PI3KαWT). OKI-219 is currently in a first-in-human Phase 1 monotherapy dose-escalation trial in H1074R-mutated advanced solid tumors including breast cancer. Early clinical data are anticipated in the fourth quarter of 2024. In addition to OKI-219, the Company is also pursuing programs designed to selectively target the other specific mutations of PI3Kα.

The unaudited interim financial statements included in this Quarterly Report on Form 10-Q are representative of Reneo's operations prior to the closing of the Merger, the adoption of OnKure's business plan and the commencement of conducting OnKure's business. Unless the context otherwise requires, references to

the “Company” or “OnKure” refer to OnKure Therapeutics, Inc. and its subsidiaries after completion of the Merger. In addition, references to “Reneo” refer to the Company prior to the completion of the Merger.

Liquidity

From its inception in 2014, Reneo incurred significant losses and negative cash flows from operations and expects to continue to incur net losses into the foreseeable future and may never become profitable. As of September 30, 2024, Reneo had cash, cash equivalents and short-term investments of $76.7 million.

Following the completion of the Merger, as described in more detail in Note 10, management believes the Company’s cash, cash equivalents and short-term investments will be sufficient to fund OnKure’s current operating plan for at least the next 12 months from the date of issuance of these unaudited condensed financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

Reneo has prepared the accompanying unaudited consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and note disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) have been condensed or omitted, although Reneo believes that the disclosures made are adequate to make the information not misleading. Reneo recommends that the unaudited consolidated financial statements be read in conjunction with the audited consolidated financial statements and the notes thereto included in Reneo’s Annual Report on Form 10-K for the year ended December 31, 2023.

In the opinion of management, all adjustments, including normal recurring adjustments, considered necessary for a fair statement of the financial statements, have been included in the accompanying unaudited financial statements. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

The accompanying unaudited consolidated financial statements include the accounts of Reneo and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Concurrently with the closing of the Merger on October 4, 2024, as described in more detail in Note 10, Subsequent Events, Reneo effected the Reverse Stock Split. All share and per share amounts, excluding the number of authorized shares and par value, (which were unchanged as a result of the Reverse Stock Split), contained in these financial statements and accompanying notes, and this Quarterly Report on Form 10-Q give retroactive effect to the Reverse Stock Split.

Summary of Significant Accounting Policies

The significant accounting policies used in the preparation of these consolidated financial statements for the nine months ended September 30, 2024 are consistent with those discussed in Note 2 to the consolidated financial statements in Reneo’s Annual Report on Form 10-K for the year ended December 31, 2023.

New Accounting Pronouncements

There were various accounting standards and interpretations issued recently, none of which are expected to have a material impact on Reneo’s financial position, operations or cash flows.

3. Net Loss Per Share

Reneo computes basic loss per share by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share assumes the conversion, exercise or issuance of all potential common stock

equivalents, unless the effect of inclusion would be anti-dilutive. For purposes of this calculation, common stock shares to be issued upon exercise of all outstanding stock options and vesting of restricted stock units were excluded from the diluted net loss per share calculation for the three and nine months ended September 30, 2024 and 2023 because such shares are anti-dilutive.

Historical outstanding anti-dilutive securities not included in the diluted net loss per share calculation include the following:

	As of September 30,	
	2024	**2023**
Common stock options outstanding	467,129	609,580
Unvested restricted stock units	29,658	44,150
Total	496,787	653,730

4. Fair Value Measurements

ASC Topic 820, *Fair Value Measurement*, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and Reneo's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of Reneo. Unobservable inputs are inputs that reflect Reneo's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

ASC Topic 820 identifies fair value as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC Topic 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

- Level 1 – Observable inputs such as quoted prices in active markets for identical assets or liabilities.
- Level 2 – Inputs, other than quoted prices in active markets, which are observable for the asset or liability, either directly or indirectly.
- Level 3 – Unobservable inputs in which there is little or no market data, which requires Reneo to develop its own assumptions.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Reneo's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. Reneo's financial assets are subject to fair value measurements on a recurring basis.

Reneo categorizes its money market funds as Level 1, using the quoted prices in active markets. Commercial paper and U.S. treasury securities are categorized as Level 2, using significant other observable inputs. The fair value of Reneo's investments in certain money market funds is their face value and such instruments are classified as Level 1 and are included in cash and cash equivalents on the consolidated balance sheets.

In connection with Reneo's chief executive officer's (CEO) employment agreement, he was entitled to receive a special performance bonus in the amount of $7.5 million (Performance Award), payable in cash, common stock or a combination of cash and common stock, at the election of Reneo, based on achievement of certain conditions as described in more detail in Note 8. Reneo estimated the fair value of the Performance Award using a Monte Carlo simulation, which incorporates the stock price at the date of the valuation and utilizes Level 3 inputs such as volatility, probabilities of success, and other inputs that are not observable in active markets. The Performance Award is required to be measured at fair value on a recurring basis each reporting period, with changes in the fair value recognized in general and administrative expense in the consolidated statements of operations and comprehensive loss over the derived service period of the award.

No assets or liabilities were transferred into or out of their classifications during the nine months ended September 30, 2024.

The recurring fair value measurement of the Company's assets and liabilities measured at fair value at September 30, 2024 consisted of the following (in thousands):

	Quoted Prices in Active Markets For Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Cash and cash equivalents:				
Money market investments	$ 57,629	$ —	$ —	$ 57,629
Short-term investments:				
U.S. treasury securities	—	15,979	—	15,979
Total	$ 57,629	$ 15,979	$ —	$ 73,608

The recurring fair value measurement of Reneo's assets and liabilities measured at fair value at December 31, 2023 consisted of the following (in thousands):

	Quoted Prices in Active Markets For Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Cash and cash equivalents:				
Money market investments	$ 10,983	$ —	$ —	$ 10,983
U.S. treasury securities	—	9,928	—	9,928
Short-term investments:				
U.S. treasury securities	—	75,331	—	75,331
Total	$ 10,983	$ 85,259	$ —	$ 96,242
Liabilities				
Performance award	$ —	$ —	$ 7	$ 7
Total	$ —	$ —	$ 7	$ 7

The following table sets forth a summary of changes in the fair value measurements of the Performance Award liability (in thousands):

	Performance Award
Balance as of January 1, 2024	$ 7
Change in fair value	(7)
Balance as of September 30, 2024	$ 0

5. Marketable Debt Securities

Reneo's investments in debt securities are carried at fair value and classified as current assets available-for-sale and represent the investment of funds available for current operations. Accretion of bond discount and interest income on marketable securities is included in other income as a separate component of other income (expense) on the statement of operations and comprehensive loss. Unrealized gains and losses on

available-for-sale debt securities are included in other comprehensive income or loss, and charged to income or expense in the period when realized. The following tables summarize the gross unrealized gains and losses of Reneo's available-for-sale securities (in thousands):

	As of September 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale securities:				
U.S. treasury securities	$ 15,976	$ 2	$ —	$ 15,978
Total	$ 15,976	$ 2	$ —	$ 15,978

	As of December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Available-for-sale securities:				
U.S. treasury securities	$ 75,324	$ 8	$ (1)	$ 75,331
Total	$ 75,324	$ 8	$ (1)	$ 75,331

As of September 30, 2024, Reneo considered the unrealized losses in its investment portfolio to be temporary in nature and not due to credit losses. Reneo has the intent and ability to hold such investments until their recovery at fair value. Reneo did not have any realized gains or losses in its available for sale securities during the three and nine months ended September 30, 2024 and 2023.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of September 30, 2024	As of December 31, 2023
Accrued clinical and regulatory	$ —	$ 3,661
Accrued contract manufacturing cost	—	1,100
Accrued compensation	361	3,948
Accrued other	364	420
Total accrued expenses	$ 725	$ 9,129

7. Leases

Prior to the closing of the Merger on October 4, 2024, Reneo's headquarters was located in Irvine, California, where it leases office space under a lease agreement that expires in November 2026. Reneo leases additional office space located in Sandwich, United Kingdom under a lease agreement that expires in October 2027, with an option to early terminate in October 2025 with no termination fee. In January 2024, Reneo exercised its early termination option and made the final termination lease payment of $0.2 million in July 2024.

Other information related to Reneo's operating leases as of the balance sheet dates presented are as follows:

	As of September 30,	
	2024	2023
Weighted incremental borrowing rate	5%	5%
Weighted average remaining lease term (in years)	2.1	3.8
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	$ 291	$ 397
Lease expense (in thousands)	$ 214	$ 338

Maturities of lease liabilities by fiscal year for Reneo's operating leases are as follows (in thousands):

	As of September 30, 2024
2024 (remaining three months)	$ 98
2025	371
2026	285
Total lease payments	754
Less: Imputed interest	(89)
Present value of lease liabilities	$ 665

8. Stock-Based Compensation

In March 2021, Reneo's Board of Directors adopted Reneo's 2021 Equity Incentive Plan (2021 Plan), which is the successor to Reneo's 2014 Equity Incentive Plan (2014 Plan). As of the effective date of the 2021 Plan, awards granted under the 2014 Plan that are forfeited or otherwise become available under the 2014 Plan will be included and available for issuance under the 2021 Plan. Under the 2021 Plan, Reneo may grant stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other awards to individuals who are employees, officers, directors or consultants of Reneo and its affiliates.

Under the 2014 Plan, certain employees were granted the ability to early exercise their options. The shares of common stock issued pursuant to the early exercise of unvested stock options are restricted and continue to vest over the requisite service period after issuance. Reneo has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. The shares purchased by the employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest. As of September 30, 2024, there were no unvested shares of common stock outstanding that were issued pursuant to the early exercise of stock options.

Shares Reserved for Future Issuance

As of September 30, 2024, Reneo had reserved shares of its common stock for future issuance as follows:

	Shares Reserved
Common stock options outstanding	467,129
Unvested restricted stock units	29,658
Available for future grants under the 2021 Equity Incentive Plan	442,366
Available for future grants under the 2021 Employee Stock Purchase Plan	78,009
Total shares of common stock reserved	1,017,162

Upon the close of the Merger, all shares available for issuance under the 2021 Plan and 2021 ESPP were cancelled. See Note 10, *Subsequent Events*, for discussion of the new equity plans adopted as part of the Merger.

Stock Options

A summary of Reneo's stock option activity and related information for the nine months ended September 30, 2024 is as follows:

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	530,125	$ 47.60	6.9	$ —
Forfeited/Expired	(62,996)	$ 49.05		
Outstanding at September 30, 2024	467,129	$ 47.39	6.3	$ —
Vested at September 30, 2024	360,725	$ 50.20	6.3	$ —
Exercisable at September 30, 2024	368,048	$ 50.17	6.3	$ —

Options exercisable at September 30, 2024 include vested options and options eligible for early exercise. All outstanding options as of September 30, 2024 are expected to vest.

Unrecognized stock-based compensation expense as of September 30, 2024 was $2.8 million, which is expected to be recognized over a weighted-average vesting term of 1.7 years. See Note 10, *Subsequent Events*, for information regarding compensation expense recognized on the closing date of the Merger related to acceleration of unvested shares.

Reneo estimates stock awards fair value on the date of grant using the Black-Scholes valuation, with the vesting being subject to service requirements. Reneo accounts for forfeitures when they occur. Reneo did not grant any stock options during the nine months ended September 30, 2024.

Restricted Stock Units (RSUs)

RSUs consist of time-based units (TSUs), performance-based units (PSUs) and market-based units (MSUs). The following table summarizes RSU activities during the nine months ended September 30, 2024:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2023	32,650	$ 59.00
Released	(1,491)	$ 65.93
Cancelled	(1,500)	$ 69.79
Unvested at September 30, 2024	29,659	$ 58.09

Time-Based Units

TSUs typically vest over four years, with 25% vesting on the one-year anniversary of the employee's hire date and the remainder vesting monthly or quarterly over the following three years subject to the employee's continued employment with Reneo through the vesting dates. The fair value of the awards was based on the value of Reneo's common stock at the grant date of the award and expense is recognized on a straight-line basis. Reneo had 4,209 unvested shares underlying TSUs as of September 30, 2024. The stock-based compensation expense related to such TSUs for the three and nine months ended September 30, 2024 and 2023 was immaterial. Unrecognized stock-based compensation expense as of September 30, 2024 was $0.3 million, which is expected to

be recognized over a weighted-average vesting term of 2.9 years. See Note 10, *Subsequent Events*, for information regarding compensation expense recognized on the closing date of the Merger related to acceleration of unvested shares.

Performance-Based Units

The vesting of the PSUs is based on Reneo achieving certain regulatory milestones and is subject to the employee's continued employment with Reneo through the achievement date. The fair value of the awards was based on the value of Reneo's common stock at the grant date of the award and expense recognition is based on the probability of achieving the performance conditions. Stock-based compensation expense is adjusted in future periods for subsequent changes in the expected outcome of the performance conditions. Reneo had 13,450 unvested shares underlying PSUs as of September 30, 2024. Reneo concluded that achievement of the performance conditions was not probable as of September 30, 2024 and 2023, and therefore no stock-based compensation expense was recognized for the three and nine months ended September 30, 2024 and 2023 in connection with the PSUs. As of September 30, 2024, there was $1.0 million of unrecognized stock-based compensation expense related to PSUs that were deemed not probable of vesting.

Market-Based Units

The vesting of the MSUs is based on Reneo's closing stock price trading above $20 per share for 30 consecutive trading days subject to the employee's continued employment with Reneo through the date of achievement. The share price of Reneo's common stock on the date of issuance of the MSUs was $2.78 per share (without giving effect to the Reverse Stock Split). The fair value was based on Monte Carlo simulation model on the grant date. Stock-based compensation expense is recognized over the derived service period of approximately 3 years. Reneo had 12,000 unvested shares underlying MSUs as of September 30, 2024. Stock-based compensation expense related to the MSUs during the three and nine months ended September 30, 2024 and 2023 was immaterial. As of September 30, 2024, unrecognized stock-based compensation expense related to the MSUs was immaterial.

Performance Award

In connection with the CEO's employment agreement, he was entitled to receive a Performance Award in the amount of $7.5 million, payable in cash, common stock or a combination of cash and common stock, at the election of Reneo, in the event that (i) Reneo's market value exceeds $750.0 million utilizing the volume-weighted average of the closing sale price of its common stock on the Nasdaq Stock Market or other principal exchange for each of the 30 trading days immediately prior to the measurement date, or (ii) the fair market value of the net proceeds available for distribution to Reneo's stockholders in connection with a change in control as defined in Reneo's severance benefit plan, as determined in good faith by its Board of Directors, exceeds $750.0 million. Reneo has determined that the Performance Award is subject to ASC 718, *Compensation – Stock Compensation* and includes both market and performance conditions. Since Reneo's initial public offering (IPO), neither of the events have been satisfied. Reneo estimated the fair value of the Performance Award at each reporting period using the Monte Carlo simulation (Note 4), which is recognized as stock-based compensation expense over the derived service period. As of September 30, 2024, Reneo has reduced the liability associated with the Performance Awards to zero as the conditions were not probable of being achieved on or before the completion of the Merger.

2021 Employee Stock Purchase Plan

In March 2021, Reneo's Board of Directors adopted Reneo's 2021 Employee Stock Purchase Plan (ESPP), which became effective immediately prior to the execution of the underwriting agreement in connection with Reneo's IPO. As of September 30, 2024, 28,846 shares have been issued under the ESPP.

In September 2021, the compensation committee of Reneo's Board of Directors (Compensation Committee) adopted Reneo's 2021 UK Sharesave Sub-plan (SAYE). An allocation of 2,587 shares of common stock from the

ESPP reserve pool was approved and reserved for issuance under the SAYE. The Compensation Committee terminated the SAYE in January 2024 and the reserved shares were returned to the ESPP reserve pool. No shares were issued under the SAYE prior to its termination.

Reneo did not recognize stock-based compensation expense related to the ESPP and the SAYE for the three and nine months ended September 30, 2024. The stock-based compensation expense related to the ESPP and the SAYE for the three and nine months ended September 30, 2023, was immaterial.

Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense, including expense associated with options, TSUs, MSUs and award modifications for unvested options, reflected in the consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 245	$ 537	$ 742	$ 1,504
General and administrative	581	892	2,151	2,289
Total	$ 826	$ 1,429	$ 2,893	$ 3,793

9. License Agreement

In December 2017, Reneo entered into a License Agreement (the vTv License Agreement) with vTv Therapeutics LLC (vTv Therapeutics), under which Reneo obtained an exclusive, worldwide, sublicensable license under certain vTv Therapeutics intellectual property to develop, manufacture and commercialize PPARδ agonists and products containing such PPARδ agonists, including mavodelpar, for any therapeutic, prophylactic or diagnostic application in humans. Since Reneo has suspended all development activity related to mavodelpar, it is not currently performing any development efforts under the vTv License Agreement.

Under the terms of the vTv License Agreement, Reneo has paid vTv Therapeutics an initial upfront license fee of $3.0 million and $2.0 million of milestone payments and issued an aggregate of 576,443 shares of its common stock to vTv Therapeutics. On October 30, 2023, Reneo repurchased from vTv Therapeutics all 576,443 shares of its common stock previously issued to vTv Therapeutics under the vTv License Agreement for an aggregate purchase price of approximately $4.4 million in a private, non-underwritten transaction.

On October 22, 2024, the Company provided vTv Therapeutics notice of its intention to terminate the vTv License Agreement effective 90 days from the date of notice. Following termination of the vTv License Agreement, the Company intends to cease maintenance and prosecution of all mavodelpar intellectual property.

10. Subsequent Events

On October 4, 2024, Reneo consummated the previously announced Merger pursuant to the terms Merger Agreement. Pursuant to the Merger Agreement, on the Closing Date, (i) Reneo effected a the Reverse Stock Split of Reneo's issued common stock at a ratio of 1:10, (ii) Reneo changed its name to "OnKure Therapeutics, Inc.", (iii) Reneo reclassified all of its common stock as Class A Common Stock. Concurrently with the closing of the Merger, Reneo completed a private placement with the PIPE Investors to purchase 2,839,005 shares of Class A Common Stock at a price per share of approximately $22.895 per share for an aggregate purchase price of approximately $65.0 million, as described in more detail in Note 1, *Organization and Business*.

Upon the closing of the Merger, (i) an aggregate of 6,470,281 shares of Class A Common Stock and 686,527 shares of Class B Common Stock of the Combined Company were issued in exchange for the shares of Legacy OnKure capital stock outstanding as of immediately prior to the Effective Time and (ii) outstanding shares of Reneo common stock were reclassified into an aggregate of 3,343,525 shares of Class A Common Stock. Immediately after the Merger, there were approximately 12,652,811 shares of Class A Common Stock outstanding,

686,527 shares of Class B Common Stock outstanding, and 905,204 shares of Class A Common Stock subject to outstanding options and RSUs under the Combined Company's equity incentive plans.

In addition, the Company adopted the 2024 Equity Incentive Plan (the 2024 Plan) and 2024 Employee Stock Purchase Plan (the 2024 ESPP Plan). Under the 2024 Plan a total of 2,480,000 shares of Class A Common Stock were initially reserved for issuance. In addition, shares reserved for issuance under the 2024 Plan will include shares of Class A Common Stock equity awards granted under the Reneo 2021 Plan and any shares of Class A Common Stock equity awards that were assumed in the Merger. Under the 2024 ESPP Plan, an aggregate of 137,500 shares of Class A Common Stock are currently reserved and available for issuance.

As of the open of trading on October 7, 2024, the Class A Common Stock of the Combined Company began trading on the Nasdaq Global Market (Nasdaq) under the symbol "OKUR."

In October in connection with the Merger, the Company paid approximately $4.3 million in severance and retention bonuses to its former Reneo employees in accordance with their Separation and Retention Agreements. Additionally, Reneo recognized stock-based compensation of $3.0 related to vesting acceleration of approximately 92,480 shares and 24,700 shares of unvested options and restricted stock, respectively, immediately prior to the Merger.

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

You should read the following discussion and analysis of Reneo's financial condition and results of operations together with (i) the consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, (ii) the audited consolidated financial statements and notes thereto and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in Reneo's Annual Report on Form 10-K for the year ended December 31, 2023, (iii) Legacy OnKure's audited financial statements and the related notes for the years ended December 31, 2023 and 2022 included in the proxy statement/prospectus (the Proxy Statement/Prospectus) filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the SEC on August 26, 2024 and (iv) the unaudited pro forma condensed combined financial statements for the six months ended June 30, 2024 and for the year ended December 31, 2023 included in the Proxy Statement/Prospectus. Unless otherwise indicated, all references in this Quarterly Report on Form 10-Q to "OnKure," the "Company," "we," "our," "us" or similar terms refer to OnKure Therapeutics, Inc. and its subsidiaries after completion of the Merger. In addition, references to "Reneo" refers to the Company prior to the completion of the Merger.

Forward-Looking Statements

In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "project," "positioned," "potential," "seek," "should," "target," "will," "would" or the negative of these terms or other similar expressions.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

Merger

On the Closing Date, Reneo, consummated the previously announced Merger pursuant to the terms of the Merger Agreement, by and among Reneo, Merger Sub I, Merger Sub II, and Legacy OnKure. Pursuant to the Merger Agreement, on the Closing Date, (i) Reneo effected the Reverse Stock Split, (ii) Reneo changed its name to "OnKure Therapeutics, Inc.", (iii) Reneo reclassified all of its common stock as Class A Common Stock, and (iv) Merger Sub I merged with and into Legacy OnKure, with Legacy OnKure as the surviving company in the Merger and, after giving effect to such Merger, Legacy OnKure became a wholly-owned subsidiary of OnKure Therapeutics, Inc. Pursuant to the terms of the Merger Agreement, we determined that the Merger would qualify for the intended tax treatment even if only the merger with Merger Sub I was consummated, and therefore the parties determined not to consummate the second merger with Merger Sub II contemplated by the Merger Agreement.

Concurrently with the closing of the Merger, Reneo completed a private placement with certain investors (the PIPE Investors) to purchase 2,839,005 shares of Class A Common Stock at a price per share of approximately $22.895 per share for an aggregate purchase price of approximately $65.0 million, including the conversion of outstanding convertible notes and accrued but unpaid interest thereon held by certain Legacy OnKure investors (the Concurrent PIPE Investments). In connection with the Concurrent PIPE Investments, Reneo entered into a registration rights agreement with the PIPE Investors, pursuant to which Reneo agreed to use commercially reasonable efforts to prepare and file a registration statement with the SEC within 45 calendar days after the Closing Date, registering the resale of the shares of Class A Common Stock issued pursuant to the Concurrent PIPE

Investments. The Company filed such Registration Statement on Form S-1 with the SEC, and it was declared effective by the SEC on October 30, 2024. Immediately after the effective time of the Merger, following the consummation of the Concurrent PIPE Investments, Legacy OnKure stockholders owned approximately 53.6%, pre-Merger Reneo stockholders owned approximately 25.1%, and the PIPE Investors owned approximately 21.3% of the Combined Company's outstanding common stock.

As of the open of trading on October 7, 2024, the Class A Common Stock of the Combined Company began trading on the Nasdaq Global Market (Nasdaq) under the symbol "OKUR."

Post-Merger Business

As a result of the Merger, Reneo's historic business operations ceased and our go-forward operations will be those of Legacy OnKure.

We are a clinical-stage biopharmaceutical company focused on the discovery and development of precision medicines designed to target biologically validated drivers of cancers underserved by available therapies. Using a structure- and computational chemistry-driven drug design platform, we are committed to improving clinical outcomes for patients by building a robust pipeline of small molecule drugs designed to selectively target specific mutations thought to be key drivers of cancer. Our lead product candidate, OKI-219, is a highly selective inhibitor of 3 kinase alpha (PI3Kα), a key mediator in cancer growth signaling, harboring the H1047R mutation (PI3KαH1047R) that has a much smaller impact on non-mutated (or wild-type) PI3Kα (PI3KαWT). OKI-219 is currently in a first-in-human Phase 1 monotherapy dose-escalation trial in H1074R-mutated advanced solid tumors including breast cancer. Early clinical data are anticipated in the fourth quarter of 2024. In addition to OKI-219,we are also pursuing programs designed to selectively target the other specific mutations of PI3Kα.

The unaudited interim financial information included in this section are representative of Reneo's operations prior to the closing of the Merger, the adoption of our business plan and the commencement of conducting our business.

License Agreement

In December 2017, Reneo entered into a License Agreement (vTv License Agreement) with vTv Therapeutics LLC (vTv Therapeutics), under which Reneo obtained an exclusive, worldwide, sublicensable license under certain vTv Therapeutics intellectual property to develop, manufacture and commercialize PPARδ agonists and products containing such PPARδ agonists, including mavodelpar, Reneo's product candidate, for any therapeutic, prophylactic or diagnostic application in humans. Since all development activity related to mavodelpar has been suspended, no development efforts under the vTv License Agreement are currently being performed.

Under the terms of the vTv License Agreement, Reneo paid vTv Therapeutics an initial upfront license fee of $3.0 million and $2.0 million of milestone payments and issued an aggregate of 576,443 shares of Reneo's common stock to vTv Therapeutics. On October 30, 2023, Reneo repurchased from vTv Therapeutics all 576,443 shares of Reneo's common stock previously issued to vTv Therapeutics under the vTv License Agreement for an aggregate purchase price of approximately $4.4 million in a private, non-underwritten transaction.

On October 22, 2024, we provided vTv Therapeutics notice of our intention to terminate the vTv License Agreement effective 90 days from the date of notice. Following termination of the vTv License Agreement, we intend to cease maintenance and prosecution of all mavodelpar intellectual property.

Components of Reneo's Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses primarily related to preclinical and clinical development of mavodelpar. Research and development expenses included:

- personnel expenses, including severance payments, salaries, benefits, and stock-based compensation expense;
- external expenses incurred under agreements with contract research organizations (CROs), investigative sites and consultants to conduct and support our preclinical studies and clinical trials;
- raw materials related to manufacturing of Reneo's product candidate for clinical trials and preclinical studies, including fees paid to third-party manufacturers;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies;
- expenses related to medical affairs activities, including field teams to initiate relevant disease education and publications;
- depreciation and maintenance expenses; and
- fees for maintaining licenses under Reneo's third-party licensing agreements.

Reneo recognized research and development expenses as incurred and capitalized payments made prior to the receipt of goods or services to be used in research and development until receipt of the goods or services. Costs for certain activities, such as manufacturing and preclinical studies and clinical trials, were generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to Reneo by its vendors and collaborators. Reneo expensed amounts paid to acquire licenses associated with products under development when the ultimate recoverability of the amounts paid was uncertain and the technology had no alternative future use when acquired.

General and Administrative Expenses

General and administrative expenses consisted primarily of costs related to the Merger, personnel expenses, including severance payments, salaries, benefits, and stock-based compensation expenses for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for accounting, legal, and commercial development, insurance and corporate facility costs not otherwise included in research and development expenses.

Other Income

Other income consisted of interest income on Reneo's cash, cash equivalents and short-term investments.

Reneo's Results of Operations

Comparison of Three Months Ended September 30, 2024 and 2023 (Unaudited)

The following table summarizes Reneo's results of operations for the three months ended September 30, 2024 and 2023 (unaudited and in thousands):

	Three Months Ended September 30,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 904	$ 13,622	$ (12,718)
General and administrative	3,760	7,266	(3,506)
Total operating expenses	4,664	20,888	(16,224)
Loss from operations	(4,664)	(20,888)	16,224
Other income	972	1,692	(720)
Net loss	$ (3,692)	$ (19,196)	$ 15,504

Operating Expenses

Research and Development Expenses

Research and development expenses decreased by $12.7 million during the three months ended September 30, 2024, compared to the three months ended September 30, 2023. This decrease was primarily due to the suspension of development activities for mavodelpar and cash preservation activities, including workforce reductions in December 2023 and February 2024.

General and Administrative Expenses

General and administrative expenses decreased by $3.5 million during the three months ended September 30, 2024, compared to the three months ended September 30, 2023. This decrease was primarily due to a decrease of $2.1 million in commercial development and consulting costs due to the suspension of mavodelpar development activities and a decrease of $1.3 million in facility and personnel-related costs related to Reneo's workforce reductions in December 2023 and February 2024.

Other Income

The decrease in other income for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, relates to a decrease in Reneo's short-term investment balance during 2024.

Comparison of Nine Months Ended September 30, 2024 and 2023 (Unaudited)

The following table summarizes Reneo's results of operations for the nine months ended September 30, 2024 and 2023 (unaudited and in thousands):

	Nine Months Ended September 30,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 6,436	$ 39,009	$ (32,573)
General and administrative	14,155	19,038	(4,883)
Total operating expenses	20,591	58,047	(37,456)
Loss from operations	(20,591)	(58,047)	37,456
Other income	3,112	4,213	(1,101)
Net loss	$ (17,479)	$ (53,834)	$ 36,355

Operating Expenses

Research and Development Expenses

Research and development expenses decreased by $32.6 million during the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. This decrease was primarily due to the suspension of development activities for mavodelpar and cash preservation activities, including workforce reductions in December 2023 and February 2024.

General and Administrative Expenses

General and administrative expenses decreased by $4.9 million during the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. This decrease was primarily due to a decrease of $3.4 million in commercial development and consulting costs due to the suspension of mavodelpar development activities and a decrease of $3.3 million in facility and personnel-related costs related to Reneo's workforce reductions in December 2023 and February 2024, offset by an increase of $2.1 million in legal and advisory fees related to the proposed Merger.

Other Income

The decrease in other income for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, relates to a decrease in Reneo's short-term investment balance during 2024.

Liquidity and Capital Resources

Since inception, Reneo has incurred significant losses and negative cash flows from operations, and financed its operations primarily through the sale of equity securities. Reneo has not generated any revenue from the sale of any products. As of September 30, 2024, Reneo had available cash, cash equivalents and short-term investments of approximately $76.7 million.

As a result of the Merger, Reneo's historic business operations ceased and our go-forward operations will be those of Legacy OnKure. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing our product candidates to support commercialization and providing general and administrative support for our operations, including the costs associated with operating

as a public company following the Closing. As a result, we will need additional capital to fund our operations, which we may seek to obtain from equity or debt financings, collaborations, licensing arrangements or other sources.

After giving effect to the Merger and the PIPE Financing in October 2024, we believe the resulting cash resources are sufficient to fund our planned operations for at least the next 12 months from the date of issuance of these unaudited condensed financial statements.

Funding Requirements

Our primary uses of cash to date have been to fund our research and development activities, including with respect to our PI3Kα and other programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these activities.

We have never generated any revenue from product sales and do not expect to generate any meaningful product revenue unless and until we obtain regulatory approval for our product candidates, and management does not know when, or if, that will occur. Until we can generate significant revenue from product sales, if ever, we will continue to require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. We are subject to all the risks inherent in the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business.

In order to complete the development of our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize product candidates, if approved, we will require substantial additional capital. Accordingly, until such time that we can generate a sufficient amount of revenue from product sales or other sources, we expect to seek to raise any necessary additional capital through equity financings, debt financings or other capital sources, which could include income from collaborations, partnerships, licensing or other strategic arrangements with third parties. To the extent that we raise additional capital through equity financings or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our own common stock, make certain investments or engage in merger, consolidation, licensing or asset sale transactions. If we raise capital through collaborations, partnerships and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional capital from these sources on favorable terms, or at all.

Our ability to secure capital is dependent upon a number of factors, including our success in developing our product candidates. The failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. We cannot provide assurance that we will ever generate positive cash flow from operating activities.

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

- the scope, timing, progress, results and costs of researching and developing OKI-219, and conducting preclinical studies and clinical trials;
- the scope, timing, progress, results and costs of researching and developing other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution for our product candidates for which it receives marketing approval;

- the costs of manufacturing commercial-grade products and producing sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sales of our products, should its product candidates receive marketing approval;
- the cost and timing of attracting, hiring and retaining skilled personnel to support our operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish, maintain and derive value from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties on favorable terms, if at all;
- the extent to which we acquire or in-licenses other product candidates and technologies, if any; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of OKI-219 or any of our future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional capital to meet the capital requirements associated with such operating plans.

Reneo's Cash Flows

The following table summarizes Reneo's cash flows for the nine months ended September 30, 2024 and 2023 (unaudited and in thousands):

	Nine Months Ended September 30,	
	2024	**2023**
Net cash used in operating activities	$ (30,102)	$ (43,929)
Net cash provided by (used in) investing activities	61,248	(29,254)
Net cash provided by financing activities	1,911	64,993
Net increase (decrease) in cash and cash equivalents	$ 33,057	$ (8,190)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2024 was $30.1 million, consisting primarily of Reneo's net loss of $17.5 million adjusted for non-cash items of $1.2 million primarily due to $2.9 million of stock-based compensation expense, offset by $1.9 million of amortization/accretion on short-term investments and a $13.8 million net change in operating assets and liabilities. The change in Reneo's net operating assets and liabilities was primarily due to a decrease in prepaid and other current assets of $3.4 million, offset by a decrease in accounts payable and accrued expenses of $16.9 million due to timing of payments.

Net cash used in operating activities for the nine months ended September 30, 2023 was $43.9 million, consisting primarily of Reneo's net loss of $53.8 million adjusted for non-cash items of $1.8 million primarily due to $3.8 million of stock-based compensation expense and $1.0 million in fair value of a performance award, offset by $3.6 million of amortization/accretion on short term investments and an $8.1 million net change in operating assets and liabilities. The change in Reneo's net operating assets and liabilities was primarily due to a decrease in prepaid and other current assets of $2.1 million and an increase in accounts payable and accrued expenses of $6.4 million due to timing of receipt of invoices and payments.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2024 was $61.2 million, consisting primarily of the net proceeds from maturities of available-for-sale short-term investments.

Net cash used in investing activities for the nine months ended September 30, 2023 was $29.3 million, consisting primarily of the net purchase of available-for-sale short-term investments.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was $0.1 million consisting primarily of cash deposits received in connection with the Concurrent PIPE Investments.

Net cash provided by financing activities for the nine months ended September 30, 2023 was $65.0 million, consisting primarily of the net proceeds of $58.9 million, $4.7 million, and $1.0 million from the sale of common stock in Reneo's May 2023 public offering, Reneo's May 2023 private placement, and Reneo's May 2022 at-the-market equity offering sales agreement, respectively.

Reneo's Material Cash Requirements

The discussion below summarizes Reneo's significant contractual obligations and commitments as of September 30, 2024.

Leases. See Note 7 of Notes to Reneo's Consolidated Financial Statements included in this Quarterly Report on Form 10-Q for information regarding our leases, including the future operating lease minimum payments.

vTv License Agreement. See Note 9 of Notes to Reneo's Consolidated Financial Statements included in this Quarterly Report on Form 10-Q for information regarding the vTv License Agreement terminated in October 2024, including potential milestone and royalty payments.

Critical Accounting Policies and Estimates

Reneo's management's discussion and analysis of its financial condition and results of operations are based on its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements required Reneo to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Reneo based its estimates on historical experience, known trends and events, and various other factors that it believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Reneo's critical accounting policies are described in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates" in its Annual Report on Form 10-K for the year ended December 31, 2023, and the notes to the consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the nine months ended September 30, 2024, there were no material changes to Reneo's critical accounting policies from those discussed in its Annual Report on Form 10-K for the year ended December 31, 2023.

Recent Accounting Pronouncements

See Note 2 of Notes to Reneo's Consolidated Financial Statements included in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to Reneo's consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our principal executive officer and our principal financial officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our principal executive officer and our principal financial officer have concluded that as of September 30, 2024, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission (SEC) rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

Merger Proceedings

In connection with the Merger, two complaints were filed in the Supreme Court of the State of New York, County of New York, captioned Thomas v. Reneo Pharmaceuticals, Inc., et al., Index No. 654628/2024 (filed September 5, 2024) and Kent v. Reneo Pharmaceuticals, Inc., et al., Index No. 654642/2024 (filed September 6, 2024) (together, the Complaints). The Complaints generally allege that the Proxy Statement/Prospectus filed by Reneo with the SEC misrepresented and/or omitted certain purportedly material information relating to Reneo management's financial projections for Reneo and us, the data and inputs underlying the financial valuation analyses that support the fairness opinion provided by Leerink Partners, Reneo's financial advisor, and potential conflicts of interest with Leerink Partners LLC, Evercore Group L.L.C., and LifeSci Capital LLC, which were the placements agents for the Concurrent PIPE Investments that closed concurrently with the Merger. The Complaints assert violations of negligent misrepresentation and concealment in violation of New York common law and negligence in violation of New York common law. The Complaints sought orders enjoining the proposed Merger, or in the event that the Merger was consummated, orders rescinding the Merger or awarding actual and punitive damages, as well as all of the plaintiffs' fees and expenses in connection with the litigation, including reasonable attorneys' and experts' fees and expenses.

We cannot predict the outcome of the Complaints or any other litigation that might be filed arising out of the Merger or the Concurrent PIPE Investments. The Company and the individual defendants intend to vigorously defend against the Complaints and any subsequently filed, similar actions. It is possible additional lawsuits may be filed arising out of the Merger or the Concurrent PIPE Investments. Absent new or significantly different allegations, the Company will not necessarily disclose such additional filings.

Other Proceedings

From time to time, we may be subject to legal proceedings and claims arising in the ordinary course of our business. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors

You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including the unaudited condensed consolidated financial statements and related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other public filings in evaluating our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Summary of Risk Factors

We face many risks and uncertainties, as more fully described in this section. Some of these risks and uncertainties are summarized below. The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained below.

- We are early in our development efforts and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and future viability.

- We have incurred significant net losses in each period since inception, and expect to continue to incur significant net losses for the foreseeable future.
- We have never generated revenue from product sales and may never achieve or maintain profitability.
- We will need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital on favorable terms, on a timely basis or at all, we would be forced to delay, reduce or eliminate our product development and clinical programs and may not have the capital required to otherwise operate our business
- We are substantially dependent on OKI-219. If we are unable to advance OKI-219 through clinical development, obtain regulatory approval and ultimately commercialize such product candidate, or experience significant delays in doing so, our business will be materially harmed.
- We have limited resources and are currently focusing our efforts on OKI-219 for development in particular indications and advancing our other discovery research programs. As a result, we may fail to capitalize on programs, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- 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 would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- If we experience delays or difficulties in the enrollment or retention of subjects in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates on acceptable terms, we may be unable to successfully commercialize our product candidates that obtain regulatory approval.
- If we are unable to obtain and maintain sufficient intellectual property protection for our technology and products and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and, if approved, commercialize our product candidates may be adversely affected.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct, supervise and monitor certain aspects of our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements and meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.
- The market price of our Class A Common Stock is expected to be volatile.
- We expect to incur losses for the foreseeable future and might never achieve profitability.

- Our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and provisions under Delaware law could make an acquisition of our company more difficult and may prevent attempts by our stockholders to replace or remove our management.
- As a result of the Merger, we are subject to the SEC requirements applicable to reporting shell company business combinations. As a result, we are subject to more stringent reporting requirements, offering limitations and resale restrictions.
- An active trading market for our Class A Common Stock may not develop, and the holders of our Class A Common Stock may not be able to resell their shares of our Class A Common Stock for a profit, if at all.
- We could be subject to securities class action litigation, which is expensive and could divert management attention.
- Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Risks Related to Our Operating History, Financial Position and Need for Additional Capital

We are early in our development efforts and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and future viability.

We are a clinical-stage biopharmaceutical company, have no products approved for commercial sale and have never generated any revenue. Our operations to date have been limited to organizing the company, raising capital and developing our product candidates. We have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be difficult for investors to accurately predict our likelihood of success and viability.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. We also expect that, as we advance our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses in each period since inception, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses in each reporting period since inception, have not generated any revenue from the sale of products, and have funded our operations primarily from the sale and issuance of equity securities and convertible debt. Legacy OnKure's net losses were $35.3 million and $29.5 million for the years ended December 31, 2023 and 2022, respectively. We have no products approved for sale. As a result, we expect that it will be many years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses to discover, develop and market additional product candidates.

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 such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue, if any. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates, our ability to achieve and maintain profitability and the performance of our stock.

We have never generated revenue from product sales and may never achieve or maintain profitability.

We have never generated any revenue from commercial product sales. To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities can include completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products that are approved and satisfying any post-marketing requirements. We do not anticipate generating any revenue from product sales for many years. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives, including:

- successful and timely completion of clinical development of OKI-219 and preclinical and clinical development of other pipeline programs and any other future programs;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development of OKI-219 and any other future programs;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is 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 our value and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

Any changes in the manufacturing process, suppliers, or facilities will require further comparability analysis and approval by the U.S. Food and Drug Administration (the FDA) before implementation, which could delay our

clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy.

We have not previously submitted a New Drug Application (NDA) to the FDA or similar approval filings to a comparable foreign regulatory authority for any product candidate. An NDA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product candidate. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we receive regulatory approval and have commercial rights, the availability of competitive therapies and whether there are sufficient levels of reimbursement and adoption by physicians.

We will need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital on favorable terms, on a timely basis or at all, we would be forced to delay, reduce or eliminate our product development and clinical programs and may not have the capital required to otherwise operate our business.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We have not generated any revenues from the commercial sale of products and will not be able to generate any product revenues until, and only if, we receive approval to sell our product candidates from the FDA or other regulatory authorities. Our cash, cash equivalents and short term investments are expected to fund operations into the fourth quarter of 2026. However, as we have not generated any revenue from commercial sales to date and do not expect to generate any revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our general corporate activities and to fund our research and development, including our currently planned clinical trials and plans for new clinical trials and product development.

We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations or, if such funds are available, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution and new investors could gain rights, preferences and privileges senior to the holders of common stock. Debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that may not be favorable.

Given our capital constraints, we will need to prioritize spending on our clinical and preclinical programs. If we are unable to raise sufficient funds to support our current and planned operations, we may elect to discontinue certain of our ongoing activities or programs. Our inability to raise additional funds could also prevent us from taking advantage of opportunities to pursue promising new or existing programs in the future.
Our forecasts regarding the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. These estimates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than currently expected.

Risks Related to Our Development and Commercialization of Our Product Candidates

We are substantially dependent on OKI-219. If we are unable to advance OKI-219 through clinical development, obtain regulatory approval and ultimately commercialize such product candidate, or experience significant delays in doing so, our business will be materially harmed.

We are currently evaluating OKI-219 in a Phase 1 clinical trial. We will be required to demonstrate thorough, adequate and well-controlled clinical trials that OKI-219 is safe and effective, with a favorable benefit risk profile, for use in its target indication before we can seek regulatory approvals for its commercial sale. Our initial clinical trials will begin with relatively small cohorts before expanding in size in subsequent cohorts. If safety issues arise in an early cohort, we may be delayed or prevented from subsequently expanding into larger trial cohorts. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of OKI-219. We are not permitted to market or promote any product candidate before we receive marketing approval from the FDA, European Medicines Agency (EMA) or any comparable foreign regulatory authorities, and we may never receive such marketing approvals.

We have limited resources and are currently focusing our efforts on OKI-219 for development in particular indications and advancing our other discovery research programs. As a result, we may fail to capitalize on programs, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We are currently focusing our resources and efforts on OKI-219 and advancing our other research programs. Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forgo or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development activities for OKI-219 and our other research programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for OKI-219 and our other research programs, or the product candidates we are currently developing in these programs, we may relinquish valuable rights to our product candidates or programs 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 or program.

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 would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. We do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any jurisdiction. Our product candidates may fail to demonstrate efficacy in humans, and particularly across tumor types. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk we face is the possibility that none of our product candidates under development will successfully gain market approval from the FDA, EMA or other comparable foreign regulatory authorities, resulting in our being unable to derive any commercial revenue from them after investing significant amounts of capital in their development.

If the results of our ongoing or future preclinical studies and future clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if our trials do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or adverse events. In such an event, our trials could be suspended or terminated and the FDA, EMA 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. Treatment-related side effects could also 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, financial condition and prospects significantly. Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow indications or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

Our product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing.

Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. For example, FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in early clinical setting, among other goals. How the FDA plans to implement these goals and their impact on specific clinical programs and the industry are unclear. 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, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than originally requested or may impose other prescribing limitations or warnings that limit the product candidate's commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, are 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;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests required for our product candidates; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, even if clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. For example, although we have sought and received feedback from the FDA on the designs of our clinical trials and intend to continue to do so, the FDA may ultimately disagree that our trials support approval for OKI-219. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available, to conduct additional trials in support of potential approval of our product candidates. Even if we secure regulatory approval for any of our product candidates, the terms of such approval may limit the scope and use of the product candidate, which may also limit its commercial potential.

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;
- be subject to changes in the way the product is administered; or
- have regulatory authorities withdraw or suspend their approval of the product.

We cannot be certain that our planned clinical trials or any other future clinical trials will be successful.

Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and pricing of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, the pricing of a prescription drug candidate is subject to regulatory approval before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fails to comply with the regulatory requirements in international markets or fails to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

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

Trials may be subject to delays as a result of patient withdrawal or patient enrollment taking longer than anticipated. 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 subjects to participate to such trials' conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. While our Phase 1 dose-escalation and expansion cohort trial, OKI-219-101, known as PIKture-01, has begun enrollment, future difficulties we experience relating to enrollment in our clinical trials, or complications in the PIKture-01 trial or future clinical trials, could delay regulatory approval for OKI-219 or our future product candidates.

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 subjects who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment for any of our future clinical trials may be affected by other factors, including:

- size and nature of the patient population, and process for identifying patients;
- severity and difficulty of diagnosing the condition under investigation;

- availability and efficacy of approved drugs and other competing therapeutic candidates for the condition under investigation;
- the eligibility and exclusion criteria for the trial in question as defined in the protocol;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the clinical trial;
- perceived risks and benefits of the product candidate under study;
- participants' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- participant referral practices of doctors;
- the ability to monitor participants adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective trial subjects;
- continued enrollment of prospective subjects by clinical trial sites; and
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion.

Our inability to enroll a sufficient number of subjects 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 and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we will have limited influence over their performance. Even if we are able to enroll a sufficient number of subjects for our clinical trials, we may have difficulty maintaining enrollment of such subjects in our clinical trials.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to interrupt, delay or abandon their development or limit development to more narrow 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. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Patients in our ongoing and planned clinical trials may suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients enrolled in our clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, and other comparable regulatory authorities or an institutional review board (IRB) may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

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 clinical trials will be successful. For example, we previously decided to cease developing another product candidate, known as OKI-179, despite promising early data. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

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 dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We may also experience issues in conducting our clinical trials that would delay or prevent us from satisfying the applicable requirements of the FDA and other regulatory authorities, including:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials for any future product candidates;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in reaching agreement with the FDA or other regulatory authorities as to the design or implementation of our clinical trials;

- obtaining regulatory authorization to commence a clinical trial;
- delays in reaching, or fail to reach, agreement on acceptable terms with clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- obtaining approval at each trial site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with applicable regulatory requirements, including the FDA's current Good Clinical Practices (GCP) requirements, or applicable regulatory requirements in other countries;
- addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- adding a sufficient number of clinical trial sites;
- manufacturing sufficient quantities of product candidate for use in clinical trials; or
- suspensions or terminations by IRBs of the institutions at which such trials are being conducted, or by the FDA or other regulatory authorities due to a number of factors, including those described above.

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 or significantly increase the cost of such trials, including:

- changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials 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;
- 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 for various reasons, including non-compliance with regulatory requirements, a finding that a product candidate has 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 may be greater than we anticipate and we may not have funds to cover the costs;
- the supply or quality of product candidates or other materials necessary to conduct clinical trials 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.

We do not know whether any clinical trials we may conduct will demonstrate efficacy and safety sufficient to obtain approval to market any of our product candidates.

Interim, initial, "top-line" and preliminary data from clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, preliminary or top-line data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete 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 or as patients from our clinical trials continue other treatments for their condition. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, preliminary and top-line data should be viewed with caution until the final data are available. We also make assumptions, estimations, and calculations, and draws conclusions, as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program or the approvability or commercialization of the particular product candidate, and could have a material adverse effect on the success of our business. In addition, the information we choose to disclose publicly regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our Class A Common Stock.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

We may develop programs in combination with other therapies, which exposes us to additional risks.

We intend to develop OKI-219, and may develop any other product candidate we develop, in combination with one or more currently approved cancer therapies or therapies in development. Patients may not be able to tolerate our product candidates in combination with other therapies, or dosing of our product candidates in combination with other therapies may have unexpected consequences. Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to risks that the FDA or other comparable foreign regulatory authorities could revoke

approval of the therapy used in combination with our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates may be approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our products being removed from the market or being less successful commercially. If the FDA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or successfully market any or all of the product candidates we develop.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies is prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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 are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies, and new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors. As a result of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing product candidates in our field before we do.

There are multiple PI3Kα-pathway targeted agents either approved or under clinical development that will potentially compete with OKI-219 and our PI3Kα-targeted portfolio. These include the marketed medicines alpelisib (Piqray, a PI3Kα-selective inhibitor marketed by Novartis) and capivasertib (Truquap, an AKT1 inhibitor marketed by Astra Zeneca), both of which are approved for the treatment of PI3Kα-mutated breast cancer patients in combination with the selective estrogen receptor degrader (SERD) fulvestrant. We are also aware of several novel PI3K-targeted therapies that are in clinical development. This includes both multiple non-mutation-selective PI3K inhibitors (inavolisib, developed by Roche Holdings AG; gedatolisib (Celcuity Inc.); MEN1611 (menarini) and TOS-358 (Totus Medicines)) and inhibitors designed to have greater selectivity for mutated PI3Kα, including RLY-2608 (Relay Therapeutics), STX-473 (Scorpion Therapeutics) and LOXO-783 (Loxo Oncology). Multiple other companies have disclosed or published research efforts in PI3K inhibitors that are at an early stage, but could potentially advance to the clinical trial stage. Finally, there are numerous other investigational therapies, spanning many modalities that are being evaluated preclinically and in clinical trials for breast cancer.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects or are more convenient or lessexpensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we can, which could make our development more complicated or result in our competitors establishing a strong market position before we are able to enter the market.

Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our product candidates, if approved, could be adversely affected.

Even if OKI-219 or any other product candidate receives marketing approval, they may fail to achieve market acceptance among physicians, patients, third-party payors and others in the medical community.

If OKI-219 or any other product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of OKI-219 or any other product candidate that we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of our product candidates compared to alternative treatments, including the existing standard of care;
- our ability to offer products for sale at competitive prices;
- the clinical indications for which the product is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a Risk Evaluation Mitigation Strategy (REMS), if any, which may not be required of alternative treatments and competitor products;
- the cost of treatment in relation to alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of doctors to prescribe these therapies;
- the strength of our marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of an approved product candidate for use as a combination therapy;
- the potential for our competitors to limit our access to the market through anti-competitive contracts or other arrangements;
- unfavorable publicity relating to our product candidates;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications. If any of our product candidates are approved but do not achieve an adequate level of market acceptance, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates on acceptable terms, we may be unable to successfully commercialize our product candidates that obtain regulatory approval.

If OKI-219 or another product candidate is approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we intend to sell and market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing and building out an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our

internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products, if approved.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If our product candidates are approved for marketing, such claims could still result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of such products, our manufacturing processes and facilities or our marketing programs. These investigations could potentially lead to a recall of our products or more serious enforcement actions, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in injury to our reputation, withdrawal of clinical trial participants, costs to defend the related litigation, a diversion of management's time and our resources, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business and cause the price of our Class A Common Stock to decline. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain or obtain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including those caused by product liability claims.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of

Health and Human Services (HHS). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe that the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of a product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We are developing regulatory strategies for our product candidates outside the United States and, accordingly, we expect that we or our partners would seek regulatory approval of our product candidates outside of the United States. As such, we expect that we will be subject to additional risks related to operating in foreign countries if we or such partners obtain the necessary approvals, including:

- differing regulatory requirements and drug pricing regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with our international operations or those of any applicable international partners may materially adversely affect our ability to attain or maintain profitable operations.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, including sanctions, treaties, tariffs, taxes, regulatory requirements, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain interactions with certain Chinese biotechnology companies. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what interactions, including products or services, may be subject to such actions, or what actions may be taken by the other countries in retaliation. If our interactions with parties affected by any such actions are limited or no longer possible, our business, liquidity, financial condition, or results of operations could be materially and adversely affected.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our technology and products and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and, if approved, commercialize our product candidates may be adversely affected.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our development programs and product candidates. Our success depends in part on our ability to obtain and maintain patent protection in the United States and other countries with respect to OKI-219 and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs, product candidates and novel discoveries that are important to our business. The patent prosecution process is expensive and time consuming, and we may not be able to file, prosecute, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patents and patent applications that we own may fail to result in issued patents with claims that protect OKI-219 or any future product candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which

can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover OKI-219 or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, the scope and coverage of such patents may be so narrow that a third party could successfully design around our patents without materially impacting the therapeutic effectiveness of the resulting drug product. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the United States Patent and Trademark Office (the USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- the USPTO requires us to disclose all material references to the patent examiner during prosecution of our patent applications, and failure to do so could result in a third party successfully challenging our ability to enforce a patent against an infringer;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of which have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments of diseases or conditions that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws that are less favorable to patentees, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents in the public domain. 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. Moreover, if we choose to license certain patent rights in the future from third parties, we may not have the right to control the preparation, filing and prosecution of such patent applications, or to maintain the patents, directed to technology that we license from those third parties. We may also require the cooperation of our future licensor, if any, to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, any licensed patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by any of our future licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize

products or product candidates may be adversely affected, and we may be unable to prevent competitors from making, using and selling competing products.

If the patent applications we hold or may in-license in the future with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for OKI-219 or any future product candidate, it could dissuade other companies from collaborating with us to develop product candidates, and threaten our ability to commercialize OKI-219 or future product candidates. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been and will continue to be the subject of litigation and new legislation, resulting in court decisions, including U.S. Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications in 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 know with certainty whether we were the first to make the inventions claimed in our own patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, 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 that protect our technology or products, in whole or in part, or that 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. For example, the America Invents Act created new administrative post-grant proceedings, including post-grant review, inter partes review and derivation proceedings that allow third parties to challenge the validity of issued patents. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending patents or enforcing proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize their 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents and patent applications may be challenged in the courts or patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. An adverse decision in any such challenge may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and

products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay incurred by the USPTO in examining the patent application (patent term adjustment). The scope of patent protection may also be limited.

Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such 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.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. 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 product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a U.S. patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent.

Depending upon the timing, duration and specifics of FDA marketing approval of OKI-219 and future product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during drug development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is based on the first approved use of a product and is limited to only one patent that covers the approved product, the approved use of the product or a method of manufacturing the product. Such patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. However, the applicable authorities, including the FDA and the USPTO in the United States and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

Laws governing analogous patent term extension (PTE) in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, apply prior to expiration of relevant patents or otherwise satisfy applicable requirements. If we are unable to obtain PTE or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our products will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

Obtaining and maintaining our patent protection depends on 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 noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications will be due to the USPTO and other foreign patent agencies in several stages over the lifetime of our patents and patent applications. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or any of our licensors fails to maintain the patents and patent applications covering OKI-219 or any future product candidate, our competitors may be able to enter the market, which would have an adverse effect on our business.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use or sale of our product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly

predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We may become involved in third-party claims of intellectual property infringement, which may delay or prevent the development and commercialization of OKI-219 and any future product candidate.

Our commercial success depends in part on us avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights and who allege that our product candidates, uses and/or other proprietary technologies infringe their intellectual property rights. Numerous U.S.- and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and future product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future product candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon their rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process, methods of treating certain diseases or conditions that we are pursuing with our product candidates, our formulations including combination therapies, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our current and future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not

exist which might be enforced against our product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the price of our Class A Common Stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property rights, or the patents or other intellectual property rights of any licensors, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe or otherwise violate our patents or other intellectual property rights, or those of our licensors. To counter infringement or unauthorized use or misappropriations, we or any future licensors may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents or any of our current or future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us, such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours or a future licensor is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our or any future licensors' patent claims do not cover the invention, or decide that the other party's use of our or any future licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our or any future licensors' patents could limit our ability to assert our own or any future licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position and our business, financial condition, results of operations and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. For any patents and patent applications that we license from third parties, we may have limited or no right to participate in the defense of such licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our Class A Common Stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our patents, any patents that may be issued as a result of our future patent applications, or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in our best interest or that of our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (the UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any

litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC over the first seven years of the court's existence and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries that are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Patents are of national or regional effect, and filing, prosecuting and defending patents covering OKI-219 and any future product candidate throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions in which we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or any future licensors' inventions in all countries outside the United States, even in jurisdictions where we or any future licensors do pursue patent protection, or from selling or importing products made using our or any future licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or any future licensors' technologies in jurisdictions where we have not obtained patent protection to develop our own products and, further, may export otherwise infringing products to territories where we may have or obtain patent protection, but where patent enforcement is not as strong as in the United States. These unauthorized competitors' products may compete with our products in such jurisdictions and take away our market share where we do not have any issued or licensed patents, and any future 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, trade secrets and other intellectual property protection, particularly those relating to biotechnology products. This could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. In addition, some courts inside and outside of the United States may be less willing or unwilling 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. Even if we are successful, such lawsuits would consume our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we may seek to rely on trade secret protection to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other

elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by our patents. We may not be able to meaningfully protect our trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed to our competitors or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Because we expect to rely on third parties to manufacture OKI-219 and any future product candidates, and we expect to collaborate with third parties on the continuing development of OKI-219 and any future product candidates, we must, at times, share trade secrets with them. We also expect to conduct R&D programs that may require us to share trade secrets under the terms of our partnerships or agreements with CROs. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality and use restrictions and obligations, including material transfer agreements, consulting agreements, manufacturing and supply agreements, confidentiality agreements or other similar agreements with our advisors, employees, contractors, contract manufacturing organizations (or CMOs), CROs, other service providers and consultants prior to disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors CMOs, CROs, other service providers and consultants to publish data potentially relating to our trade secrets, although such agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover such trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Monitoring unauthorized disclosure and detection of unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be 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. For example, significant elements of our products, including confidential aspects of sample preparation, methods of manufacturing, and related processes and software, are based on unpatented trade secrets. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

We may become subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties or claims asserting ownership of what we regard as our own intellectual property.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies, or at research institutions, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may become subject to claims that these individuals have or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of such individual's current or former employer. Further, although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. 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. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or product candidates. In addition, we may lose personnel as a result of such claims, and any such litigation, or the threat thereof, may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies or product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may also be subject to claims that former employers, consultants or other third parties have an ownership interest in our patents or patent applications as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such challenges may also result in our inability to develop, manufacture or commercialize our technologies and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technologies and product candidates. Even if we are successful, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

If our future trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or foreign agencies. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to those of ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement

claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

In addition, any proprietary name we propose to use with our current or future product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

Our intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make formulations or compositions that are the same as or similar to our current or future product candidates, but that are not covered by the pending patent applications or patents that we own or any pending patent applications or patents that we may in-license in the future;
- others may be able to make products that are similar to our current or future product candidates, but that are not covered by the patents that we own or exclusively license and have the right to enforce;
- we, or our future licensors or collaborators, may not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in-license in the future;
- we, or our future licensors, may not have been the first to file patent applications covering certain of our or those licensors' inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our owned intellectual property rights or any patent applications that we may license in the future;
- it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we either own or that we may license in the future may be revoked, modified or held valid or unenforceable, as a result of legal challenges by our competitors;
- issued patents that we either own or may license in the future may not provide us with any competitive advantages;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;

- our competitors may conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our or any future licensors' patent applications, including whether the patent applications that we own or, in the future, in-license, will result in issued patents with claims directed to our product candidates or uses thereof in the United States or in other foreign countries;
- a court may not hold that our patents are valid, enforceable or infringed;
- we may need to initiate litigation or administrative proceedings to enforce or defend our patent rights, which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving the subject matter covered by our patent applications.

Any collaboration or partnership arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in our strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current and future product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

If we fail to comply with our obligations under any license, collaboration or other agreement, such agreements may be terminated, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates.

We may license or otherwise acquire development or commercialization rights to current and future product candidates or data from third parties. If any future licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize future product candidates that may be subject of such licensed rights could be adversely affected. In spite of our efforts, any future licensors might conclude that we are in material breach of obligations under our license agreements. If we breach any material obligations, or uses the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors will have the freedom to seek regulatory approval of, and to market, products identical to our product candidates, and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. Any of these events could adversely affect our business, financial condition, results of operations and prospects.

Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- either party's financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights under our collaborative development relationships to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any of our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we license prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our current or future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities

Further, we or our current or future licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, ownership, claim scope or requests for patent term adjustments. If our current or future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, even where we have the right to control patent prosecution of patents and patent applications under a license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our acquired technologies and current or future licensed technology may be subject to retained rights. Our predecessors or licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or future licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired technologies or current or future licensed technologies, or if we lose our rights to critical acquired or in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products. Our business strategy may depend on the successful development of acquired technologies, and current or future licensed technology, into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidates.

We may not be able to license or acquire new or necessary intellectual property rights or technology from third parties.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these third-party proprietary rights. Further, other parties, including our competitors, may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these patents, we may find it necessary or prudent to obtain licenses to such patents from such parties. The licensing or acquisition of intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. No assurance can be given that we will be successful in-licensing any additional rights or technologies from third parties. Our inability to license the rights and technologies that we have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Failure to obtain any necessary rights or licenses may detrimentally affect our planned development of our current or future product candidates and

could increase the cost and extend the timelines associated with the development of such other product candidates, and we may have to abandon development of the relevant program or product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates or future methods or product candidates, resulting in either an injunction prohibiting their manufacture or future sale or, with respect to their future sale, an obligation on our part to pay royalties or other forms of compensation to third parties, which could be significant.

Risks Related to Our Regulatory Approval and Other Legal Compliance Matters

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory oversight, which may result in significant additional expense, and we may experience unanticipated problems with our product candidates or be subject to penalties if we fail to comply with regulatory requirements.

Even if we obtain regulatory approval for one or more of our product candidates, such product candidates will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submission of safety or other post-market information, among other things. Any regulatory approvals that we receive for our product candidates will require surveillance to monitor safety and efficacy. The FDA may also require a REMS, limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-market testing and surveillance studies, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the product candidate. An unsuccessful post-marketing study or failure to complete such a study could result in requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools as conditions of approval.

Any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased compliance costs. We must also comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval, commonly known as off-label promotion. The holder of an approved NDA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling or manufacturing process. A company that is found to have improperly promoted off-label uses of our products may be subject to significant civil, criminal and administrative penalties.

In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with FDA's current Good Manufacturing Practices (cGMPs) and adherence to commitments made in the NDA or foreign marketing application. If we, the FDA or a comparable foreign regulatory authority discovers previously unknown problems with our product candidates, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug was manufactured, or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

Failure by us to comply with applicable regulatory requirements following approval of any product candidates may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-marketing clinical trials to demonstrate the safety of the product;
- suspension or withdrawal of regulatory approvals;
- issuance of fines, untitled letters, warning letters or holds on clinical trials;
- refusal by regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of a product candidates; and
- injunctions or the imposition of civil or criminal penalties.

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. 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. 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. It is difficult to predict how current and future legislation, executive actions and litigation, including the executive orders, will be implemented, and the extent to which they will impact our business and clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including the FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. To the extent any executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Disruptions at the FDA, the SEC or other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown or other disruption occurs, or if global health or other concerns prevent the FDA or other

regulatory authorities from conducting their regular inspections, reviews or other regulatory activities in a timely manner, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, the FDA announced its intention to postpone most inspections of foreign and domestic manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities, if a prolonged government shutdown occurs, either for global health related reasons or other reasons, preventing the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material effect on our business.

We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example:

- changes to our manufacturing arrangements;
- additions or modifications to product labeling;
- the recall or discontinuation of our products; or
- additional record-keeping requirements.

Any such changes imposed on us could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (as amended, the ACA), was passed, which substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacted the U.S. pharmaceutical industry. The ACA contained provisions that may reduce the profitability of drug products through, among other things, increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. In August 2022, Congress passed the Inflation Reduction Act of 2022 (the IRA), which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including among other changes allowing the federal government to negotiate a maximum fair price for certain high-priced single-source Medicare drugs, imposing penalties and excise taxes for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries. HHS has issued and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, CMS announced the list of the first ten drugs that will be subject to price negotiations. However, various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, as well as future legislative, executive and administrative actions and any future healthcare measures and agency rules

implemented by the government on us and the pharmaceutical industry as a whole, is difficult or impossible to predict. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates if approved.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through the FDA's accelerated approval pathway. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center, which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control prescription drug 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 bulk purchasing and importation from other countries. A number of states are considering or have recently enacted drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. 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.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry, and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict what initiatives may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a competitive price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital

The implementation of cost containment measures or other healthcare reforms may lower the pricing of competitor products or procedures, which in turn may constrain the pricing of our product candidates, if approved, and prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure to what extent these legislative and regulatory proposals will be implemented by the federal and state governments, whether additional legislative

changes will be enacted, whether FDA regulations, guidance or interpretations will be changed or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our current and future arrangements with healthcare professionals, clinical investigators, CROs and customers 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 plan to market, sell and distribute products for which we obtain marketing approval.

Laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute (the AKS), which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Violations are subject to civil and criminal fines and penalties, plus up to three times the remuneration involved, imprisonment and exclusion from government healthcare programs;
- federal civil and criminal false claims laws, including the False Claims Act (FCA), which can be enforced through civil "qui tam" or "whistleblower" actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting or causing to be presented claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the AKS, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the ACA and its implementing regulations, which requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws that may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, including our advisory board arrangements with physicians and any sales and marketing activities after a product candidate has been approved for marketing in the United States, could be subject to legal challenge and enforcement actions. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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, customer incentive programs and other business arrangements. Misconduct by these parties 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 misconduct by these parties, 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 comply with these laws 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, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

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 the success of 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 and radioactive 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 biological, or hazardous materials.

In addition, we may incur substantial costs 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.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations and can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of such trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with

officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials or to obtain necessary permits, licenses, patent registrations and other regulatory approvals, and we may be held liable for the corrupt or other illegal activities of our personnel, agents or partners even if we do not explicitly authorize or have prior knowledge of such activities.

Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct, supervise and monitor certain aspects of our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements and meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

We have relied upon, and plan to continue to rely upon, third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our preclinical studies and clinical trials and to monitor and manage data for our ongoing clinical programs.

We rely on these parties for execution of our trials and generally do not control their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable clinical investigation plan and protocol as well as legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities, for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or CROs fails to comply with applicable GCPs, the clinical data may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators and CROs are not our employees, and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely.

In many cases, our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third parties terminates, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a

new CRO commences work. As a result, delays occur, which can materially impact our ability to meet desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials, and expects 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 such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization and do not intend to develop such infrastructure and capabilities. We rely, and expect to continue to rely, on third party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. Furthermore, we rely on single-source suppliers for our drug substance manufacturing (PharmaBlock Sciences (Nanjing), Inc.) and for our drug product manufacturing (STA Pharmaceutical Hong Kong Limited). We have entered into a master services agreement with each of these service providers; however, under the terms of the master services agreements, the service provider is not obligated to enter into any particular statement of work and there is no pre-determined pricing for the manufacturing services. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing preclinical studies and clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required 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 failure of the third party to manufacture our product candidates 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 their agreements with us;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of their agreements with us;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of third parties to manufacture product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- 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 misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent upon, 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, EMA or others, we will not be able to secure and/or maintain marketing approval for our manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA 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 product candidates or drugs and harm our business and results of operations. 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 product candidates that receive marketing approval on a timely and competitive basis.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity, potency and stability. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage, shipping, quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to Our Business Operations

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified executives, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and need to add executives with operational and commercialization experience as we plan for commercialization of our product candidates and operations as a public company. Failure to attract and retain qualified personnel, particularly at the management level, could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and, as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel and may be required to expend significant financial resources in employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited, and the potential for successfully growing our business will be harmed.

If we engage in acquisitions, in-licensing or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of equity securities resulting in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of management's attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership;
- loss of key personnel;
- uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and our existing products or product candidates; and
- our inability to generate revenue from acquired intellectual property, technology or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in regulatory approval efforts and significantly increase 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 personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly

disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and such an event could disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay clinical development of our product candidates.

Risks Related to Ownership of Our Class A Common Stock

The market price of our Class A Common Stock is expected to be volatile.

The market price of our Class A Common Stock could be subject to significant fluctuations. Some of the factors that may cause the market price of our Class A Common Stock to fluctuate include:

- price and volume fluctuations in the overall stock market from time to time;
- the timing and results of clinical trials for our current product candidates and any future product candidates that we may develop;
- commencement or termination of collaborations for our product development and research programs;
- failure to achieve development, regulatory or commercialization milestones under our collaborations;
- failure or discontinuation of any of our product development and research programs;
- results of preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- the level of expenses related to any of our research programs, clinical development programs or product candidates;
- the results of our efforts to develop additional product candidates;
- regulatory actions with respect to our or our competitors' product candidates or products;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- announced or completed acquisitions of businesses, products or intellectual property by us or our competitors;
- actual or anticipated changes in the financial projections or development timelines we may provide to the public or our failure to meet those projections or timelines;
- market conditions in the biotechnology and pharmaceutical sectors;
- changes in the structure of healthcare payment systems;
- sales of our Class A Common Stock by us or our stockholders, or expectations that such sales may occur, and the expiration of lock-up agreements;
- the recruitment or departure of key personnel;
- the public's reaction to our press releases, other public announcements and our filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- fluctuations in the trading volume of our Class A Common Stock or the size of our public float;
- actual or anticipated changes or fluctuations in our results of operations;
- actual or anticipated developments in our business, our competitors' businesses or changes in the market valuations of similar companies and the competitive landscape generally;

- changes in the market valuations of similar companies;
- failure of securities analysts to maintain coverage of our Class A Common Stock, changes in actual or future expectations of investors or securities analysts or our failure to meet these estimates or the expectations of investors;
- litigation involving us, our industry or both;
- governmental or regulatory actions or audits;
- regulatory or legal developments in the United States and other countries;
- general economic conditions and trends;
- announcement or expectation of additional financing efforts;
- sales of securities by us or our securityholders in the future;
- if we do not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our Class A Common Stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our Class A Common Stock. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results, financial condition and cash flows.

We may be unable to successfully integrate the businesses of Reneo and Legacy OnKure and realize the anticipated benefits of the Merger.

The Merger involved the combination of two companies that previously operated as independent companies. Following the Merger, we must devote significant management attention and resources to integrating the business practices and operations of the separate companies. We may fail to realize some or all of the anticipated benefits of the Merger if the integration process takes longer than expected or is more costly than expected. Potential difficulties in the integration process include the following:

- the inability to successfully combine the businesses of Reneo and OnKure in a manner that permits us to achieve the anticipated benefits from the Merger in the time frame currently anticipated or at all;
- creation of uniform standards, controls, procedures, policies and information systems; and
- potential unknown liabilities and unforeseen increased expenses, delays or regulatory conditions associated with the Merger.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. These competitors also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We will be highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We will incur significant legal, accounting and other expenses as a public company that Legacy OnKure did not incur as a private company, including costs associated with public company reporting obligations under the Exchange Act. Our management team consists of the executive officers of Legacy OnKure prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We will continue to be an emerging growth company and a smaller reporting company, and it cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our Class A Common Stock less attractive to investors.

For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of Reneo's initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires, among other things, that the market value of our Class A Common Stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (if we are also a non-accelerated filer at that time) and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. It cannot be predicted if investors will find our Class A Common Stock less attractive because we may rely on these exemptions. If some investors find

our Class A Common Stock less attractive as a result, there may be a less active trading market for our Class A Common Stock and the price of our Class A Common Stock may be more volatile.

Under the Jumpstart Our Business Startups Act (JOBS Act), emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. It is expected that we will continue to elect to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult. As a result, changes in rules of GAAP or their interpretation, the adoption of new guidance, or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

Additionally, once we are no longer an emerging growth company or a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our Class A Common Stock may be harmed.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, Legacy OnKure was not required to test its internal controls within a specified period. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

In addition to the matters described above in the context of Legacy OnKure being a private company, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our Class A Common Stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and provisions under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our Amended and Restated Certificate of Incorporation and our Amended and Restated 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 holders of our Class A Common Stock might otherwise receive a premium price for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Class A Common Stock, thereby depressing the market price of our Class A Common Stock. In addition, because our board of directors will be responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or

remove current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our Common Stock;
- provide for a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of the stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed (i) only for cause and (ii) only by the affirmative vote of the holders of 66 2/3% or more of the outstanding shares of capital stock then entitled to vote at an election of directors;
- expressly authorize our board of directors to make, alter, amend or repeal our Amended and Restated Bylaws; and
- require supermajority votes of the holders of our Class A Common Stock to amend specified provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then-current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of management.

Our Amended and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative forum, certain designated courts will be the sole and exclusive forum for certain legal actions between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our Amended and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees, to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws; (v) any claim or cause of action as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any of our current or former directors, officers or other employees, governed by the internal-affairs doctrine or otherwise related to our internal affairs, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named

as defendants. This provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

Unless we consent in writing to the selection of an alternate forum, the United States federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our Amended and Restated Bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to these exclusive forum provisions. The forum selection provisions in our Amended and Restated Bylaws may limit our stockholders' ability to litigate disputes with us in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. There is uncertainty as to whether a court would enforce such provisions, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our Amended and Restated Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over actions brought under the Securities Act or the rules and regulations promulgated thereunder. In addition, these forum selection provisions may impose additional litigation costs for stockholders who determine to pursue any such lawsuits against us.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the DGCL, our Amended and Restated Bylaws and the indemnification agreements that we have entered with our directors and officers provide that:

- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we are not obligated pursuant to our Amended and Restated Bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our Amended and Restated Bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend the provisions of our Amended and Restated Bylaws to reduce our indemnification obligations to directors, officers, employees and agents.

We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably

believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our Class A Common Stock will be your sole source of gain, if any, for the foreseeable future.

An active trading market for our Class A Common Stock may not develop, and the holders of our Class A Common Stock may not be able to resell their shares of our Class A Common Stock for a profit, if at all.

Prior to the Merger, there had been no public market for shares of Legacy OnKure capital stock. An active trading market for our Class A Common Stock may never develop or be sustained. If an active market for our Class A Common Stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares of our Class A Common Stock at an attractive price or at all.

We could be subject to securities class action litigation, which is expensive and could divert management attention.

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 resources, which could harm our business, operating results, or financial condition.

Reneo's winddown of its historical operations, the suspension of development activities and the Merger, resulting in the conversion of Legacy OnKure into a public company, make us subject to the SEC requirements applicable to reporting shell company business combinations. As a result, we will be subject to more stringent reporting requirements, offering limitations and resale restrictions.

According to SEC guidance, the requirements applicable to reporting shell company business combinations apply to any company that sells or otherwise disposes of its historical assets or operations in connection with or as part of a plan to combine with a non-shell private company in order to convert the private company into a public one. Prior to the Merger, Reneo suspended its development activities and, as such, we are subject to the SEC requirements applicable to reporting shell company business combinations, which are as follows:

- we were required file a Current Report on Form 8-K to report the Form 10 type information (the Super 8-K) after the closing of the Merger reflecting our status as an entity that is not a shell company;
- we are not eligible to use a Form S-3 until one year after the filing of the Super 8-K;
- we must wait at least 60 calendar days after the filing of the Super 8-K to file a Form S-8 for any equity plans or awards;
- we are an "ineligible issuer" for three years following the closing of the Merger, which will prevent us from (i) incorporating by reference in our Form S-1 filings, (ii) using a free writing prospectus or (iii) taking advantage of the well-known seasoned issuer (also known as a WKSI) status despite our public float;
- investors who (i) were affiliates of Legacy OnKure at the time the Merger was submitted for the vote or consent of Legacy OnKure stockholders, (ii) received securities in the Merger and (iii) publicly offer

or sell such securities will be deemed to be engaged in a distribution of such securities, and therefore would be underwriters with respect to resales of those securities; and

- Rule 144(i)(2) limits the ability of holders of restricted securities and any affiliates of the public company to publicly resell Rule 145(c) securities per Rule 145(d), as well as any other of our "restricted" or "control" securities per Rule 144, until one year after the Super 8-K is filed with the SEC.

The foregoing SEC requirements will increase our time and cost of raising capital, offering stock under equity plans, and complying with securities laws. Furthermore, such requirements will add burdensome restrictions on the resale of our Class A Common Stock by our affiliates and any holders of our "restricted" or "control" securities.

Future sales of shares by existing stockholders could cause our Class A Common Stock price to decline.

If existing securityholders sell, or indicate an intention to sell, substantial amounts of our Class A Common Stock in the public market after legal restrictions on resale lapse, the trading price of our Class A Common Stock could decline. Of the outstanding shares of our Class A Common Stock, approximately 6,796,137 shares will be available for sale in the public market beginning 180 days after the closing of the Merger as a result of the expiration of lock-up agreements between Reneo and Legacy OnKure on the one hand and certain securityholders of Reneo and Legacy OnKure on the other hand. All other outstanding shares of our Class A Common Stock, other than "restricted" or "control" securities per Rule 144, are currently freely tradable, without restriction, in the public market. In addition, shares of our Class A Common Stock that are subject to outstanding options or warrants will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our Class A Common Stock could decline.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 49.8% of the outstanding shares of our Class A Common Stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the stock price and trading volume of our Class A Common Stock could decline.

The trading market for our Class A Common Stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our Class A Common Stock, and such lack of research coverage may adversely affect the market price of our Class A Common Stock. In the event that we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our Class A Common Stock could decline if one or more equity research analysts downgrades our stock or issues other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on it regularly, demand for our Class A Common Stock could decrease, which in turn could cause our stock price or trading volume to decline.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which

changes may have retroactive application) could adversely affect us or our stockholders. For example, the United States recently enacted the IRA, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act of 2017 (the Tax Act) eliminated the option to deduct research and development expenditures and required taxpayers to amortize them generally over five or fifteen years. However, recently proposed tax legislation, if enacted, would restore the ability to deduct domestic research and development expenditures in the current year through 2025 and would retroactively restore this benefit for 2022 and 2023. Any change in tax law will be accounted for in the period of enactment. We will assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we will make about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business condition.

Our ability to use net operating loss carryforwards and other tax attributes may be limited, including as a result of the Merger.

As of December 31, 2023 and 2022, Reneo had U.S. federal net operating loss carryforwards of $110.9 million and $74.7 million, respectively (which are not subject to expiration other than the net operating loss carryforwards generated prior to 2018 of $1.6 million, which will begin to expire in 2034), and state net operating loss carryforwards of $1.8 million and $1.6 million, respectively (which begin to expire in various amounts in 2034). In addition, as of December 31, 2023, Legacy OnKure had approximately $36.7 million of federal and state net operating loss carryforwards. Approximately $1.5 million federal net operating loss carryforwards expire through 2037 and approximately $35.2 million have an indefinite life. Legacy OnKure's state net operating loss carryforwards are subject to similar survival periods.

Under current law, U.S. federal net operating loss carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such net operating loss carryforwards is limited to 80% of taxable income for taxable periods beginning after December 31, 2020. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Code, U.S. federal net operating loss carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points (by value) over their lowest ownership percentage within a rolling three-year period. Legacy OnKure had not conducted a study to determine whether such an ownership change has occurred in the previous years to impair the use of its net operating loss carryforwards. Reneo may have experienced such ownership changes in the past, and Reneo is expected to be deemed to have experienced an ownership change in connection with the Merger and the Concurrent PIPE Investments. Our ability to utilize these net operating loss carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including, as discussed above, in connection with the Merger and the Concurrent PIPE Investments or other transactions. Similar rules may apply under state tax laws. In addition, California has recently proposed a temporary suspension on the use of state net operating loss carryforwards for certain businesses, which may adversely affect us if we earn taxable income in the impacted tax years. Other state tax limitations may apply. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected.

Unfavorable global economic conditions could adversely affect our business, financial condition, results of operations or cash flows.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly

resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

Reneo commenced its initial public offering (IPO) pursuant to the registration statement on Form S-1 (File No. 333-254534) that was declared effective on April 8, 2021 and registered an aggregate of 7,187,500 shares of our common stock. On April 13, 2021, Reneo completed its IPO and sold 6,250,000 shares of its common stock at a public offering price of $15.00 per share for aggregate gross proceeds of $93.8 million before deducting underwriters' discounts and commissions and offering-related expenses. Net proceeds, after deducting underwriting discounts and commissions of $6.6 million and offering expenses of approximately $2.6 million, were $84.6 million. Jefferies LLC, SVB Securities LLC (now Leerink Partners LLC) and Piper Sandler & Co. acted as joint book-running managers.

As of September 30, 2024, Reneo used approximately $83.5 million of the net proceeds from the IPO. We have invested the remaining net proceeds in highly liquid money market funds and short-term investments. The remaining net proceeds from the IPO will be used to fund our operations. None of the offering proceeds were paid directly or indirectly to any of Reneo or our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
2.1*	Agreement and Plan of Merger, dated May 10, 2024, by and among the Registrant, Radiate Merger Sub I, Inc., Radiate Merger Sub II, LLC and OnKure, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 13, 2024).
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 8, 2024).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 8, 2024).
4.1	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated December 9, 2020 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-254534), filed with the SEC on March 19, 2021).
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* Certain exhibits and/or schedules (and similar attachments) have been omitted pursuant to the provisions of Regulation S-K, Item 601(a)(5). The Registrant hereby undertakes to furnish supplementally to the SEC upon request by the SEC copies of any of the omitted exhibits and schedules (or similar attachments).

** The certification attached as Exhibit 32.1 accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

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

Date: November 7, 2024

RENEO PHARMACEUTICALS, INC.

By:	/s/ Nicholas A. Saccomano, Ph.D.
Name:	Nicholas A. Saccomano, Ph.D.
Title:	President and Chief Executive Officer (Principal Executive Officer)

By:	/s/ Jason Leverone
Name:	Jason Leverone
Title:	Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Nicholas A. Saccomano, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OnKure Therapeutics, Inc. (the "registrant");
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.

Date: November 7, 2024

By:	/s/ Nicholas A. Saccomano, Ph.D.
Name:	Nicholas A. Saccomano, Ph.D.
Title:	President and Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Jason Leverone, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OnKure Therapeutics, Inc. (the "registrant");
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.

Date: November 7, 2024

By:	/s/ Jason Leverone
Name:	Jason Leverone
Title:	Chief Financial Officer
	(Principal Financial and Accounting Officer)

Exhibit 32.1

Statement Pursuant to 18 U.S.C. Section 1350,
As required by Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Gregory J. Flesher, President and Chief Executive Officer of OnKure Therapeutics, Inc. (the "Company"), and Jennifer P. Lam, Senior Vice President, Finance and Administration of the Company, each hereby certifies that, to the best of his or her knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2024	By:	/s/ Nicholas A. Saccomano, Ph.D.
	Name:	Nicholas A. Saccomano, Ph.D.
	Title:	President and Chief Executive Officer (Principal Executive Officer)
Date: November 7, 2024	By:	/s/ Jason Leverone
	Name:	Jason Leverone
	Title:	Chief Financial Officer (Principal Financial and Accounting Officer)

This certification accompanies the Quarterly Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.