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 June 30, 2026
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**	**80301**
(Address of Principal Executive Offices)	**(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 August 3, 2026, the registrant had 40,496,309 shares of Class A common stock, $0.0001 par value per share outstanding.

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CAUTIONARY 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:

- the ability of our current and future clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the beneficial characteristics, and the potential safety, efficacy, and therapeutic effects of our current and future product candidates;
- 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;
- the sufficiency of our cash, cash equivalents and marketable securities to fund our operations;
- the initiation, timing, progress and results of our preclinical and clinical activities for OKI-345, OKI-355 and any other product candidates we are developing or may in the future develop, including the timing of initiation and completion of studies or trials and related preparatory work, the anticipated timing for our disclosure of the results of such studies or trials and the announcement of product candidates;
- the potential of our technologies and our ability to execute on our corporate strategy;
- expectations regarding the approval and use of our product candidates in combination with other drugs;
- our expectations regarding the market opportunities for our product candidates and PI3Kα inhibitors generally;
- 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;
- expectations regarding our reliance on third parties for the manufacture of our product candidates for clinical trials;
- our competitive position and the success of competing therapies that are or may become available; and
- existing regulations and regulatory developments in the United States and other jurisdictions.

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.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

ONKURE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(Unaudited)

	June 30, 2026	December 31, 2025
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 166,502	$ 59,050
Marketable securities, available for sale	9,884	—
Prepaid expenses and other current assets	1,291	1,789
Total current assets	177,677	60,839
Property and equipment, net	435	618
Operating lease right-of-use asset	840	387
Other assets	401	273
Total assets	$ 179,353	$ 62,117
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,999	$ 1,433
Accrued expenses and other current liabilities	4,308	3,939
Operating lease liabilities, current portion	336	549
Total current liabilities	6,643	5,921
Long-term operating lease liabilities	590	—
Other long-term liabilities	12	12
Total liabilities	7,245	5,933
Commitments and contingencies		
Stockholders' equity:		
Common stock, Class A, $0.0001 par value; 200,000,000 shares authorized; 40,496,309 and 13,673,565 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	4	1
Common stock, Class B, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2026 and December 31, 2025	—	—
Additional paid-in capital	416,861	270,424
Accumulated other comprehensive loss	(13)	—
Accumulated deficit	(244,744)	(214,241)
Total stockholders' equity	172,108	56,184
Total liabilities and stockholders' equity	$ 179,353	$ 62,117

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

ONKURE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 12,611	$ 12,613	$ 24,318	$ 25,625
General and administrative	4,288	3,711	8,196	7,699
Total operating expenses	16,899	16,324	32,514	33,324
Loss from operations	(16,899)	(16,324)	(32,514)	(33,324)
Other income:				
Interest income	1,553	934	2,011	2,009
Total other income	1,553	934	2,011	2,009
Net loss	$ (15,346)	$ (15,390)	$ (30,503)	$ (31,315)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities, net	(13)	—	(13)	—
Total Comprehensive loss	$ (15,359)	$ (15,390)	$ (30,516)	$ (31,315)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.31)	$ (1.14)	$ (0.96)	$ (2.33)
Weighted average shares outstanding:				
Basic and diluted	49,869,177	13,509,080	31,871,862	13,466,942

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

ONKURE THERAPEUTICS, INC
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share information)
(Unaudited)

	Class A Common Stock		Class B Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, December 31, 2024	**12,660,590**	**$1**	**686,527**	**$—**	**$258,551**	**$—**	**$(154,724)**	**$103,828**
Vesting of restricted stock units, net	94,758	—	—	—	—	—	—	—
Share-based compensation	—	—	—	—	2,745	—	—	2,745
Net loss	—	—	—	—	—	—	(15,925)	(15,925)
Balance, March 31, 2025	**12,755,348**	**1**	**686,527**	**—**	**261,296**	**—**	**(170,649)**	**90,648**
Vesting of restricted stock units	88,086	—	—	—	—	—	—	—
Share-based compensation	—	—	—	—	2,908	—	—	2,908
Net loss	—	—	—	—	—	—	(15,390)	(15,390)
Balance, June 30, 2025	**12,843,434**	**1**	**686,527**	**—**	**264,204**	**—**	**(186,039)**	**78,166**
Vesting of restricted stock units	18,238	—	—	—	—	—	—	—
Share-based compensation	—	—	—	—	2,961	—	—	2,961
Net loss	—	—	—	—	—	—	(14,699)	(14,699)
Balance, September 30, 2025	**12,861,672**	**1**	**686,527**	**—**	**267,165**	**—**	**(200,738)**	**66,428**
Conversion of Class B Common Stock to Class A Common Stock	686,527	—	(686,527)	—	—	—	—	—
Issuance of Class A Common Stock under the Employee Stock Purchase Plan	107,930	—	—	—	240	—	—	240
Vesting of restricted stock units	17,436	—	—	—	—	—	—	—
Share-based compensation	—	—	—	—	3,019	—	—	3,019
Net loss	—	—	—	—	—	—	(13,503)	(13,503)
Balance, December 31, 2025	**13,673,565**	**1**	**—**	**—**	**270,424**	**—**	**(214,241)**	**56,184**
Issuance of Class A Common Stock and pre-funded warrants in connection with 2026 Private Placement, less issuance costs	26,713,638	3	—	—	140,543	—	—	140,546
Vesting of restricted stock units	8,277	—	—	—	—	—	—	—
Share-based compensation	—	—	—	—	2,780	—	—	2,780
Net loss	—	—	—	—	—	—	(15,157)	(15,157)
Balance, March 31, 2026	**40,395,480**	**4**	**—**	**—**	**413,747**	**—**	**(229,398)**	**184,353**
Issuance costs in connection with 2026 Private Placement	—	—	—	—	(138)	—	—	(138)
Issuance of Class A Common Stock under the Employee Stock Purchase Plan	92,675	—	—	—	203	—	—	203
Vesting of restricted stock units	8,154	—	—	—	—	—	—	—
Share-based compensation	—	—	—	—	3,049	—	—	3,049
Other comprehensive loss	—	—	—	—	—	(13)	—	(13)
Net loss	—	—	—	—	—	—	(15,346)	(15,346)
Balance, June 30, 2026	**40,496,309**	**$4**	**—**	**$—**	**$416,861**	**$(13)**	**$(244,744)**	**$172,108**

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

ONKURE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

(Unaudited)

	Six Months Ended June 30,	
	2026	**2025**
	(in thousands)	
Cash flows from operating activities:		
Net loss	$ (30,503)	$ (31,315)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	5,829	5,653
Depreciation and amortization	191	235
Amortization of right-of-use asset - operating	200	189
Accretion of discount on marketable securities, net	(30)	—
Change in operating assets and liabilities:		
Prepaid and other assets	370	1,057
Accounts payable, accrued and other liabilities	927	(2,876)
Lease liabilities	(276)	(262)
Other long-term liabilities	—	40
Net cash used in operating activities	(23,292)	(27,279)
Cash flows from investing activities:		
Purchases of marketable securities	(9,867)	—
Purchases of property and equipment	(8)	(31)
Net cash used in investing activities	(9,875)	(31)
Cash flows from financing activities:		
Proceeds from the issuance of Class A Common Stock and pre-funded warrants in connection with 2026 Private Placement	149,999	—
Payment of issuance costs associated with the 2026 Private Placement	(9,583)	—
Proceeds from sale of stock under the employee stock purchase plan	203	—
Payment of issuance costs associated with the Concurrent Financing	—	(37)
Payment of reverse recapitalization transaction costs	—	(40)
Net cash provided by (used in) financing activities	140,619	(77)
Net increase (decrease) in cash and cash equivalents	107,452	(27,387)
Cash and cash equivalents, beginning of period	59,050	110,761
Cash and cash equivalents, end of period	$ 166,502	$ 83,374
Supplemental disclosure of noncash financing activities:		
Leased assets obtained in exchange for operating lease liabilities, upon extension	$ 653	$ —
2026 Private Placement issuance costs included in accounts payable	$ 8	$ —

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

ONKURE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization and Business

OnKure Therapeutics, Inc. ("OnKure" or the "Company") is a clinical-stage biopharmaceutical company focused on the discovery and development of precision medicines that target biologically validated drivers of vascular anomalies and cancers that are underserved by available therapies. Using a structure- and computational chemistry-driven drug design platform, OnKure is committed to improving clinical outcomes for patients by building a pipeline of small molecule drugs designed to selectively target specific mutations thought to be key drivers of cancer and vascular anomalies. The Company was formed in 2014 as Reneo Pharmaceuticals, Inc. ("Reneo") under the laws of the State of Delaware. On October 4, 2024, the Company changed its name to OnKure Therapeutics, Inc.

Merger with Reneo

On October 4, 2024, Radiate Merger Sub I, Inc. ("Merger Sub I") a wholly owned subsidiary of Reneo completed its merger with and into OnKure, Inc. (referred to herein as "Legacy OnKure"), with Legacy OnKure continuing as the surviving entity as a wholly owned subsidiary of Reneo. This transaction is referred to as the "Merger." Following the Merger, Reneo changed its name to OnKure Therapeutics, Inc. Legacy OnKure was subsequently merged into the Company. The Merger was effected pursuant to an 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 Radiate Merger Sub II, LLC, a Delaware limited liability company ("Merger Sub II"), and Legacy OnKure. In connection with the Merger Agreement, certain parties entered into a subscription agreement with the Company to purchase shares of Reneo's common stock for an aggregate purchase price of $65.0 million contingent upon the concurrent consummation of the Merger (the "Concurrent Financing"). On October 4, 2024 (the "Merger Closing Date"), the Merger and the Concurrent Financing closed.

The Merger was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States of America ("GAAP"). For accounting purposes, Legacy OnKure is considered the accounting acquirer and Reneo is the acquired company based on the terms of the Merger Agreement and other factors, such as relative voting rights and the composition of the Company's board of directors and senior management. Accordingly, the Merger was treated as the equivalent of Legacy OnKure issuing stock to acquire the net assets of Reneo. As a result of the Merger, the net assets of Reneo were recorded at their acquisition-date fair value in the financial statements of the Company and the reported operating results prior to the Merger are those of Legacy OnKure. Legacy OnKure's historical financial statements became the historical consolidated financial statements of the Company.

Risks and Uncertainties

The board of directors of the Company (the "Board") discusses with management macroeconomic and geopolitical developments, including inflation, instability in the banking and financial services sector, tightening of the credit markets, international conflicts, cybersecurity, tariffs, and sanctions so that the Company can be prepared to react to new developments as they arise. The Board and the management of the Company are carefully monitoring these developments and the resulting economic impact on the Company's financial condition and results of operations.

Liquidity

The Company had recurring losses from operations, an accumulated deficit of $244.7 million, and cash, cash equivalents and marketable securities of $176.4 million as of June 30, 2026. The Company's ability to fund its ongoing operations is highly dependent upon raising additional capital through the issuance of equity securities, issuing debt or other financing vehicles.

On November 6, 2025, the Company filed a shelf registration statement with the U.S. Securities and Exchange Commission ("SEC") on Form S-3, which became effective with the SEC on November 25, 2025, and

that allows it to undertake various equity and debt offerings (the "Registration Statement"). Additionally, the Company filed a prospectus supplement to the Registration Statement and entered into a sales agreement (the "ATM Sales Agreement") with Leerink Partners LLC ("Leerink Partners") under which the Company may offer and sell shares (the "ATM Placement Shares") of the Company's Class A common stock, $0.0001 par value per share (the "Common Stock"), from time to time having aggregate sales proceeds of up to $16.0 million, through an "at the market offering" program (the "ATM") under which Leerink Partners acts as sales agent. The Company has not yet offered or sold any shares of Common Stock under the ATM. See Note 9 for further discussion.

On March 31, 2026 the Company closed the 2026 Private Placement (as defined below). The aggregate gross proceeds from the 2026 Private Placement were approximately $150.0 million, before deducting placement agent fees and offering expenses. See Note 9 for further discussion.

The Company expects to continue to generate operating losses in the foreseeable future. The Company's ability to secure additional capital principally depends on its potential for success in discovering and developing its product candidates. The Company cannot provide assurance that additional capital will be available on acceptable terms, if at all. The issuance of additional equity or debt securities will likely result in substantial dilution to the Company's stockholders. Should additional capital not be available to the Company, or not be available on acceptable terms, the Company may be required to modify its operational plans and may be unable to realize value from its assets or discharge its liabilities in the normal course of business, which may, among other alternatives, cause the Company to delay, substantially reduce, or discontinue operational activities to conserve cash, which could have a material adverse effect on the Company's ability to achieve its intended business objectives.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As of December 31, 2025, the Company had determined that substantial doubt about the Company's ability to continue as a going concern for a period of at least 12 months from the date of the issuance of those financial statements did exist. However, following completion of the 2026 Private Placement (see Note 9), management believes the Company's cash, cash equivalents and marketable securities will be sufficient to fund its current operating plan for at least the next 12 months from the date of issuance of these condensed consolidated financial statements and as such substantial doubt has been alleviated.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The unaudited Condensed Consolidated Financial Statements of the Company have been prepared in accordance with GAAP for interim financial information and with the rules and regulations of the SEC. Accordingly, since they are interim statements, they do not include all of the information and notes required by GAAP for complete consolidated financial statements. The Company's condensed consolidated financial statements reflect the operation of the Company and its former wholly owned subsidiaries OnKure, Inc. and Merger Sub II. As of December 31, 2025, all subsidiaries had been merged into the Company. All intercompany balances and transactions among the consolidated entities have been eliminated in consolidation.

In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Results of operations and cash flows for the interim periods presented herein are not necessarily indicative of the results that would be achieved during a full year of operations or in future periods. These unaudited Condensed Consolidated Financial Statements and notes thereto should be read in conjunction with the Consolidated Financial Statements and notes thereto included in the Company's Form 10-K.

Marketable Securities, Available-for-Sale

All marketable securities have been classified as "available-for-sale" and are carried at fair value, based upon quoted market prices. The Company considers its available-for-sale portfolio as available for use in current operations. Accordingly, the Company classifies its investments as short-term marketable securities, even though the stated maturity date may be one year or more beyond the current balance sheet date. Unrealized gains and losses, net of any related tax effects, are excluded from earnings and are included in other comprehensive income (loss) and reported as a separate component of stockholders' equity until realized. Interest income, realized gains and losses, and credit-related losses, if any, on available-for-sale securities are included in other income. The cost of securities sold is based on the specific-identification method. The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity. In accordance with the Company's investment policy,

management invests in money market funds and U. S. government securities. The Company has not experienced any allowances for credit losses on its deposits of cash, cash equivalents, and marketable securities since inception.

Segment Information

The Company operates in one operating segment: clinical research. All equipment and other property and equipment are physically located within the United States.

Use of Estimates

The preparation of the Company's consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Although these estimates are based on the Company's knowledge of current events and actions it may take in the future, actual results may ultimately differ from these estimates. The most significant estimates relate to the accrual of external research and development expenses, and the fair value of stock options.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss includes net loss as well as other changes in stockholders' equity which includes certain changes in equity that are excluded from net loss. The Company's only element of other comprehensive income is unrealized losses on marketable securities.

Research and Development Expenses

Research and development ("R&D") costs are expensed as incurred in performing research and development activities. The costs include employee-related expense, including salaries, severance, benefits, share-based compensation, costs of research and development activities conducted by third parties on the Company's behalf, costs to have clinical trial materials manufactured, fees for acquiring and maintaining licenses under third-party license agreements, consulting fees, depreciation, and facilities and overhead costs.

Accrued Research and Development Expenses

The Company records research and development expenses in the period in which it receives or takes ownership of the applicable goods or when the applicable services are performed. The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants, and contract research organizations, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company reflects research and development expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of its preclinical studies or clinical trials, as measured by the timing of various aspects of the study or related activities. The Company determines accrual estimates through a review of the underlying contracts along with the preparation of financial models considering discussions with research and other key personnel as to the progress of studies, trials, or other services being conducted. During a study or trial, the Company adjusts its rate of expense recognition if actual results differ from its estimates. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as an expense in the period that the related goods are consumed, or services are performed.

Pre-funded Common Stock Warrants

The Company accounts for warrants to purchase shares of its common stock in accordance with the guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The Company classifies warrants issued for the purchase of shares of its common stock as either equity or liability instruments based on an assessment of the specific terms and conditions of each respective contract. Such assessment includes determining whether the warrants are freestanding financial instruments or embedded in a host instrument, whether the warrants are liabilities within the scope of ASC 480, whether the warrants meet the definition of a derivative in ASC 815 and whether the warrants meet the requirements for equity classification pursuant to the indexation and equity classification criteria in ASC 815.

The Company determines the classification for its warrants at the time of issuance and updates its assessment as necessary. Warrants that meet all of the criteria for equity classification are recorded as a component of additional paid-in capital and are not subsequently remeasured. The 2026 PIPE Pre-Funded Warrants are classified as equity in the condensed consolidated financial statements.

Share-Based Compensation

The Company maintains an equity incentive compensation plan under which incentive stock options and nonqualified stock options to purchase Common Stock, and restricted stock units for Common Stock, are granted to employees, board of directors, and non-employee consultants. Stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the requisite service or performance period. The fair value of stock options granted to employees is estimated using the Black-Scholes option pricing model.

The Black-Scholes valuation method requires certain assumptions be used as inputs, such as the fair value of the underlying Common Stock, expected term of the option before exercise, expected volatility of the Company's Common Stock, risk-free interest rate and expected dividend. Options granted have a maximum contractual term of 10 years. The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted using the simplified method, which represents the arithmetic average of the original contractual term of the stock option and its weighted-average vesting term. The expected volatility of stock options is based on the historical volatility of several publicly traded companies in similar stages of clinical development. The Company will continue to apply this process until enough historical information regarding the volatility of its stock price becomes available. The risk-free interest rates used are based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to the expected term of the stock options. The Company has historically not declared or paid any dividends and does not currently expect to do so in the foreseeable future, and therefore has estimated the dividend yield to be zero. (See Note 10).

The Company recognizes stock-based compensation expense for grants under its various equity incentive plans and employee stock purchase plan. The Company accounts for all stock-based awards granted to employees and directors at their fair value and recognizes compensation expense over the award's vesting period. Determining the amount of stock-based compensation to be recorded requires the Company to develop estimates of fair values of stock options as of the grant date. The Company calculates the grant date fair values of stock options using the Black-Scholes valuation model, which requires the input of subjective assumptions, including but not limited to expected stock price volatility over the term of the awards and the expected term of stock options. The fair value of restricted stock awards granted to employees is based on the quoted closing market price per share on grant date.

The Company estimates stock awards fair value on the date of grant using the Black-Scholes valuation, with the vesting being subject to service requirements. The Company accounts for forfeitures when they occur.

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values.

The carrying amounts of the Company's financial assets and liabilities, such as cash, cash equivalents, marketable securities, receivables, prepaid and other current assets, accounts payable, and accrued expenses approximate their fair values because of the short term nature of these instruments.

Cash and Cash Equivalents

All highly liquid investments with maturities of 90 days or less, at the time of purchase, are classified as cash equivalents. Cash equivalents are reported at cost, which approximates fair value. The Company's cash and cash equivalents consist of money held in demand depository accounts, money market funds and U. S. government securities with maturities of 90 days or less. The carrying amount of cash and cash equivalents was $166.5 million and $59.1 million as of June 30, 2026 and December 31, 2025, respectively, which approximates fair value and was determined based upon Level 1 inputs. The money market account is valued using quoted market prices with no valuation adjustments applied and is categorized as Level 1.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains accounts in federally insured financial

institutions. At times, amounts held in federally insured accounts are above the federally insured limit of $250 thousand. Management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which these deposits are held and of the money market funds in which these investments are made.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity issuances as deferred offering costs until such equity issuances are consummated. After consummation of the equity issuance, these costs are recorded as a reduction in the capitalized amount associated with the equity issuance. Should the equity issuance be abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the statement of operations. Deferred offering costs as of June 30, 2026 and December 31, 2025 were $0.4 million and $0.2 million. Such costs are classified in other non-current assets in the accompanying balance sheets

Leasing – Lessee Accounting

The Company determines if an arrangement is a lease at inception. The Company's operating lease agreements are primarily for office space and research labs.

For operating leases with a term greater than one year, the Company recognizes the right-of-use ("ROU") assets and lease liabilities related to the lease payments on its balance sheet. The lease liabilities are initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date. The ROU assets represent the Company's right to use the underlying assets for the term of the lease and the lease liabilities represent the Company's obligation to make lease payments arising for the agreements. ROU assets are initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received. The ROU asset is periodically reviewed for impairment unless a triggering event occurs. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Variable lease payments, except for the ones that depend on index or rate, are excluded from the calculation of the ROU assets and lease liabilities and are recognized as variable lease expense in the statements of operations and comprehensive loss in the period in which they are incurred. Sublease inflows are netted against the respective lease outflows.

As the interest rate implicit in the Company's leases is not readily determinable, the Company uses its estimated incremental borrowing rate in its present value calculations. Operating leases with a term of less than one year are recognized as a lease expense over the term of the lease, with no asset or liability recognized on the balance sheet.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This ASU requires more detailed disclosures, on an annual and interim basis, about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. This ASU may be applied either prospectively or retrospectively. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued *ASU 2025-11 Interim Reporting (Topic 270): Narrow-Scope Improvements.* This standard clarifies current interim reporting requirements on Topic 270 and introduces a disclosure principle requiring entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. This standard will be effective for fiscal years beginning after December 15, 2027, with the option to apply it retrospectively. Early adoption is allowed. The Company is currently assessing the potential impact of this guidance on its consolidated financial statement disclosures.

In December 2025, the FASB issued *ASU 2025-12 Codification Improvements.* This standard makes certain incremental improvements to generally accepted accounting principles. This standard will be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual periods. The Company is currently assessing the potential impact of this guidance on its consolidated financial statements and related disclosures.

The Company continues to monitor new accounting pronouncements issued by the FASB and does not believe any accounting pronouncements issued through the date of this report will have a material impact on its financial statements.

3. Segment

The Company is a publicly listed company focused on the development of clinical and pre-clinical product candidates with a single reportable segment: clinical research. The accounting policies of the clinical research segment are the same as those described in the summary of significant accounting policies.

The Company has yet to generate revenue and anticipates substantial expenses and operating losses as it advances its product candidates through clinical trials and regulatory processes.

The Company's Chief Operating Decision Maker ("CODM") is the senior executive committee that is comprised of the Chief Executive Officer and the Chief Financial Officer. The CODM assesses financial performance primarily using operating expenses as reported on the statement of operations, supplemented by internal budget and forecast models to guide resource allocation and performance evaluation. Segment assets are reported as total assets on the Company's consolidated balance sheet, and segment loss is reflected as net loss in the Company's consolidated statements of operations and comprehensive loss, effectively mirroring the Company's overall financial position due to its single-segment structure. The Company does not have intra-entity sales or transfers.

	Clinical Research Segment			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
	(in thousands)			
Operating expenses:				
Direct program expense	$ 7,487	$ 7,491	$ 14,204	$ 15,363
Indirect program expense	722	432	1,196	958
Workforce salaries and benefits	4,234	4,343	8,694	8,750
Share-based compensation expense	3,049	2,908	5,829	5,653
General corporate expenses	1,407	1,150	2,591	2,600
Segment net loss	16,899	16,324	32,514	33,324
Reconciliation of loss:				
Interest income	(1,553)	(934)	(2,011)	(2,009)
Adjustments and reconciling items	(1,553)	(934)	(2,011)	(2,009)
Net loss	$ 15,346	$ 15,390	$ 30,503	$ 31,315

4. Leases

The Company's headquarters are located in Boulder, Colorado, where it leases office and lab facilities under operating leases that were amended in June 2026 to extend the lease for an additional three year period and which expire in December 2029, resulting in an additional $653 thousand ROU asset and lease liabilities recognized in June 2026. In the Merger with Reneo, the Company assumed the lease in Irvine, California, where it leases office space under a lease agreement that expires in November 2026 (the "Irvine lease"). In January 2025, the Company entered into a sublease on the Irvine lease for all of the leased square footage, which expires in November 2026. Payments under the sublease for the three and six months ended June 30, 2026 were $61 and $122 thousand, respectively, and were netted against operating lease costs in the Statement of Operations. Payments under the sublease for the three and six months ended June 30, 2025 were $59 thousand and $113 thousand, respectively, and were netted against operating lease costs in the Statement of Operations

ROU assets and lease liabilities for operating leases as included in the Company's financial statements are as follows (in thousands):

	June 30, 2026	December 31, 2025
Operating lease right-of-use assets	$ 840	$ 387
Current operating lease liabilities	336	549
Noncurrent operating lease liabilities	590	—
Total lease liabilities	$ 926	$ 549

Lease expense for operating leases, net of sublease receipts, as included in the Company's financial statements are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating lease cost	$ 49	$ 45	$ 92	$ 96
Variable lease expense	42	29	85	74

Lease term, discount rates, and additional information for operating leases are as follows (in thousands):

	As of June 30,	
	2026	2025
Weighted-average remaining lease term - operating leases (years)	3.08	1.57
Weighted-average discount rate - operating leases	8.8%	4.5%
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 291	$ 282

The aggregate maturities of the Company's operating lease liabilities were as follows as of June 30, 2026 (in thousands):

Remaining in 2026	$ 269
2027	255
2028	262
2029	270
Total future minimum lease payments	1,056
Less: imputed interest	(130)
Less: current portion	(336)
Operating lease liability, net of current portion	$ 590

5. Net Loss Per Share

The Company 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, including the weighted average effect of the 2026 PIPE Pre-Funded Warrants, 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. Shares of Common Stock to be issued upon exercise of all outstanding stock options and restricted stock units were excluded from the diluted net loss per share calculation for the six months ended June 30, 2026 and 2025 because such shares are anti-dilutive.

Anti-dilutive securities outstanding during the period not included in the diluted net loss per share calculation include the following:

	June 30,	
	2026	**2025**
Outstanding common stock options	4,084,043	3,054,036
Unvested restricted stock units	24,488	59,983
	4,108,531	3,114,019

6. 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 the Company'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 the Company. Unobservable inputs are inputs that reflect the Company'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 the Company 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. The Company'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. The Company's financial assets are subject to fair value measurements on a recurring basis.

The Company categorizes its money market funds as Level 1 and U.S. treasury securities as Level 2. The fair value of the Company'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. The fair value of the Company's investments in certain U.S. treasury securities are classified as Level 2 and are included in marketable securities on the consolidated balance sheets.

The following tables summarize the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy as of June 30, 2026:

		June 30, 2026			
	Fair Value Hierarchy	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Cash equivalents:					
Money market funds	Level 1	$ 164,218	$ —	$ —	$ 164,218
U.S. treasury securities	Level 2	996	—	—	996
Marketable securities, available-for-sale:					
U.S. treasury securities	Level 2	9,897	—	(13)	9,884
Total		**$ 175,111**	**$ —**	**$ (13)**	**$ 175,098**

There were no marketable securities as of December 31, 2025.

The contractual maturity of the marketable securities as of June 30, 2026 was:

	Amortized Cost	Fair Value
Due in one year or less	$ 9,897	$ 9,884
Total	$ 9,897	$ 9,884

The Company's money market funds are classified as Level 1 because they are valued using quoted market prices. Investments in U.S. government treasury securities have been classified as Level 2 as they are valued using quoted prices in less active markets or other directly or indirectly observable inputs. Fair values of U.S. government treasury securities were derived based on input of market prices from multiple sources at each reporting period. There were no transfers of financial assets between Level 1, Level 2, or Level 3, during the periods presented.

The Company periodically reviews its portfolio of debt securities to determine if any investment is impaired due to credit loss or other potential valuation concerns. For debt securities where the fair value of the investment is less than the amortized cost basis, the Company has assessed at the individual security level for various quantitative factors including, but not limited to, the nature of the investments, changes in credit ratings, interest rate fluctuations, industry analyst reports, and the severity of impairment. Unrealized losses on marketable securities at June 30, 2026 were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities.

No assets or liabilities were transferred into or out of their classifications during the three months ended June 30, 2026 and 2025.

7. Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	June 30, 2026	December 31, 2025
Lab equipment	$ 668	$ 669
Leasehold improvements	1,090	1,090
Computer hardware and software	172	168
Furniture and fixtures	152	152
Property and equipment, gross	2,082	2,079
Less: accumulated depreciation and amortization	(1,647)	(1,461)
Property and equipment, net	$ 435	$ 618

Depreciation and amortization expense for the three and six months ended June 30, 2026 was $87 and $191, respectively. Depreciation and amortization expense for the three months and six months ended June 30, 2025 was $117 and $235, respectively.

8. Accounts Payable and Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2026	December 31, 2025
Accrued compensation and ESPP contributions	$ 1,885	$ 2,693
Accrued outsourced non-clinical studies	896	651
Accrued contract manufacturing costs	983	223
Accrued clinical trial costs	181	49
Accrued other	363	323
Total accrued expenses and other current liabilities	$ 4,308	$ 3,939

9. Equity

Securities Purchase Agreement

On March 27, 2026, the Company entered into a securities purchase agreement (the "2026 PIPE Purchase Agreement") with certain institutional accredited investors (the "2026 PIPE Investors"), pursuant to which the Company agreed to issue and sell to the 2026 PIPE Investors in a private placement (i) 26,713,638 shares (the "2026 PIPE Shares") of Common Stock at a purchase price of $4.15 per 2026 PIPE Share, and (ii) pre-funded warrants to purchase 9,430,957 shares of Common Stock (the "2026 PIPE Warrant Shares"), at a purchase price of $4.1499 per underlying 2026 PIPE Warrant Share (the "2026 Private Placement"). Also, pursuant to the 2026 PIPE Purchase Agreement, the Company's executive officers and directors entered into letter agreements pursuant to which they agreed not to sell or transfer any Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, until the later of 180 days after the closing date of the 2026 Private Placement and the effective date of registering the 2026 PIPE shares on a Registration Statement, subject to certain customary exceptions.

The 2026 Private Placement closed on March 31, 2026. The aggregate gross proceeds from the 2026 Private Placement were approximately $150.0 million, before deducting placement agent fees and offering expenses of approximately $9.6 million.

The 2026 PIPE Pre-Funded Warrants will be exercisable immediately at an exercise price of $0.0001 per 2026 PIPE Warrant Share and will not expire until exercised in full. The holders of 2026 PIPE Pre-Funded Warrants may not exercise a 2026 PIPE Pre-Funded Warrant if the holder, together with its attribution parties, would beneficially own more than a specified percentage of the number of shares of Common Stock outstanding immediately after giving effect to such exercise. The holders of 2026 PIPE Pre-Funded Warrants may increase or decrease such percentages not in excess of 19.99% by providing at least 61 days' prior notice to the Company. The 2026 PIPE Pre-Funded Warrants are classified as equity in the condensed consolidated financial statements.

Sale of Class A Common Stock Under ATM Agreement

On November 6, 2025, the Company entered into the ATM Sales Agreement with Leerink Partners to sell the ATM Placement Shares, from time to time, through an "at the market offering" program under which Leerink Partners is serving as sales agent.

On November 6, 2025, the Company filed the Registration Statement with the SEC, which became effective on November 25, 2025. The Registration Statement registered an aggregate of up to $200 million of securities that may be issued and sold by the Company from time to time, including initially up to an aggregate offering price of $16.0 million of Common Stock (which is included in the $200 million aggregate offering price set forth in the base prospectus) that may be issued and sold pursuant to the ATM Sales Agreement.

As of June 30, 2026, no shares of Common Stock had been sold under the ATM Sales Agreement and the Company will not be issuing or selling any Common Stock for the 180 day-period after March 31, 2026, due to the lock-up restrictions contained in the 2026 PIPE Purchase Agreement, subject to certain exceptions.

10. Share-Based Compensation

The Company amended and restated its 2024 Equity Incentive Plan (the "A&R 2024 Plan"), effective as of June 3, 2026 upon approval by the stockholders of the Company.

The amendments to the Company's 2024 Equity Incentive Plan included (1) a one-time increase to the number of shares of common stock reserved for issuance under the A&R 2024 Plan of 3,231,638 shares, (2) an amendment to the annual "evergreen" provision to remove the annual limit of 2,407,100 shares, while maintaining the annual increase at 5% of the Company's outstanding shares, and (3) a limit on the number of shares that can be issued as incentive stock options under the A&R 2024 Plan.

Stock Options

A summary of the Company's stock option activity and related information is as follows:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding - December 31, 2025	2,714,651	$ 15.54	8.52	$ 22
Granted	1,485,625	4.07		
Exercised	—	—		
Expired	(39,785)	14.88		
Forfeited	(76,448)	9.07		
Options outstanding - June 30, 2026	4,084,043	$ 11.49	8.66	$ 836
Options exercisable - June 30, 2026	1,468,017	$ 16.96	7.87	$ 133

All outstanding options as of June 30, 2026 are expected to vest, subject to forfeitures.

The aggregate intrinsic value is calculated as the difference between the exercise price and the estimated fair value of the Company's Common Stock as of June 30, 2026.

Restricted Stock Units (RSUs)

RSUs vest based on a service requirement and a liquidity event, which was satisfied upon completion of the Merger, plus service requirement. The following table summarizes RSU activities during the six months ended June 30, 2026:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested balance as of December 31, 2025	41,376	$ 22.89
Granted	—	—
Vested and released	(16,431)	22.89
Forfeited	(457)	22.89
RSUs outstanding - June 30, 2026	24,488	$ 22.89
Unvested balance as of June 30, 2026	24,488	$ 22.89

2024 Employee Stock Purchase Plan

In October 2024, the Board adopted the 2024 Employee Stock Purchase Plan (the "2024 ESPP"), which became effective immediately upon completion of the Merger. The Company recorded approximately $49 and $88 thousand of share-based compensation expense during the three and six months ended June 30, 2026, respectively, related to the 2024 ESPP. The Company recorded approximately $55 thousand of share-based compensation expense during the three and six months ended June 30, 2025, related to the 2024 ESPP, which is reflected in the Share-Based Compensation Expense table below.

Share-Based Compensation Expense

The following table shows the allocation of share-based compensation expense related to the Company's employee and non-employee share-based awards (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development	$ 1,427	$ 1,410	$ 2,711	$ 2,727
General and administrative	1,622	1,498	3,118	2,926
Total	$ 3,049	$ 2,908	$ 5,829	$ 5,653

11. Income Taxes

In accordance with GAAP, a valuation allowance should be provided if it is more likely than not that some or all of the Company's deferred tax assets will not be realized. The Company's ability to realize the benefit of its deferred tax assets will depend on the generation of future taxable income. Due to the uncertainty of future profitable operations and taxable income, the Company has recorded a full valuation allowance against its net deferred tax assets. The Company believes its tax filing positions and deductions related to tax periods subject to examination will be sustained upon audit and, therefore, has no reserve for uncertain tax positions.

12. Commitments and Contingencies

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 OnKure, 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 Financing 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. The plaintiffs have not pursued their claims in the Complaints and there has been no activity on either docket; however, the Complaints remain pending.

We cannot predict the outcome of the Complaints or any other litigation that might be filed arising out of the Merger or the Concurrent Financing. 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 Financing. Absent new or significantly different allegations, the Company will not necessarily disclose such additional filings.

From time-to-time in the future, the Company could be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of business, which may have a material adverse effect on the Company's consolidated results of operations or financial position.

Indemnification

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with its officers and members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs because of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its financial statements as of June 30, 2026 and December 31, 2025.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and notes thereto and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our audited financial statements and the related notes for the years ended December 31, 2025 and 2024 included in our Annual Report on Form 10-K for the year ended December 31, 2025, and subsequent filings. 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.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery and development of precision medicines that target biologically validated drivers of vascular anomalies and cancers that are 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 pipeline of small molecule drugs designed to selectively target specific mutations thought to be key drivers of cancer and vascular anomalies. By improving selectivity for the mutated form of these disease-driving proteins, we aim to discover and develop drugs with improved safety and efficacy by sparing toxicity that arises from non-selective inhibition of the non-mutated (or wild-type) version of the protein. We work under the belief that inhibiting target proteins with specific mutations instead of wild-type variants should enable precise patient selection that will, in turn, improve the probability of clinical success. We designed our current product candidates utilizing disciplined medicinal chemistry, x-ray crystallography, and computational chemistry to inhibit specified mutated versions of PI3Kα, a key mediator in cancer growth signaling.

Next-Generation PI3Kα Pan-Mutant Programs

Our portfolio includes two next-generation PI3Kα pan-mutant programs, OKI-345 in breast cancer and OKI-355 in vascular anomalies. These candidates are designed to selectively inhibit mutant PI3Kα while sparing wildtype PI3Kα, potentially enabling a wider therapeutic index and avoidance of class-limiting toxicities. High and sustained target coverage across all hotspot PI3Kα mutations can support the potential for deep and durable responses in breast cancer, both as monotherapy and in combination regimens where applicable. The PI3Kα pan-mutant candidates are designed to have minimal drug-drug interaction potential, supporting broad combinability with current standards of care where applicable. We plan to submit an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration for each of OKI-345 and OKI-355 in the first half of 2027.

Merger

On October 4, 2024, we completed the Merger. Refer to Note 1 "Organization and Business" to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for information regarding the Merger.

Macroeconomic and Geopolitical Considerations

Our business and operations may be negatively affected by macroeconomic, geopolitical, and regulatory developments, including inflation, instability in the banking and financial services sector, tightening of the credit markets, international conflicts, cybersecurity, tariffs, sanctions, export controls, government policy positions, and changes in regulatory agencies with oversight of our operations. These developments could affect our supply chain, manufacturing processes, regulatory compliance costs, regulatory approval timelines, and cross-border operations. Further, it is possible that U.S. and non-U.S. government policy changes and related uncertainty about policy changes could increase market volatility and our operating expenses. The extent, severity, and duration of the impacts of these events and conditions on our business cannot be predicted and may not be fully reflected in our results of operations until future periods. If economic uncertainty continues or increases, or if the global economy worsens, our business, financial condition, and results of operations may be harmed. For further discussion of the potential impacts of macroeconomic events and conditions on our business, financial condition, and operating results, see the section titled "Risk Factors" included in this Quarterly Report.

Financial Overview

Since our inception, our operations have primarily focused on raising capital, establishing and protecting our intellectual property portfolio, organizing and staffing our company, business planning, and conducting preclinical

and clinical development of and manufacturing development for our product candidates. We do not have any product candidates approved for sale, have not generated any revenue from product sales, and do not expect to generate revenues from the commercial sale of any products for the foreseeable future, if ever.

Since our inception, we have incurred significant operating losses. Our net losses were $30.5 million and $59.5 million for the six months ended June 30, 2026 and the year ended December 31, 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $244.7 million and cash, cash equivalents and marketable securities of $176.4 million.

We have funded our operations primarily through private placements of our common stock and preferred stock and the issuance of convertible debt. As of June 30, 2026, we believe our cash resources are sufficient to fund our planned operations for at least the next 12 months from the date of issuance of our unaudited condensed consolidated financial statements for the quarter ended June 30, 2026.

Components of Our Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses primarily relate to expenses incurred in connection with the discovery and development of our product candidates.

Research and development expenses include:

- employee-related expenses, including salaries, severance, retention, benefits, insurance, and share-based compensation expense;
- expenses incurred under agreements with CROs, which are investigative sites that conduct our clinical trials, other clinical trial-related vendors, and clinical consultants;
- the costs of acquiring, developing, and manufacturing and testing clinical and preclinical materials, including costs incurred under agreements with CMOs;
- costs associated with non-clinical activities and regulatory operations; and
- facilities, depreciation, market research, and other expenses, which include allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and laboratory supplies.

We make non-refundable advance payments for goods and services that will be used in future research and development activities. These payments are recorded as expenses in the period in which we receive or take ownership of the goods or when the services are performed. At any one time, we are working on multiple research or drug discovery programs and internal resources. Employees and infrastructure are not directly tied to any one program and are typically deployed across multiple programs; therefore, we do not track these research and development expenses on a program-specific basis.

Conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time-consuming. As we initiate new clinical trials, our research and development expenses may increase. Product candidates in later stages of development generally have higher development costs than those in earlier stages. As a result, we expect that our research and development expenses will increase substantially over the next several years as we advance product candidates through preclinical studies into and through clinical trials, continue to discover and develop additional product candidates, undertake activities to expand, maintain, protect, and enforce our intellectual property portfolio, and hire additional research and development personnel.

Successful development of product candidates is highly uncertain and may not result in approved products. The probability of success for each product candidate may be affected by numerous factors, including clinical data, preclinical data, competition, manufacturability, and commercial viability. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis

in response to our ability to enter strategic alliances with respect to each program or product candidate, the scientific and clinical success of each product candidate, and ongoing assessments as to each product candidate's commercial potential. We will need to raise additional capital and may seek strategic alliances in the future to advance our various programs.

General and Administrative

General and administrative expenses consist primarily of salaries, bonuses and related benefits, share-based compensation, and severance and retention benefits related to our executive, finance, and administrative functions, professional fees for auditing, tax, consulting, and legal services, as well as insurance, board of director compensation, consulting, and other administrative expenses. We recognize general and administrative expenses in the periods in which they are incurred.

We expect that our general and administrative expenses will increase over the next several years as we hire additional personnel to support the growth of our business. In addition, we will incur significant additional expenses associated with being a public company, including expenses related to accounting, audit, legal, regulatory, public company reporting and compliance, director and officer insurance, investor and public relations, and other administrative and professional services.

Other Income

Interest Income

Interest income primarily consists of interest income generated from our cash equivalents and marketable securities in interest-bearing money market accounts and short-term government securities.

Results of Operations

Comparison of the three months ended June 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended June 30,		
	2026	2025	$ Change
	(in thousands)		
Operating expenses:			
Research and development	$ 12,611	$ 12,613	$ (2)
General and administrative	4,288	3,711	577
Total operating expenses	16,899	16,324	575
Loss from operations	(16,899)	(16,324)	(575)
Other income:			
Interest income	1,553	934	619
Total other income and (expense)	1,553	934	619
Net loss	$ (15,346)	$ (15,390)	$ 44

Research and Development Expenses

Research and development expenses were $12.6 million for both the three months ended June 30, 2026 and June 30, 2025. The research and development expenses for the three months ended June 30, 2026 included a $0.5 million increase in clinical trial costs which was offset by a decrease of $0.5 million in outsourced preclinical research and development expenses.

General and Administrative Expenses

General and administrative expenses were $4.3 million for the three months ended June 30, 2026 compared to $3.7 million for the three months ended June 30, 2025. The increase of approximately $0.6 million was primarily

due to $0.3 million in increased personnel-related costs, including $0.1 million of increased share-based compensation charges. In addition, consulting fees increased by $0.2 million.

Other Income

Other income was $1.6 million for the three months ended June 30, 2026 compared to $0.9 million for the three months ended June 30, 2025. The change was primarily due to an increase in interest income due to an increase in cash, cash equivalents and marketable securities available to invest during the quarter ended June 30, 2026 as compared to the quarter ended June 30, 2025.

Comparison of the six months ended June 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated:

	Six Months Ended June 30,		
	2026	2025	$ Change
	(in thousands)		
Operating expenses:			
Research and development	$ 24,318	$ 25,625	$ (1,307)
General and administrative	8,196	7,699	497
Total operating expenses	32,514	33,324	(810)
Loss from operations	(32,514)	(33,324)	810
Other income:			
Interest income	2,011	2,009	2
Total other income and (expense)	2,011	2,009	2
Net loss	$ (30,503)	$ (31,315)	$ 812

Research and Development Expenses

Research and development expenses were $24.3 million for the six months ended June 30, 2026 compared to $25.6 million for the six months ended June 30, 2025. The decrease of approximately $1.3 million was primarily due to $1.5 million of decreased outsourced preclinical research and development expenses and $0.4 million of personnel-related costs, partially offset by an increase of $0.6 million clinical trial and outsourced manufacturing costs.

We expect research and development expenses in 2026 to be higher than 2025 due to continued efforts to advance our programs.

General and Administrative Expenses

General and administrative expenses were $8.2 million for the six months ended June 30, 2026 compared to $7.7 million for the six months ended June 30, 2025. The increase of approximately $0.5 million was primarily due to a $0.5 million increase in personnel-related costs, including $0.2 million of increased share-based compensation charges, and $0.1 million increase in consulting costs. These increases were partially offset by a $0.1 million decrease in legal and filing fee costs.

We expect general and administrative expenses in 2026 to be higher than 2025.

Other Income

Other income was $2.0 million for the six months ended June 30, 2026 which was consistent with the six months ended June 30, 2025.

We expect other income in 2026 to be higher than 2025 with higher average available cash to invest during 2026 given the 2026 Private Placement that closed March 31, 2026.

Liquidity and Capital Resources

Since inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the 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 initiating and conducting clinical trials and manufacturing our product candidates to support such clinical trials and commercialization and providing general and administrative support for our operations. 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.

In March 2026, we completed the 2026 Private Placement for aggregate gross proceeds of approximately $150.0 million, before deducting placement agent fees and offering expenses. Pursuant to the 2026 PIPE Purchase Agreement, we agreed to use the proceeds from the 2026 Private Placement for research and development expenses for our vascular anomalies and breast cancer programs, excluding our former lead product candidate, OKI-219, and for working capital and other general corporate purposes.

In November 2025, we filed the Registration Statement, which registered an aggregate of up to $200 million of securities that may be issued and sold from time to time, including initially up to an aggregate offering price of $16.0 million of Common Stock (which is included in the $200 million aggregate offering price set forth in the base prospectus) that may be issued and sold pursuant to the ATM Sales Agreement. As of June 30, 2026, no shares have been sold under the ATM Sales Agreement.

We have funded our operations primarily through private placements of equity and convertible debt. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations for at least the next 12 months from the date of issuance of our unaudited condensed consolidated financial statements for the quarter ended June 30, 2026.

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, or 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 and our ability to access the capital markets. 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-345, OKI-355, and any other product candidates, 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 we receive 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 our 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-345 and OKI-355 or any other 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.

Cash Flows

The following table summarizes our cash flows for the periods indicated, in thousands:

	Six Months Ended June 30,	
	2026	**2025**
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (23,292)	$ (27,279)
Investing activities	(9,875)	(31)
Financing activities	140,619	(77)
Net increase (decrease) in cash and cash equivalents	$ 107,452	$ (27,387)

Cash Flows from Operating Activities

Cash used in operating activities during the six months ended June 30, 2026 was $23.3 million. This consisted primarily of a net loss of $30.5 million, a net increase in operating assets and liabilities of $1.0 million, offset by non-cash share-based compensation of $5.8 million.

Cash used in operating activities during the six months ended June 30, 2025 was $27.3 million. This consisted primarily of a net loss of $31.3 million, a net decrease in operating assets and liabilities of $2.0 million, and non-cash share-based compensation of $5.7 million.

Cash Flows from Investing Activities

Cash used in investing activities was $9.9 million for six months ended June 30, 2026, and primarily related to purchases of marketable securities. Cash used in investing activities was $31 thousand for six months ended June 30, 2025, related to purchase of property and equipment.

Cash Flows from Financing Activities

Cash provided by financing activities during the six months ended June 30, 2026 was $140.6 million and primarily related to the net proceeds from the sale of Common Stock and pre-funded warrants in connection with the 2026 Private Placement and proceeds from the sale of stock under the employee stock purchase plan.

Cash used in financing activities during the six months ended June 30, 2025 was $77 thousand and related to payment of issuance costs from the Concurrent Financing and reverse recapitalization transaction costs in connection with the Merger.

Material Cash Requirements

The discussion below summarizes our significant contractual obligations and commitments as of June 30, 2026.

Leases. See Note 4 of Notes to our Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q for information regarding our leases, including the future operating lease minimum payments.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of these condensed consolidated financial statements requires us 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 condensed consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe 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.

Our critical accounting policies are described in our audited financial statements and the related notes for the years ended December 31, 2025 and 2024 included in our Annual Report on Form 10-K for the year ended December 31, 2025, and the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the three months ended June 30, 2026, there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K for the year ended December 31, 2025.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Exchange Act and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

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 June 30, 2026, 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 June 30, 2026 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors

RISK FACTORS

You should carefully consider the risks described below, as well as the other information in this Quarterly Report, including our 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 Risk Factors

Our business operations are subject to numerous risks and uncertainties, including those outside of our control, that could cause our actual results to be harmed, including risks regarding the following:

- 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.
- If we are unable to advance OKI-345 and OKI-355 through preclinical and clinical development, obtain regulatory approval and ultimately commercialize one or more of such product candidates, or experience significant delays in doing so, our business will be materially harmed.
- We have limited resources. 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 product candidates, 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 has been and is expected to continue to be volatile.

- Our Amended Certificate of Incorporation, our Amended Bylaws, and provisions of Delaware law could make acquiring us 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 than some other companies.

- 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. Our net losses were $30.5 million and $59.5 million for six months ended June 30, 2026 and the year ended December 31, 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $244.7 million. 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 initiation and completion of preclinical and clinical development of OKI-345, OKI-355, our research programs and any other future programs;
- establishing and maintaining relationships with contract research organizations (or "CROs") and clinical sites for the clinical development of OKI-345, OKI-355 and any other product candidates;
- 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 an 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. Our cash, cash equivalents and marketable securities are expected to fund operations into 2029. 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. For example, pursuant to the 2026 Private Placement, we issued and sold 26,713,638 shares of our Common Stock and pre-funded warrants to purchase 9,430,957 shares of our Common Stock, which resulted, and may continue to result, in a significant increase in the number of our outstanding shares of common stock and substantially diluted the ownership interests of our existing stockholders. Debt financing, if available, may involve restrictive covenants, and equity financing, if available, may include restrictions on our use of proceeds. For example, pursuant to the 2026 PIPE Purchase Agreement, we are unable to use the proceeds from the 2026 Private Placement for research and development of our former lead product candidate, OKI-219, for which we subsequently disclosed that we do not plan to pursue further clinical development independently. We may experience similar or more onerous restrictions on use of proceeds in future financings. 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 very early in our development efforts of OKI-345 or OKI-355. If we are unable to advance OKI-345 or OKI-355 through preclinical and clinical development, obtain regulatory approval and ultimately commercialize one or more of such product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts of OKI-345 or OKI-355. We plan to submit an IND application to the FDA for each of OKI-345 and OKI-355 in the first half of 2027. If we do not successfully complete preclinical testing of OKI-345 or OKI-355 and initiate and complete our planned clinical trials of such product candidates in a timely manner, or fail to achieve favorable results from the trials, we may experience significant delays or other issues in advancing our programs. We will be required to demonstrate thorough, adequate, and well controlled clinical trials that our product candidates are 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. 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 advancing OKI-345 or OKI-355 and our 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 advancing OKI-345 or OKI-355 and our research programs. Because we have limited financial and managerial resources, we must focus on a limited number of product candidates and research programs 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. For example, following our 2026 Private Placement, we no longer plan to pursue further clinical development of OKI-219, our former lead product candidate, independently at this time. 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-345, OKI-355 and our research programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for OKI-345, OKI-355 and our 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. 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.

In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, such as those implemented by the Department of Government Efficiency, which may prevent or delay approval of our products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. In view of the overturning of the *Chevron* doctrine in *Loper Bright Enterprises v. Raimondo*, this Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies. Additionally, changes in the leadership of the FDA and other federal agencies under the current U.S. presidential administration may also lead to new policies and changes in the regulations and operations of the FDA, which may impact our clinical development plans.

Further, under the new leadership at the HHS under the current administration, agency reorganization, mass layoffs due to the reduction in force initiative, and other measures implemented by the Department of Government Efficiency may impact the normal operations of FDA as well as other federal agencies. FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. In January 2025, an executive order entitled “Unleashing Prosperity Through Deregulation”, was issued calling for at least ten existing regulations to be repealed whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation. Elimination of agency guidance documents could interfere with FDA programs or lead to more Complete Response Letters or refusals to approve products. Recent developments at the FDA include implementation of Elsa, a generative AI tool, across all centers at the agency, announcement of a plan to phase out animal testing for monoclonal antibodies and certain other drugs, and the announcement of a new Commissioner’s National Priority Voucher program to companies supporting certain U.S. national health priorities and interests. The FDA has also increased its scrutiny of foreign drug manufacturing facilities and other contractors based in China, especially with respect to the transfer of biological materials, genetic data, and other sensitive data of American patients to parties located in China. FDA’s “real-time” release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our competitive advantage and intellectual property. There is significant uncertainty in the industry around how federal agencies like the FDA will change in

the coming years under the current administration. It is unclear how our industry and our clinical programs will be affected by policies and regulations implemented under the current administration and FDA commissioner, or other executive orders. There is significant uncertainty in the industry regarding the ways in which federal agencies like the FDA will change in the coming years under the current administration. To the extent the agency reorganization and other agency changes lead to disruptions in FDA's operations, our correspondence and regulatory review processes with FDA may be materially delayed.

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. Difficulties we experience relating to enrollment in our planned clinical trials, or complications in such clinical trials, could delay regulatory approval for our 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 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 our former lead product candidate, OK-219, and another product candidate, known as OKI-179, despite promising early data. In addition, much of our preclinical data, including with respect to cellular selectivity, potency and antitumor activity of OKI-345 and OKI-355, as well as preclinical data generated in comparisons of our product candidates to other compounds, was generated internally by us in a limited number of cell lines, assays and animal models, has not been independently verified or generated in head-to-head clinical trials, and may not be reproducible or predictive of results in humans. Preclinical tumor regressions and selectivity or therapeutic-index advantages observed in our models may not translate into clinical efficacy, tolerability or a differentiated safety profile, and any associated comparative or superiority conclusions may not be reproducible in clinical development or accepted by regulatory authorities.

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 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;
- 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 failing 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 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 draw 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 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-345 and OKI-355 and may develop other product candidates, 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 our PI3Kα-targeted portfolio. Alpelisib (Piqray, a PI3Kα-selective inhibitor marketed by Novartis) and capivasertib (Truqap, an AKT1 inhibitor marketed by AstraZeneca) are marketed medicines, both of which are approved for the treatment of PI3Kα-mutated breast cancer patients in combination with the selective estrogen receptor degrader ("SERD") fulvestrant. Additionally, the PI3Kα-selective inhibitor inavolisib (Itovebi™) has been approved in combination with the SERD fulvestrant and the CDK4/6 inhibitor palbociclib (Ibrance™) in endocrine resistant HR+/HER2- locally advanced or metastatic breast cancer.

We are also aware of several novel PI3K-targeted therapies that are in clinical development. These include both multiple non-mutation-selective PI3K inhibitors (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-478 (LLY4064809) (Loxo Oncology), and SNV4818 (Synnovation Therapeutics). 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 less expensive 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-345, OKI-355 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-345, OKI-355 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-345, OKI-355 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 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 any of our product candidates 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 any 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 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 new or reinstated or adjusted 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 FCPA 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.

Increased tariffs on imports, including tariffs imposed by the United States and China, trade sanctions, other trade restrictions, or a global trade war could increase our costs and materially and adversely affect our business operations and financial condition.

Our business could be negatively affected by tariffs, trade restrictions, and other governmental protectionist measures, any of which can be imposed suddenly and unpredictably. For example, following Russia's invasion of Ukraine, the United States and other countries imposed economic sanctions and severe export control restrictions against Russia, Belarus and the occupied regions of Ukraine. The situation continues to evolve, and the United States, the EU, the United Kingdom, and other countries have implemented and may continue to implement additional sanctions, export controls, or other measures against Russia and other countries, regions, officials, individuals, companies, or industries in the respective territories, as well as entities or individuals in other countries that are providing support to the sanctioned parties. Such sanctions and measures, as well as existing and potential further responses from Russia or other countries, could adversely affect the global economy and financial markets, as well as our business, financial condition, and results of operations, which may also magnify the impact of other risks described in this "Risk Factors" section.

There is also currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, trade regulations, and tariffs. In February 2025, the current U.S. presidential administration stated its intent to modify U.S. trade policy and, in some cases, to renegotiate, or potentially terminate, certain existing bilateral or multilateral trade agreements. Beginning that month, the administration imposed "fentanyl-related" tariffs of 10-35% on imported products of China, Canada, and Mexico, with an exception for goods that qualify for duty-free treatment under the U.S.-Mexico-Canada Agreement. Beginning in April 2025, the administration also imposed "reciprocal" tariffs of 10% or more on imports from almost all U.S. trading partners other than Canada and Mexico, including China and the European Union. Both of the foregoing tariffs were implemented under authorities asserted under the International Emergency Economic Powers Act ("IEEPA") and rescinded on February 24, 2026, following a Supreme Court decision invalidating the use of IEEPA to authorize these tariffs. Though the U.S. government has begun refunding payments made in connection with the IEEPA tariffs, but the availability, timing, and amount of any related refunds associated with payments of these tariffs remain uncertain and subject to further legal, regulatory, and administrative action. Following the recission of these tariffs, between February 24, 2026, and July 24, 2026, the U.S. government implemented a global "temporary import surcharge" of 10% on many of the same products affected by the prior reciprocal tariffs, under authorities provided for in Section 122 of the Trade Act of 1974. Upon expiration of the Section 122 temporary import surcharge on July 24, 2026, the U.S. government implemented tariffs of up to 10% or 12.5% on imported commodities from 60 U.S. trading partners, with certain items (including certain chemicals used for pharmaceutical applications) excepted, under authorities provided under Section 301 of the Trade Act of 1974, following a determination by the U.S. Trade Representative that these trading partners insufficiently enforce forced labor laws. The foregoing tariffs supplement existing non-IEEPA tariff measures, including those already imposed under authorities provided in Section 232 of the Trade Expansion Act of 1962 and other tariffs imposed under Section 301. For example, the U.S. government announced in April 2026 that it would impose a new Section 232 tariff of up to 100% on certain patented or branded pharmaceuticals and pharmaceutical products beginning in July

2026. The U.S. Commerce Department is currently conducting targeted investigations related to national security risks associated with imports of certain items under Section 232 which could result in additional tariffs on imports of those items. The administration continues to implement new, reinstated, or adjusted tariffs, and we expect that the administration will continue with this practice. These tariffs (and the uncertainty around their implementation) could affect inputs to our products, as well as equipment, materials, or components that we import into the United States from our suppliers, which could significantly impact the cost of these items. Retaliatory tariffs and trade barriers could also negatively affect our ability to export and sell our potential products into those countries. If these tariffs are implemented, reinstated or adjusted, if additional tariffs are placed, or if any related countermeasures are taken by China, the European Union, or other countries, our business, financial condition, and results of operations may be materially harmed.

Trade restrictions, tariffs, and other general economic or political conditions may limit our ability to obtain key materials, components, or equipment for our products or significantly increase supply chain costs and other expenses associated with our business, which could further materially and adversely affect our results of operations, financial condition, and prospects. We may not be able to forecast such impacts accurately. Although we continue to work with our vendors to mitigate our exposure to current or potential tariffs and trade restrictions, we cannot assure you that we will be able to offset any increased costs or supply shortages. The ultimate impact of any tariffs or trade restrictions will depend on various factors, including the timing of implementation and the duration, amount, scope, and nature of the tariffs and trade restrictions. If we are not successful in offsetting the impact of any such tariffs or trade restrictions, our operating results may be adversely affected.

The tariffs are subject to a number of uncertainties as they are implemented, including timing, future adjustments, and other changes. The ultimate reaction of other countries and the impact of these tariffs or other actions on the United States, the global economy, and our business, financial condition, and results of operations, cannot be predicted at this time, nor can we predict the impact of any other developments with respect to global trade. Further, the imposition of additional tariffs by the United States could result in the adoption of additional tariffs by other countries, as well as export controls and further retaliatory actions by any affected country. Any resulting trade war could negatively affect the global market for pharmaceuticals and could have a significant adverse effect on our business. These developments may have a material adverse effect on global economic conditions and the stability of global financial markets, and they may significantly reduce global trade. Any of these factors could depress economic activity, restrict our access to potential customers or suppliers, and have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our technology and product candidates, 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-345, OKI-355 and any other 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-345, OKI-355 or any other 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-345, OKI-355 or any other 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 or in patents with meaningful scope, coverage or exclusivity;

- 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-345, OKI-355 or any other product candidate, it could dissuade other companies from collaborating with us to develop product candidates, and threaten our ability to commercialize OKI-345, OKI-355 or other 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-345, OKI-355 and any other 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-345, OKI-355 or any other 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-345, OKI-355 and any other 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 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 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-345, OKI-355 and any other 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-345, OKI-355 and any other product candidates, and we expect to collaborate with third parties on the continuing development of OKI-345, OKI-355 and any other product candidates, we must, at times, share trade secrets with them. We also expect to conduct research and development 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 use 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, global health concerns, government shutdown, or a lapse of U.S. government appropriations 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. Changes in the leadership of the FDA and other federal agencies under the current U.S. presidential administration, as well as policy changes including return-to-office directives, hiring freezes, and layoffs, may also lead to changes in the operations of the FDA, which may have a material impact on the industry. 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, a lapse of U.S. government appropriations, 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.

If a prolonged government shutdown occurs, as it has previously, 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.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, including as a result of the current U.S. presidential administration. 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. Only high-expenditure, single-source drugs that have been approved for at least seven years (11 years for single-source biologics) qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, CMS selected 10 high-cost Medicare Part D drugs in 2023 and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. In June 2026, the CMS issued a proposed rule that would codify policies established in guidance documents for the Medicare Drug Price Negotiation

Program for initial price applicability year 2029 and beyond. CMS plans to release guidance to implement policies related to the effectuation of the maximum fair pricing for the Medicare Drug Price Negotiation Program for 2028. 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. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. Government agreements with pharmaceutical companies and other government measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or increase generic and biosimilar drug entry sooner than expected, could have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover research and development costs, or ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chains or manufacturing in the United States. 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.

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 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 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;

- 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 and related 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.

Restrictive laws and regulations govern the collection, use, transfer, and other processing of personal information.

In conducting and enrolling patients in current or future clinical trials, we are subject to restrictions relating to privacy, data protection, and cybersecurity, and may be subject to additional restrictions associated with clinical

operations in the future. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the General Data Protection Regulation ("GDPR"), which is wide-ranging in scope and imposes numerous requirements on companies that process personal data. The GDPR permits data protection authorities to impose large penalties for violations, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater, for the most serious violations. The GDPR also confers a private right of action on data subjects and consumer associations. Certain aspects of cross-border data transfers under the GDPR are uncertain as the result of legal proceedings in the EU, including a July 2020 decision by the Court of Justice for the European Union ("CJEU") that invalidated the EU-U.S. Privacy Shield and called into question the efficacy and legality of using standard contractual clauses ("SCCs"). To address certain concerns of the CJEU, the European Commission issued revised SCCs in June 2021. The EU also has enacted numerous new laws and regulations addressing cybersecurity.

In the United Kingdom ("UK"), the Data Protection Act of 2018 implements and complements the GDPR and is effective along with a version of the GDPR referred to as the UK GDPR. These regimes authorize significant fines, up to the greater of £17.5 million or 4% of global turnover, and expose us to two parallel regimes and potentially divergent enforcement actions. Further, aspects of data protection in the UK remain uncertain. In 2021, the European Commission issued an adequacy decision pursuant to which personal data generally may be transferred from the EU to the UK without restriction. This adequacy decision was renewed in December 2025 to extend through December 2031. The UK's adequacy determination may, however, be revoked or modified at any time. Additionally, the UK's Information Commissioner's Office has issued standard contractual clauses to support personal data transfers out of the UK ("UK SCCs"). Regulatory guidance and other developments relating to cross-border personal data transfers, including the necessity of putting in place SCCs and UK SCCs, may increase the complexity of transferring personal data across borders and may require us to engage in additional contractual negotiations or to modify our policies and practices. Other jurisdictions also increasingly maintain laws and regulations addressing privacy, data protection, and cybersecurity. We may incur liabilities, expenses, and other operational losses under the GDPR and local laws of applicable EU member states, the UK, and other regions in connection with any measures we take to comply with them.

In the United States, in addition to HIPAA, HITECH, and state laws addressing health-related information, numerous federal and state laws and regulations govern the collection, use, disclosure, and other processing of information relating to individuals. In California, the California Consumer Privacy Act ("CCPA") requires covered companies to provide disclosures to consumers about such companies' data collection, use and sharing practices, provide such consumers ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action in data breach situations. The CCPA went into effect on January 1, 2020, and was modified significantly by the California Privacy Rights Act ("CPRA"), which was approved by California voters in the 2020 election and became effective January 1, 2023. The CCPA has prompted numerous proposals for federal and state privacy legislation. Numerous U.S. states have proposed, and in certain cases enacted, laws addressing privacy and cybersecurity matters. Many of these laws are comprehensive privacy statutes imposing obligations similar to the CCPA. Certain U.S. states have also enacted laws and regulations addressing specific subject matter, such as Washington State's My Health, My Data Act which, among other things, provides for a private right of action. The U.S. Department of Justice also has issued rules restricting, and imposing requirements in connection with, certain bulk transfers of sensitive personal information.

Compliance with U.S. and international laws and regulations relating to privacy, data protection, and cybersecurity could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use, and disclose data, or, in some cases, impact our ability to operate in certain jurisdictions, and may increase our costs of doing business or require us to change our policies and practices. Any actual or alleged failure to comply with U.S. or international laws and regulations relating to privacy, data protection, or cybersecurity could result in governmental investigations, proceedings, and enforcement actions (which could include civil or criminal penalties), private litigation, adverse publicity, and harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose such information or impose other obligations or restrictions in connection with our use, retention, or other processing of information, and we may otherwise face contractual restrictions applicable to these activities. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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 expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or 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.

While we are working to diversify our supply chain beyond single-source suppliers, 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. Additionally, changes to immigration policies in the United States, such as changes to H-1B and other visa programs, and restrictions on travel could limit the flow of technical and professional talent into the United States and may inhibit our ability to hire qualified personnel. 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 internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants, or potential future collaborators, may fail or suffer actual or suspected security or privacy breaches or incidents or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, significant liabilities, harm to our brand and material disruption of our operations, and potentially significant delays in our delivery to market.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and external processing and storage (e.g., cloud) systems, and those of our third-party CROs, other contractors (including sites performing our current or future clinical trials), consultants and other third-party service providers, these systems are potentially vulnerable to breakdown or other damage or interruption. Our systems and the systems of third parties who support our operations are vulnerable to service interruptions, system malfunction, natural disasters, terrorism, war (such as conflicts in the Middle East and between Ukraine and Russia), and telecommunication and electrical failures, as well as security breaches and incidents arising from or caused by inadvertent or intentional actions by our employees, contractors, consultants, business partners, or other third parties, or from cyberattacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, or availability of information), which may compromise our system infrastructure or lead to unauthorized access to or disruption of our or third-party systems and the unauthorized access to, misuse, disclosure, loss, destruction, alteration or dissemination of, or damage to, our data, including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information. For example, companies have experienced an increase in phishing and social engineering attacks in recent years. Further, the increasing availability and sophistication of artificial intelligence technologies may enable threat actors to more rapidly identify and exploit vulnerabilities in our systems and those of our service providers and other third parties, conduct more sophisticated phishing, social engineering, impersonation and deepfake attacks, accelerate the

development of malicious code, automate cybersecurity attacks, and otherwise increase the scale, speed and effectiveness of cyber threats, resulting in heightened risks of security breaches and incidents. Our employees generally work in a hybrid model in our offices and from home, and we may need to adjust our working model from time to time. As a result, we may have increased cyber security and data security risks, due to increased use of home wi-fi networks and virtual private networks. While we implement controls to reduce the risk of a resulting cyber security or data security incident or breach, we may experience data security incidents, and there is no guarantee that the measures we have implemented will be adequate to safeguard all systems and data, especially with some employees working from home or in a hybrid model where it is more difficult for us to monitor.

Any disruption, security incident, or security breach resulting in any loss, destruction, unavailability, alteration or dissemination of, or damage to, our data (including confidential information) or other data we or any of our CROs, other contractors, consultants, potential future collaborators, or other third-party service providers maintain or otherwise process, or our applications, or for it to be believed or reported that any of these occurred, could result in us incurring liability and reputational damage, and the development and commercialization of our product candidates could be delayed. For example, if a security incident were to cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss or unavailability of clinical trial data for our product candidates could result in delays in our marketing approval efforts and result in us incurring significant costs to recover or reproduce the data. Furthermore, disruptions of our internal information technology systems or those of third parties used in our business, or security breaches or incidents affecting us or any of our CROs, other contractors, consultants, potential future collaborators, or other third-party service providers, could result in the loss, misappropriation, or unauthorized access to, use or disclosure of, or the inability to access, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. Unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to notify individuals or regulators under data breach notification laws, cause us to incur costs related to investigation of the incident (including legal expenses, forensic examination costs, and remediation costs), subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damage that could have an adverse effect on our business. Our preclinical studies in China could increase our risk to such disruptions.

We expect to incur significant costs in our efforts to detect, prevent, and respond to security incidents. We also rely on third parties to manufacture our product candidates, and similar events relating to their systems could also have a material adverse effect on our business. There have been and may continue to be significant supply chain attacks and operational technology attacks globally, and we cannot guarantee that our systems or those of third-party service providers or other third parties that support us or our operations have not been breached or that they do not contain exploitable defects or bugs that could result in a security incident or breach of, or other disruption to, our systems or the systems of third parties that support us and our operations. Any disruption or security incident may result in damage to, or loss, destruction, alteration, or other unauthorized processing of our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations and other proceedings and actions, delays in the development and commercialization of our product candidates, and subject us to significant fines, penalties, and other liabilities. Litigation, governmental investigations, and other actions and proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, and adversely affect our reputation. We could be required to fundamentally change our business activities and practices in response to such litigation or investigations, which could have an adverse effect on our business. Any actual or perceived inability to adequately protect data in our possession, custody, or control could have a material adverse effect upon our reputation, business, operations, or financial condition.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption to, failure or security breach of, or incident impacting, our systems or third-party systems where information important to our business operations is stored. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Risks Related to Ownership of Our Class A Common Stock

The market price of our Class A Common Stock has been and is expected to continue to be volatile.

The market price of our Class A Common Stock has been and could continue to 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 candidates and research programs;
- failure to achieve development, regulatory or commercialization milestones under our collaborations;
- failure or discontinuation of any of our product candidates 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 product candidates or research programs;
- 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 could have an adverse effect on our operating results, financial condition and cash flows.

We expect to incur losses for the foreseeable future and might never achieve profitability.

We may never become profitable, even if we are able to complete clinical development for one or more product candidates and eventually commercialize such product candidates. We will need to successfully complete significant research, development, testing and regulatory compliance activities that, together with projected general and administrative expenses, is expected to result in substantial increased operating losses for at least the next several years. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

We incur significant legal, accounting and other expenses as a public company, including costs associated with public company reporting obligations under the Exchange Act. Our management team, including executive officers and other personnel, need to devote substantial time to ensuring that we comply with applicable public company reporting requirements and applicable laws and regulations. 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 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 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. This requires that we incur substantial professional fees and internal costs in connection with 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.

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 and our Amended and Restated Bylaws and provisions of Delaware law could make acquiring 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 ("Amended Certificate of Incorporation") and our Amended and Restated Bylaws ("Amended Bylaws") may discourage, delay or prevent a merger, acquisition or other change in control of the Company that stockholders may consider favorable, including transactions in which holders of our 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 Common Stock, thereby depressing the market price of our Common Stock. In addition, because the Board 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 the Board. Among other things, these provisions:

- authorize "blank check" preferred stock, which could be issued by the Board 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 the Board;
- 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 the Board;
- provide that vacancies on the Board 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 the Board to make, alter, amend, or repeal the Amended Bylaws; and
- require supermajority votes of the holders of our Common Stock to amend specified provisions of our Amended Certificate of Incorporation and Amended 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 the Board, 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 the Board, which is responsible for appointing the members of management.

Our Amended 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 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 employees arising out of or pursuant to any provision of the DGCL, our Amended Certificate of Incorporation or our Amended Bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce, or determine the validity of our Amended Certificate of Incorporation or our Amended 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 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 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 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 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 Certificate of Incorporation and Amended 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 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 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 or brought to enforce a right to indemnification;

- the rights conferred in our Amended 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 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.

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, made us 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 than some other companies.

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 were not eligible to use a Form S-3 until one year after the filing of the Super 8-K;

- we waited 60 calendar days after the filing of the Super 8-K to file a Form S-8 for our equity plans or awards;

- we are an "ineligible issuer" through October 4, 2027, 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 OnKure at the time the Merger were submitted for the vote or consent of 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 accordingly such securities may not be included in the Form S-1 resale shelf registration statement that was filed after the closing of the Merger unless such securities are sold only in a fixed price offering in which such investors are named as underwriters in the prospectus; and

- Rule 144(i)(2) limited 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 was filed with the SEC. Non-affiliate Reneo stockholders prior the Merger were not subject to such restrictions on public resales of their shares.

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.

We have issued a substantial number of pre-funded warrants which are exercisable into shares of our Class A Common Stock which could result in substantial dilution to the ownership interests of our existing stockholders.

Pursuant to the 2026 PIPE Purchase Agreement, we issued the 2026 PIPE Pre-Funded Warrants. As of August 3, 2026, approximately 9,430,957 shares of our Class A Common Stock were reserved for issuance upon exercise of the 2026 PIPE Pre-Funded Warrants. The exercise of these securities will result in a significant increase in the number of outstanding shares and substantially dilute the ownership interests of our existing stockholders.

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

Sales of a substantial number of our Class A Common Stock in the public market could occur at any time. If existing securityholders sell, or indicate an intention to sell, substantial amounts of our Class A Common Stock in the public market, the trading price of our Class A Common Stock could decline. All outstanding shares of our Class A Common Stock, other than shares held by our affiliates, are freely tradable, without restriction, in the public market.

For example, we registered all of the 36,144,595 shares of our Class A Common Stock issued (or issuable upon the exercise of the 2026 PIPE Pre-Funded Warrants) by us in the 2026 Private Placement on a Form S-3, which was declared effective by the SEC in May 2026. 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.

As of August 1, 2026, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 60.3% 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 Internal Revenue Service (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. 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, 2025, we had U.S. federal net operating loss carryforwards of $236.5 million. 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. Net operating loss carryforwards may be subject to similar limitations under state 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 had 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 we believe that Reneo experienced an ownership change in connection with the Merger and the private placement Reneo completed concurrently with the closing of the Merger. 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 private placement or other transactions. Similar rules may apply under state tax laws. In addition, California has recently enacted 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 that is apportioned to California. 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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

No officers or directors, as defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408, during the last fiscal quarter.

Item 6. Exhibits

EXHIBIT INDEX

			Incorporated by Reference			
Exhibit Number		**Description**	**Form**	**Filing Date**	**Number**	**Filed Herewith**
2.1		Agreement and Plan of Merger, dated May 10, 2024, by and among Reneo Pharmaceuticals, Inc., Radiate Merger Sub I, Inc., Radiate Merger Sub II, LLC and OnKure, Inc.	8-K	5/13/2024	2.1	
3.1		Amended and Restated Certificate of Incorporation, as amended.	8-K	10/8/2024	3.2	
3.2		Amended and Restated Bylaws.	8-K	10/8/2024	3.3	
4.1		Form of Pre-Funded Warrant.	8-K	3/30/2026	4.1	
10.1		Amended and Restated 2024 Equity Incentive Plan.	8-K	6/4/2026	10.1	
31.1		Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2		Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
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.				X
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				X
101.SCH		Inline XBRL Taxonomy Extension Schema Document				X

Exhibit Number	Description	Form	Filing Date	Number	Filed Herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				X

† This certification shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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: August 4, 2026

ONKURE THERAPEUTICS, 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: August 4, 2026

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: August 4, 2026

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), Nicholas A. Saccomano, President and Chief Executive Officer of OnKure Therapeutics, Inc. (the "Company"), and Jason Leverone, Chief Financial Officer 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 June 30, 2026, 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: August 4, 2026	By:	/s/ Nicholas A. Saccomano, Ph.D.
	Name:	Nicholas A. Saccomano, Ph.D.
	Title:	President and Chief Executive Officer (Principal Executive Officer)
Date: August 4, 2026	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.