



2,938,005 Shares of Class A Common Stock

This prospectus supplement updates and amends the prospectus dated March 21, 2025 (as supplemented to date, the “Prospectus”), which forms a part of our Registration Statement on Form S-1 (Registration Statement No. 333-282792) for which Post-Effective Amendment No.1 was filed with the Securities and Exchange Commission (the “SEC”) on March 20, 2025 and declared effective by the SEC on March 21, 2025.

The Prospectus and this prospectus supplement relate to the resale by certain of the selling securityholders named in the Prospectus (each a “selling securityholder” and, collectively, the “selling securityholders”) of 2,938,005 shares of Class A Common Stock, par value \$0.0001 per share (the “Common Stock”) issued in the PIPE Financing (as defined in the Prospectus). The Prospectus also covers any additional securities that may become issuable by reason of stock splits, stock dividends or other similar transactions.

This prospectus supplement should be read in conjunction with the Prospectus, which is to be delivered with this prospectus supplement. This prospectus supplement updates, amends and supplements the information included or incorporated by reference in the Prospectus. If there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, including any amendments or supplements to it.

Quarterly Report on Form 10-Q and Current Report on Form 8-K

On November 6, 2025, we filed a Quarterly Report on Form 10-Q and a Current Report on Form 8-K with the SEC. The Quarterly Report on Form 10-Q and the Current Report on Form 8-K are attached hereto.

We are an “emerging growth company,” as defined under the federal securities laws, and, as such, may elect to comply with certain reduced public company reporting requirements for future filings.

Investing in our securities involves a high degree of risk. Before buying any securities, you should carefully read the discussion of the risks of investing in our securities in the section titled “[Risk Factors](#)” beginning on page 9 of the Prospectus.

You should rely only on the information contained in the Prospectus, this prospectus supplement, or any further prospectus supplement or amendment hereto. We have not authorized anyone to provide you with different information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is November 6, 2025.

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

FORM 10-Q

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2025
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
(State or other jurisdiction of incorporation or organization)

6707 Winchester Circle, Suite 400
Boulder, Colorado
(Address of Principal Executive Offices)

47-2309515
(I.R.S. Employer Identification No.)

80301
(Zip Code)

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

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

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

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

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

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

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

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

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

As of November 5, 2025, the registrant had 12,861,672 shares of Class A common stock, \$0.0001 par value per share, and 686,527 shares of Class B common stock, \$0.0001 par value per share, outstanding.

Explanatory Note

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

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

The financial statements included in this Quarterly Report on Form 10-Q include historical financial information of OnKure Therapeutics, Inc., including as of and for the three and nine months ended September 30, 2025, unless otherwise indicated or as the context otherwise requires. In addition, except where otherwise indicated, the information in this Quarterly Report on Form 10-Q as of and for the periods prior to the effective time of the Merger gives effect to the Merger.

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

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 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 OKI-219 and any other product candidates we have or may in the future develop;
- our future results of operations and financial position;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our current and future product candidates, subject to regulatory approvals;
- our cash runway and our ability to extend our operating capital;
- the initiation, timing, progress and results of our preclinical and clinical activities for OKI-219 and any other product candidates we have or may in the future develop, including the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the studies or trials may become available, research development programs, 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 PI3K α 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;
- existing regulations and regulatory developments in the United States and other jurisdictions; and
- our ability to realize some or all of the anticipated benefits of the Merger.

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

or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

ONKURE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(Unaudited)

	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 70,331	\$ 110,761
Prepaid expenses and other current assets	1,195	2,242
Total current assets	71,526	113,003
Property and equipment, net	720	1,025
Operating lease right-of-use asset	485	770
Other assets	104	109
Total assets	\$ 72,835	\$ 114,907
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,290	\$ 2,968
Accrued expenses and other current liabilities	4,390	7,026
Operating lease liabilities, current portion	567	536
Total current liabilities	6,247	10,530
Long-term operating lease liabilities	120	549
Other long-term liabilities	40	—
Total liabilities	6,407	11,079
Commitments and contingencies		
Stockholders' equity:		
Common stock, Class A, \$0.0001 par value; 200,000,000 shares authorized; 12,861,672 and 12,660,590 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	1	1
Common stock, Class B, \$0.0001 par value; 10,000,000 shares authorized; 686,527 shares issued and outstanding at both September 30, 2025 and December 31, 2024	—	—
Additional paid-in capital	267,165	258,551
Accumulated deficit	(200,738)	(154,724)
Total stockholders' equity	66,428	103,828
Total liabilities and stockholders' equity	\$ 72,835	\$ 114,907

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

ONKURE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(in thousands, except share and per share amounts)			
Operating expenses:				
Research and development	\$ 11,915	\$ 10,116	\$ 37,540	\$ 29,434
General and administrative	3,586	1,396	11,285	6,253
Total operating expenses	<u>15,501</u>	<u>11,512</u>	<u>48,825</u>	<u>35,687</u>
Loss from operations	<u>(15,501)</u>	<u>(11,512)</u>	<u>(48,825)</u>	<u>(35,687)</u>
Other income:				
Interest income	804	174	2,813	699
Interest and other expense	(2)	(218)	(2)	(243)
Total other income (expense)	<u>802</u>	<u>(44)</u>	<u>2,811</u>	<u>456</u>
Net loss and comprehensive loss	<u>\$ (14,699)</u>	<u>\$ (11,556)</u>	<u>\$ (46,014)</u>	<u>\$ (35,231)</u>
Net loss per share attributable to common stockholders:				
Basic and diluted	\$ (1.09)	\$ (36.55)	\$ (3.41)	\$ (111.77)
Weighted average shares outstanding:				
Basic and diluted	13,530,892	316,142	13,488,493	315,215

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

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

	Convertible Preferred Stock		Class A Common stock		Class B Common stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2023	6,840,620	\$ 129,825	313,747	\$ —	—	\$ —	\$ 209	\$ (102,051)	\$ (101,842)
Issuance of Class A Common Stock for cash upon the exercise of stock options	—	—	1,002	—	—	—	10	—	10
Share-based compensation expense	—	—	—	—	—	—	107	—	107
Net loss	—	—	—	—	—	—	—	(9,536)	(9,536)
Balance, March 31, 2024	6,840,620	129,825	314,749	—	—	—	326	(111,587)	(111,261)
Issuance of Class A Common Stock for cash upon the exercise of stock options	—	—	1,130	—	—	—	10	—	10
Share-based compensation	—	—	—	—	—	—	1,813	—	1,813
Net loss	—	—	—	—	—	—	—	(14,139)	(14,139)
Balance, June 30, 2024	6,840,620	129,825	315,879	—	—	—	2,149	(125,726)	(123,577)
Issuance of Class A Common Stock for cash upon the exercise of stock options	—	—	344	—	—	—	6	—	6
Share-based compensation	—	—	—	—	—	—	77	—	77
Net loss	—	—	—	—	—	—	—	(11,556)	(11,556)
Balance, September 30, 2024	6,840,620	129,825	316,223	—	—	—	2,232	(137,282)	(135,050)
Conversion of Convertible Preferred Stock for Class A and B Common Stock in connection with the Merger	(6,840,620)	(129,825)	6,154,093	1	686,527	—	129,824	—	129,825
Issuance of Class A Common Stock in the Concurrent Financing, less issuance costs	—	—	2,571,736	—	—	—	54,428	—	54,428
Issuance of common stock to former stockholders of Reneo Pharmaceuticals, Inc. in the reverse recapitalization	—	—	3,343,604	—	—	—	65,499	—	65,499
Reverse recapitalization transaction costs of OnKure	—	—	—	—	—	—	(2,085)	—	(2,085)
Issuance of Class A Common Stock for the conversion of Convertible Promissory Notes	—	—	267,269	—	—	—	6,120	—	6,120
Issuance of Class A common stock for the settlement of restricted stock units	—	—	7,700	—	—	—	—	—	—
Adjustment for fractional shares in the reverse recapitalization	—	—	(35)	—	—	—	—	—	—
Share-based compensation	—	—	—	—	—	—	2,533	—	2,533
Net loss	—	—	—	—	—	—	—	(17,442)	(17,442)
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

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)

	Nine Months Ended September 30,	
	2025	2024
	(in thousands)	
Cash flows from operating activities:		
Net loss	\$ (46,014)	\$ (35,231)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	8,614	1,997
Depreciation and amortization	343	343
Amortization of right-of-use asset - operating	285	111
Loss on disposal of property and equipment	2	—
Amortization of debt issuance costs	—	128
Change in operating assets and liabilities:		
Prepaid and other assets	1,052	(108)
Accounts payable, accrued and other liabilities	(4,240)	5,151
Lease liabilities	(398)	(154)
Other long-term liabilities	40	—
Net cash used in operating activities	<u>(40,316)</u>	<u>(27,763)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(37)	(37)
Net cash used in investing activities	<u>(37)</u>	<u>(37)</u>
Cash flows from financing activities:		
Payment of issuance costs associated with the Concurrent Financing	(37)	—
Payment of reverse recapitalization transaction costs	(40)	—
Proceeds from issuance of convertible notes payable	—	6,000
Payment of issuance costs associated with the issuance of convertible notes payable	—	(142)
Proceeds from the issuance of common stock in connection with equity plans	—	25
Net cash (used in) provided by financing activities	<u>(77)</u>	<u>5,883</u>
Net decrease in cash and cash equivalents	<u>(40,430)</u>	<u>(21,917)</u>
Cash and cash equivalents, beginning of period	110,761	29,876
Cash and cash equivalents, end of period	<u>\$ 70,331</u>	<u>\$ 7,959</u>
Supplemental cash flow information:		
Interest paid	\$ —	\$ —
Supplemental disclosure of noncash investing activities:		
Purchases of property and equipment in accounts payable	<u>\$ 3</u>	<u>\$ —</u>

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 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. 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 remains as a wholly-owned subsidiary of the Company, and, together with the Company, is referred to as the “Combined Company” below. 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 “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 Combined 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 Combined Company. All issued and outstanding Legacy OnKure common stock, convertible preferred stock, restricted stock units, and options to purchase common stock prior to the effective date of the Merger have been retroactively adjusted to reflect the exchange ratio for all periods presented.

See Note 3 for further discussion.

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 \$200.7 million and cash and cash equivalents of \$70.3 million as of September 30, 2025. 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.

The Company's ability to secure capital depends on its success in discovering and developing its drug 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 in the near term, or not be available on acceptable terms, the Company will 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. Changing circumstances, including due to macroeconomic and geopolitical effects outside of the Company's control, may cause the Company to consume capital significantly faster or slower than currently anticipated. The estimates included herein are based on assumptions that may prove to be wrong, and the Company could exhaust its available financial resources sooner than currently anticipated.

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. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. Management believes the Company's cash and cash equivalents 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.

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 U.S. Securities and Exchange Commission. 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 consolidated financial statements reflect the operation of the Company and its wholly owned subsidiary OnKure, Inc. All intercompany balances and transactions among the consolidated entities have been eliminated in consolidation. See Notes 1 and 3 for further discussion.

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.

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. As a result of the adoption of ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, the Company has presented the three and nine months ended September 30, 2024 amounts consistent with the corresponding 2025 period presentation.

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 and restricted stock units.

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. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

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.

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.

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, receivables, prepaid and other current assets, accounts payable, and accrued expenses approximate their fair values because of the short maturity 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 and money market funds. The carrying amount of cash and cash equivalents was \$70.3 million and \$110.8 million as of September 30, 2025 and December 31, 2024, 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 and cash equivalents. The Company maintains accounts in federally insured financial institutions. At times, amounts held in federally insured accounts are above the federally insured limit of \$250,000. 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.

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. One of the Company's lessee agreements include an option to extend the lease, which the Company does not include in its minimum lease term unless it is reasonably certain to exercise such option. 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 December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (“ASU 2023-09”), which requires enhanced income tax disclosures, including specific categories and disaggregation of information in the effective tax rate reconciliation, disaggregated information related to income taxes paid, income or loss from continuing operations before income tax expense or benefit, and income tax expense or benefit from continuing operations. The requirements of the ASU are effective for annual periods beginning after December 15, 2024, with early adoption permitted. This ASU may be applied either prospectively or retrospectively. The Company is currently evaluating the impact of this pronouncement and will apply ASU 2023-09 to its annual tax disclosures for the fiscal year ended December 31, 2025.

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.

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. Merger Agreement and Concurrent Financing

As described in Note 1, Merger Sub I merged with and into Legacy OnKure, with Legacy OnKure surviving as a wholly owned subsidiary of the Company on October 4, 2024.

At the Closing, each then-outstanding share of Legacy OnKure common stock was converted into the right to receive 0.023596 shares of common stock of Reneo based on an exchange ratio (the “Common Exchange Ratio”), which was reclassified as Class A Common Stock in connection with the Merger, and each then-outstanding share of Legacy OnKure preferred stock was converted into the right to receive 0.144794 shares of Class A Common Stock based on an exchange ratio (the “Preferred Exchange Ratio”); provided that one holder of Legacy OnKure preferred stock elected to receive 686,527 shares that it would otherwise have received in the form of Class A Common Stock in an equal number of shares of Class B Common Stock. Upon the closing of the Merger, (i) an aggregate of 6,470,281 shares of Class A Common Stock and 686,527 shares of Class B Common Stock of the Company were issued in exchange for the shares of Legacy OnKure capital stock outstanding as of immediately prior to the Closing and (ii) outstanding shares of Reneo common stock were reclassified into an aggregate of approximately 3,343,604 shares of Class A Common Stock.

In connection with the Merger Agreement, Reneo entered into a subscription agreement with certain investors, pursuant to which the investors subscribed for and purchased, concurrent with the closing of the Merger, an aggregate of 2,839,005 shares of Class A Common Stock at a price of approximately \$22.895 per share for aggregate gross proceeds of approximately \$65.0 million, including the conversion of previously funded Convertible Promissory Notes principal of \$6.0 million and accrued interest thereon of \$120 thousand, on October 4, 2024.

At the effective time of the Merger, the authorized shares of Class A Common Stock of the Company were 200,000,000 with par value of \$0.0001, and Class B Common Stock of the Company were 10,000,000 with par value of \$0.0001.

The Merger was accounted for as a reverse recapitalization in accordance with GAAP, with Legacy OnKure as the accounting acquirer of Reneo. Legacy OnKure was determined to be the accounting acquirer 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.

As a result, Legacy OnKure’s historical financial statements became the historical consolidated financial statements of the Combined Company for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders Reneo, the legal acquirer, and a recapitalization of the

equity of Legacy OnKure, the accounting acquirer. The final transaction amounts have been recorded as a reduction of proceeds in stockholders' equity.

At the effective time of the Merger, the net assets of Reneo were recorded at their acquisition-date fair value in the financial statements of the Combined Company, which approximated book value due to the short-term nature. Reneo's development programs had ceased prior to the Merger and were deemed to be de minimis in value at the transaction date. No goodwill or intangible assets were recognized.

As part of the recapitalization, excluding the Concurrent Financing, the Company acquired the assets and liabilities listed below (in thousands):

	Amount
Cash and cash equivalents	\$ 57,736
Short-term investments	15,979
Other current assets	690
Other assets	553
Accrued expenses	(9,072)
Long-term operating lease liability	(387)
Net assets acquired	<u>\$ 65,499</u>

4. 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. Before adopting the ASU, because the Company has one reportable segment, it provided only the entity-wide disclosures required by ASC 280. 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 Chief Operating Decision Maker ("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.

The Company's CODM is the senior executive committee that is comprised of the Chief Executive Officer and the Chief Financial Officer.

	Clinical Research Segment			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(in thousands)			
Operating expenses:				
Direct program expense	\$ 6,824	\$ 6,906	\$ 22,187	\$ 17,939
Indirect program expense	459	520	1,417	1,562
Workforce salaries and benefits	4,202	3,457	12,952	10,645
Share-based compensation expense	2,961	77	8,614	1,997
General corporate expenses	1,055	552	3,655	3,544
Interest and other expense	2	218	2	243
Segment net loss	<u>15,503</u>	<u>11,730</u>	<u>48,827</u>	<u>35,930</u>
Reconciliation of loss:				
Interest income	(804)	(174)	(2,813)	(699)
Adjustments and reconciling items	(804)	(174)	(2,813)	(699)
Net loss	<u>\$ 14,699</u>	<u>\$ 11,556</u>	<u>\$ 46,014</u>	<u>\$ 35,231</u>

5. Leases

The Company's headquarters are located in Boulder, Colorado, where it leases 14,790 square feet of office and lab facilities under operating leases that expire in December 2026, with rights to extend for a five-year period. 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 nine months ended September 30, 2025 were \$59 thousand and \$172 thousand and were netted against operating lease costs in the Statement of Operations.

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

	September 30, 2025	December 31, 2024
Operating lease right-of-use assets	\$ 485	\$ 770
Current operating lease liabilities	567	536
Noncurrent operating lease liabilities	120	549
Total lease liabilities	<u>\$ 687</u>	<u>\$ 1,085</u>

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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating lease cost	\$ 46	\$ 44	\$ 142	\$ 131
Variable lease expense	44	47	118	140

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

	As of September 30,	
	2025	2024
Weighted-average remaining lease term - operating leases (years)	1.16	2.25
Weighted-average discount rate - operating leases	4.5%	4.5%
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	\$ 427	\$ 154

The aggregate maturities of the Company's operating lease liabilities were as follows as of September 30, 2025 (in thousands):

Remaining in 2025	\$ 145
2026	560
Total future minimum lease payments	705
Less: imputed interest	(18)
Less: current portion	(567)
Operating lease liability, net of current portion	\$ 120

6. 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, without consideration for common stock equivalents. Diluted net loss per share assumes the conversion, exercise, or issuance of all potential common stock equivalents, unless the effect of inclusion would be anti-dilutive. For purposes of this calculation, common stock shares to be issued upon if-converted method for the convertible Series C Preferred Stock, exercise of all outstanding stock options and restricted stock units were excluded from the diluted net loss per share calculation for the nine months ended September 30, 2024 because such shares are anti-dilutive. Common stock shares 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 nine months ended September 30, 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:

	September 30,	
	2025	2024
Outstanding common stock options	2,763,057	195,228
Unvested restricted stock units	51,415	213,276
	2,814,472	408,504

7. 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, using the quoted prices in active markets. 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.

No assets or liabilities were transferred into or out of their classifications during the nine months ended September 30, 2025 and 2024.

As part of the Merger, the Company acquired, and disposed of shortly thereafter, certain short-term investments in debt securities that were carried at fair value and classified as current assets available-for-sale and represented the investment of funds available for current operations. The Company had no available-for-sale securities as of September 30, 2025 or December 31, 2024.

8. Property and Equipment, Net

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

	September 30, 2025	December 31, 2024
Lab equipment	\$ 675	\$ 705
Leasehold improvements	1,090	1,090
Computer hardware and software	163	189
Furniture and fixtures	152	160
Property and equipment, gross	2,080	2,144
Less: accumulated depreciation and amortization	(1,360)	(1,119)
Property and equipment, net	<u>\$ 720</u>	<u>\$ 1,025</u>

Depreciation and amortization expense for the three and nine months ended September 30, 2025 was \$108,000 and \$343,000, respectively. Depreciation and amortization expense for the three and nine months ended September 30, 2024 was \$114,000 and \$343,000, respectively.

9. Accrued Expenses and Other Current Liabilities

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

	September 30, 2025	December 31, 2024
Accrued compensation and ESPP contributions	\$ 2,978	\$ 3,173
Accrued contract manufacturing costs	72	1,565
Accrued clinical trial costs	123	1,302
Accrued other	1,217	986
Total accrued expenses and other current liabilities	<u>\$ 4,390</u>	<u>\$ 7,026</u>

Accrued compensation includes severance costs. For further information see Note 12.

10. Share-Based Compensation

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, 2024	2,393,824	\$ 23.54	7.90	\$ 1
Granted	774,800	4.98		
Exercised	—	—		
Expired	(405,567)	42.88		
Forfeited	—	—		
Options outstanding - September 30, 2025	<u>2,763,057</u>	<u>\$ 15.50</u>	8.84	\$ 15
Options exercisable - September 30, 2025	<u>839,941</u>	<u>\$ 19.94</u>	8.24	\$ —

All outstanding options as of September 30, 2025 are expected to vest.

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 September 30, 2025.

The Company granted 8,449 performance-based shares, which are included in the table above, during the year ended December 31, 2023. There was no performance-based compensation expense for the nine months ended September 30, 2025. The Company recognized \$0 and \$30,000 in performance-based compensation expense for the three and nine months ended September 30, 2024.

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.

Restricted Stock Units (RSUs)

RSUs vest based on a service requirement and a liquidity event plus service requirement. The following table summarizes RSU activities during the nine months ended September 30, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested balance as of December 31, 2024	213,254	\$ 22.88
Granted	26,724	2.95
Vested and released	(188,563)	20.06
Forfeited	—	—
RSUs outstanding - September 30, 2025	<u>51,415</u>	<u>\$ 22.89</u>
Unvested balance as of September 30, 2025	<u>51,415</u>	<u>\$ 22.89</u>

During the three months ended March 31, 2025, 4,481 shares were used to settle grantee's tax withholding obligations for vesting of restricted stock units.

In addition to the RSUs in the table above, in connection with the Merger, the Company assumed 24,700 RSUs which were fully vested at the time of the Merger. The RSUs were releasable upon set timeframes after completion of the Merger. The 17,000 RSUs that were unreleased as of December 31, 2024 were released in January 2025.

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. As of September 30, 2025, no shares have been issued under the 2024 ESPP. The Company recorded \$62,000 and \$117,000 of share-based compensation expense during the three and nine months ended September 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 share-based awards (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	\$ 1,431	\$ 31	\$ 4,158	\$ 1,586
General and administrative	1,530	46	4,456	411
Total	\$ 2,961	\$ 77	\$ 8,614	\$ 1,997

There were no modifications during the nine months ended September 30, 2025. The Company recorded accelerated share-based compensation expenses related to modifications of RSUs under certain separation agreements of \$40 thousand and \$1.7 million during the three and nine months ended September 30, 2024, respectively, which is reflected in the above table. See Note 12 for further discussion on severance.

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.

On July 4, 2025, the One Big Beautiful Bill Act was signed into law in the United States, which contains a broad range of tax reform provisions affecting businesses. The Company is evaluating the full effects of the legislation on its estimated annual effective tax rate, but it expects that the legislation will likely not have a material impact on the consolidated financial statements given its full valuation allowance against its net deferred tax assets.

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.

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 September 30, 2025.

Severance

A former officer of the Company terminated his employment with the Company on May 24, 2024 and entered into a separation agreement and release on that date. The separation agreement and release provides for payments and benefits including continuing payments of base salary for a period of 14 months following termination of employment, payment for or reimbursement for COBRA premiums for up to 14 months following termination of employment, a full accelerated vesting of his equity awards and extension of the post-termination exercise period applicable to his Options through the earlier of 12 months following termination of service or the applicable option expiration date. As of September 30, 2025 and December 31, 2024, \$0 and \$326,000, respectively, remained unpaid and was included in accrued compensation. The related RSU shares were released in January 2025. No expense was recorded for these severance benefits for the three or nine months ended September 30, 2025. During the three months ended June 30, 2024, the Company recorded an expense of \$622,000 for these severance benefits in research and development expense. See Note 10 for discussion of stock-based compensation recorded for the modifications of equity awards discussed above.

Certain Reneo employees became employees of the Company to assist with the Merger transition through December 31, 2024 at which time they were terminated and received severance benefits in accordance with the Reneo severance agreements. As of September 30, 2025, the December 31, 2024 balance of \$154,000 was fully paid. No expense was recorded for these severance benefits for the three or nine months ended September 30, 2025 or 2024.

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 Legacy OnKure’s audited financial statements and the related notes for the years ended December 31, 2024 and 2023 included in our Annual Report on Form 10-K for the year ended December 31, 2024, 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. and its subsidiaries after completion of the Merger. In addition, references to “Reneo” refer to the Company prior to the completion of the Merger.

Forward-Looking Statements

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

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

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery and development of precision medicines that target biologically validated drivers of cancers underserved by available therapies. Using a structure- and computational chemistry-driven drug design platform, we are committed to improving clinical outcomes for patients by building a robust pipeline of small molecule drugs designed to selectively target specific mutations thought to be key drivers of cancer. By improving selectivity for the oncogenic and mutated form of these cancer-driver 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 PI3K α , a key mediator in cancer growth signaling. Our lead product candidate, OKI-219, is a highly selective inhibitor of PI3K α ^{H1047R} that has a much smaller impact on PI3K α ^{WT}. We plan to initially focus on the development of OKI-219 in patients with advanced breast cancer of genetic subtypes that are (a) both HR+ and HER2-; and (b) HER2+. We believe we can potentially expand the application of OKI-219 by conducting appropriate clinical trials in earlier lines of treatment within breast cancer, other subtypes of breast cancer, and potentially in other solid tumors. OKI-219 is currently in a first-in-human Phase 1a/1b clinical trial.

Merger

On the Closing Date, Reneo consummated the previously announced Merger pursuant to the terms of the Merger Agreement, by and among Reneo, Merger Sub I, Merger Sub II, and Legacy OnKure.

Pursuant to the Merger Agreement, on the Closing Date, (i) Reneo effected a reverse stock split of Reneo’s issued common stock at a ratio of 1:10, (ii) Reneo changed its name to “OnKure Therapeutics, Inc.”, (iii) Reneo reclassified all of its common stock as “Class A Common Stock” or “Class B Common Stock”, and (iv) Radiate Merger Sub I merged with and into Legacy OnKure, with Legacy OnKure as the surviving company in the Merger and, after giving effect to such Merger, Legacy OnKure becoming a wholly owned subsidiary of OnKure

Therapeutics, Inc.

Concurrently with the closing of the Merger, Reneo completed a private placement with certain investors (the “Concurrent Investors”) to purchase 2,839,005 shares of Common Stock at a price per share of approximately \$22.895 per share for an aggregate purchase price of approximately \$65.0 million, including the conversion of outstanding convertible notes and accrued but unpaid interest thereon held by certain Legacy OnKure investors (the “Concurrent Financing”). In connection with the Concurrent Financing, Reneo entered into a registration rights agreement with certain investors, pursuant to which Reneo agreed to use commercially reasonable efforts to prepare and file a registration statement with the SEC within 45 calendar days after the Closing Date, registering the resale of the shares of Common Stock issued pursuant to the Concurrent Financing, which was filed in October 2024. Immediately after the effective time of the Merger, following the consummation of the Concurrent Financing, shares received by Legacy OnKure stockholders represented approximately 53.6%, pre-Merger Reneo shares outstanding represented approximately 25.1%, and the shares purchased in the Concurrent Financing represented approximately 21.3% of our outstanding Common Stock.

As of the open of trading on October 7, 2024, our Common Stock began trading on Nasdaq under the symbol “OKUR.”

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 inception, we have incurred significant operating losses. Our net losses were \$46.0 million and \$52.7 million for the nine months ended September 30, 2025 and the year ended December 31, 2024, respectively. As of September 30, 2025, we had an accumulated deficit of \$200.7 million and cash and cash equivalents of \$70.3 million.

We have funded our operations primarily through private placements of our common stock and preferred stock and issuance of convertible debt. As of September 30, 2025, 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 these financial statements.

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 our 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 in interest-bearing money market accounts.

Interest Expense

Interest expense consists primarily of interest expense generated from our convertible notes payable, which were issued in 2024 and converted at the time of the Merger in 2024.

Results of Operations

Comparison of the Three Months Ended September 30, 2025 and 2024

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

	Three Months Ended September 30,		\$ Change
	2025	2024	
	(in thousands)		
Operating expenses:			
Research and development	\$ 11,915	\$ 10,116	\$ 1,799
General and administrative	3,586	1,396	2,190
Total operating expenses	15,501	11,512	3,989
Loss from operations	(15,501)	(11,512)	(3,989)
Other income:			
Interest income	804	174	630
Interest and other expense	(2)	(218)	216
Total other income and (expense)	802	(44)	846
Net loss and comprehensive loss	\$ (14,699)	\$ (11,556)	\$ (3,143)

Research and Development Expenses

Research and development expenses were \$11.9 million for the three months ended September 30, 2025 compared to \$10.1 million for the three months ended September 30, 2024. The increase of approximately \$1.8 million was primarily due to a \$1.9 million increase in personnel-related costs, including \$1.3 million of increased share-based compensation charges.

General and Administrative Expenses

General and administrative expenses were \$3.6 million for the three months ended September 30, 2025 compared to \$1.4 million for the three months ended September 30, 2024. The increase of approximately \$2.2 million was primarily due to \$1.5 million in increased personnel-related costs, including \$1.3 million of increased share-based compensation charges. In addition, director compensation, consulting, filing fees and franchise taxes and other professional service fees, including audit fees and insurance, increased by \$0.5 million.

Other Income (Expense)

Other income (expense), net was \$0.8 million for the three months ended September 30, 2025 compared to \$0.1 million for the three months ended September 30, 2024. The change was primarily due to an increase in interest income due to an increase in cash and cash equivalents available to invest during the quarter ended September 30, 2025 as compared to the quarter ended September 30, 2024.

Comparison of the Nine Months Ended September 30, 2025 and 2024

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

	Nine Months Ended September 30,		\$ Change
	2025	2024	
	(in thousands)		
Operating expenses:			
Research and development	\$ 37,540	\$ 29,434	\$ 8,106
General and administrative	11,285	6,253	5,032
Total operating expenses	48,825	35,687	13,138
Loss from operations	(48,825)	(35,687)	(13,138)
Other income and (expense):			
Interest income	2,813	699	2,114
Interest and other expense	(2)	(243)	241
Total other income and (expense)	2,811	456	2,355
Net loss and comprehensive loss	\$ (46,014)	\$ (35,231)	\$ (10,783)

Research and Development Expenses

Research and development expenses were \$37.5 million for the nine months ended September 30, 2025 compared to \$29.4 million for the nine months ended September 30, 2024. The increase of approximately \$8.1 million was primarily due to a \$3.8 million increase in personnel-related costs, including \$2.4 million of increased share-based compensation charges. The increase was also the result of a \$2.9 million increase in clinical trial and outsourced manufacturing expenses, and a \$1.1 million increase in outsourced research expenses.

We expect research and development expenses in 2025 to be higher than 2024 due to continued efforts to advance our clinical and preclinical programs.

General and Administrative Expenses

General and administrative expenses were \$11.3 million for the nine months ended September 30, 2025 compared to \$6.3 million for the nine months ended September 30, 2024. The increase of approximately \$5.0 million was primarily due to \$4.4 million in increased personnel-related costs, including \$3.5 million of increased share-based compensation charges. In addition, director compensation, consulting, filing fees and franchise taxes and other professional service fees, including audit, filing fees and insurance, increased by \$1.6 million. These increases were partially offset by a \$1.2 million decrease in legal expenses in 2025 as compared to the same period in 2024 due to non-recurring costs related to the Merger completed in 2024.

We expect general and administrative expenses in 2025 to be higher than 2024 as we operate as a public company for the full year in 2025.

Other Income (Expense)

Other income (expense) was \$2.8 million for the nine months ended September 30, 2025 compared to \$0.5 million for the nine months ended September 30, 2024. The change was primarily due to an increase in interest income due to an increase in cash and cash equivalents available to invest during the nine months ended September 30, 2025 as compared to the nine months ended September 30, 2024.

We expect other income in 2025 to be higher than 2024 with higher average available cash available to invest during 2025.

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 clinical development of our product candidates.

We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing our product candidates to support commercialization and providing general and administrative support for our operations, including the costs associated with operating as a public company following the Closing. As a result, we will need additional capital to fund our operations, which we may seek to obtain from equity or debt financings, collaborations, licensing arrangements or other sources.

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 and cash equivalents 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 September 30, 2025.

Funding Requirements

Our primary uses of cash to date have been to fund our research and development activities, including with respect to our PI3K α 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-219, and conducting preclinical studies and clinical trials;
- the scope, timing, progress, results and costs of researching and developing other product candidates that we may pursue;
- the costs, timing, and outcome of regulatory review of our product candidates;

- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution for our product candidates for which 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-219 or any of our future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional capital to meet the capital requirements associated with such operating plans.

Cash Flows

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

	Nine Months Ended September 30,	
	2025	2024
	<i>(in thousands)</i>	
Net cash provided by (used in):		
Operating activities	\$ (40,316)	\$ (27,763)
Investing activities	(37)	(37)
Financing activities	(77)	5,883
Net decrease in cash and cash equivalents	<u>\$ (40,430)</u>	<u>\$ (21,917)</u>

Cash Flows from Operating Activities

Cash used in operating activities during the nine months ended September 30, 2025 was \$40.3 million. This consisted primarily of a net loss of \$46.0 million, a net decrease in operating assets and liabilities of \$3.5 million, and non-cash share-based compensation of \$8.6 million.

Cash used in operating activities during the nine months ended September 30, 2024 was \$27.8 million. This consisted primarily of a net loss of \$35.2 million, and a net decrease in our operating assets and liabilities of \$4.9 million, and by an increase in non-cash charges for share-based compensation and depreciation and amortization of \$2.6 million.

Cash Flows from Investing Activities

Cash used in investing activities was \$37 thousand and \$37 thousand for the nine months ended September 30, 2025 and 2024, respectively, and related to purchase of property and equipment.

Cash Flows from Financing Activities

Cash used in financing activities during the nine months ended September 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.

Cash provided by financing activities during the nine months ended September 30, 2024 was \$5.9 million and primarily related to proceeds from the issuance of convertible notes payable.

Material Cash Requirements

The discussion below summarizes our significant contractual obligations and commitments as of September 30, 2025.

Leases. See Note 5 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, 2024 and 2023 included in our Annual Report on Form 10-K for the year ended December 31, 2024, and the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the three months ended September 30, 2025, 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, 2024.

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 September 30, 2025, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or

submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission (“SEC”) rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2025 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 are substantially dependent on OKI-219. If we are unable to advance OKI-219 through clinical development, obtain regulatory approval and ultimately commercialize such product candidate, or experience significant delays in doing so, our business will be materially harmed.
- We have limited resources and are currently focusing our efforts on OKI-219 for development in particular indications and advancing our other discovery research programs. As a result, we may fail to capitalize on programs, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- If we experience delays or difficulties in the enrollment or retention of subjects in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, or other comparable foreign regulatory authorities.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates on acceptable terms, we may be unable to successfully commercialize our product candidates that obtain regulatory approval.

- If we are unable to obtain and maintain sufficient intellectual property protection for our technology and products and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and, if approved, commercialize our product candidates may be adversely affected.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct, supervise, and monitor certain aspects of our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, and meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.
- The market price of our Class A Common Stock has been and is expected to continue to be volatile.
- 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.
- 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.
- A robust trading market for our Class A Common Stock may not develop, and the holders of our Class A Common Stock may not be able to resell their shares of our Class A Common Stock for a profit, if at all.
- We could be subject to securities class action litigation, which is expensive and could divert management attention.
- Our executive officers, directors, and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

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

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

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

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving

fields. We also expect that, as we advance our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

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

We have incurred significant net losses in each reporting period since inception, have not generated any revenue from the sale of products, and have funded our operations primarily from the sale and issuance of equity securities and convertible debt. Our net losses were \$46.0 million and \$52.7 million for the nine months ended September 30, 2025 and the year ended December 31, 2024, respectively. As of September 30, 2025, we had an accumulated deficit of \$200.7 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 completion of clinical development of OKI-219 and preclinical and clinical development of other pipeline programs and any other future programs;
- establishing and maintaining relationships with contract research organizations (or “CROs”) and clinical sites for the clinical development of OKI-219 and any other future programs;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;

- commercial acceptance of our product candidates by patients, the medical community, and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing, and developing new product candidates;
- obtaining, maintaining, and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing, or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring, and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease our value and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, and continue our operations.

Any changes in the manufacturing process, suppliers, or facilities will require further comparability analysis and approval by the U.S. Food and Drug Administration (the “FDA”) before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy.

We have not previously submitted 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. We have not generated any revenues from the commercial sale of products and will not be able to generate any product revenues until, and only if, we receive approval to sell our product candidates from the FDA or other regulatory authorities. Our cash, cash equivalents and short-term investments are expected to fund operations into the fourth quarter of 2026. However, as we have not generated any revenue from commercial sales to date and do not expect to generate any revenue for several years, if ever, we will need to raise substantial additional capital in

order to fund our general corporate activities and to fund our research and development, including our currently planned clinical trials and plans for new clinical trials and product development.

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

Given our capital constraints, we will need to prioritize spending on our clinical and preclinical programs. If we are unable to raise sufficient funds to support our current and planned operations, we may elect to discontinue certain of our ongoing activities or programs. Our inability to raise additional funds could also prevent us from taking advantage of opportunities to pursue promising new or existing programs in the future.

Our forecasts regarding the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “*Risk Factors*” section. These estimates are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than currently expected.

Risks Related to Our Development and Commercialization of Our Product Candidates

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

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

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

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

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

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

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

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or adverse events. In such an event, our trials could be suspended or terminated and the FDA, EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow indications or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

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

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

Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a

product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. For example, FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in early clinical setting, among other goals. How the FDA plans to implement these goals and their impact on specific clinical programs and the industry are unclear. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than originally requested or may impose other prescribing limitations or warnings that limit the product candidate's commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control.

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

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

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

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

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements;
- be subject to changes in the way the product is administered; or
- have regulatory authorities withdraw or suspend their approval of the product.

We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

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. While our Phase 1 dose-escalation and expansion cohort trial, OKI-219-101, known as PIKture-01, has begun enrollment, future difficulties we experience relating to enrollment in our clinical trials, or complications in the PIKture-01 trial or future clinical trials, could delay regulatory approval for OKI-219 or our future product candidates.

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

- size and nature of the patient population, and process for identifying patients;
- severity and difficulty of diagnosing the condition under investigation;
- availability and efficacy of approved drugs and other competing therapeutic candidates for the condition under investigation;
- the eligibility and exclusion criteria for the trial in question as defined in the protocol;

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

Our inability to enroll a sufficient number of subjects for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we will have limited influence over their performance. Even if we are able to enroll a sufficient number of subjects for our clinical trials, we may have difficulty maintaining enrollment of such subjects in our clinical trials.

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

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

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

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, and

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

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

We will be required to demonstrate with substantial evidence through well controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. For example, we previously decided to cease developing another product candidate, known as OKI-179, despite promising early data. In addition, in December 2024, we announced preliminary safety, tolerability and PK data from PIKture-01, with a cutoff date of October 28, 2024, which supported our initiation of Part 1b of PIKture-01. These data are considered preliminary and do not include efficacy data. We plan to provide additional data in the first quarter of 2026. We cannot predict whether these additional data will be consistent with the preliminary data announced in December 2024, or whether the data will be positive or consistent with our preliminary data. If the additional data from PIKture-01 are not positive or fail to support further advancement of OKI-219, we could experience volatility or a substantial decline in our stock price. Further, even if such data are positive and we decide to pursue future clinical trials of OKI-219, these trials may not be successful.

Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols, and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation, and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

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

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

- obtaining regulatory authorization to commence a clinical trial;
- delays in reaching, or 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. For example, in December 2024, we announced preliminary safety, tolerability and PK data from PIKture-01, with a cutoff date of October 28, 2024, which supported our initiation of Part 1b of PIKture-01. These data are considered preliminary and do not include efficacy data. We plan to provide additional data in the first quarter of 2026. We cannot predict whether these additional data will be consistent with the preliminary data announced in December 2024, or whether the data will be positive or consistent with our preliminary data. If the additional data from PIKture-01 are not positive or fail to support further advancement of OKI-219, we could experience volatility or a substantial decline in our stock price. Further, even if such data are positive and we decide to pursue future clinical trials of OKI-219, these trials may not be successful.

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

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

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

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

We intend to develop OKI-219, and may develop any other product candidate we develop, in combination with one or more currently approved cancer therapies or therapies in development. Patients may not be able to tolerate our product candidates in combination with other therapies, or dosing of our product candidates in combination with other therapies may have unexpected consequences. Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to risks that the FDA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidates, or safety, efficacy, manufacturing, or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates may be approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our products being removed from the market or being less successful commercially. If the FDA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing, or supply issues arise with the therapies we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or successfully market any or all of the product candidates we develop.

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

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

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

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

There are multiple PI3K α -pathway targeted agents either approved or under clinical development that will potentially compete with OKI-219 and our PI3K α -targeted portfolio. Alpelisib (Piqray, a PI3K α -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 PI3K α -mutated breast cancer patients in combination with the selective estrogen receptor degrader (“SERD”) fulvestrant. Additionally, the PI3K α -selective inhibitor inavolisib (ItovebiTM) has been approved in combination with the SERD fulvestrant and the CDK4/6 inhibitor palbociclib (IbranceTM) 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 PI3K α , 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-219 or any other product candidate receives marketing approval, they may fail to achieve market acceptance among physicians, patients, third-party payors, and others in the medical community.

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

- the efficacy and potential advantages of our product candidates compared to alternative treatments, including the existing standard-of-care;
- our ability to offer products for sale at competitive prices;
- the clinical indications for which the product is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the cost of treatment in relation to alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of doctors to prescribe these therapies;
- the strength of our marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of an approved product candidate for use as a combination therapy;
- the potential for our competitors to limit our access to the market through anti-competitive contracts or other arrangements;
- unfavorable publicity relating to our product candidates;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

If any of our product candidates are approved but do not achieve an adequate level of market acceptance, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

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

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

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

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

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

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

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

only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (“CMS”), an agency within the U.S. Department of Health and Human Services (“HHS”). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS’s decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor’s determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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

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

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

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

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

- differing regulatory requirements and drug pricing regimes in foreign countries;
- unexpected 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 may 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, most significantly China, with respect to trade policies, treaties, trade regulations, and tariffs, and such uncertainty could continue under the current U.S. presidential administration. In February 2025, the 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. The administration has imposed a baseline tariff of 10% on virtually all imports and higher country-specific tariffs on China and other countries, including countries in the European Union. The U.S. Commerce Department is also currently conducting a targeted investigation related to imports of pharmaceuticals and pharmaceutical ingredients under section 232 of the Trade Expansion Act of 1962 which could result in tariffs on imports of finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products 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 products and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and, if approved, commercialize our product candidates may be adversely affected.

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

The patents and patent applications that we own may fail to result in issued patents with claims that protect OKI-219 or any future product candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover OKI-219 or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, the scope and coverage of such patents may be so narrow that a third party could successfully design around our patents without materially impacting the therapeutic effectiveness of the resulting drug product. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

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

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

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

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been and will continue to be the subject of litigation and new legislation, resulting in court decisions, including U.S. Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our

rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our own patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the America Invents Act created new administrative post-grant proceedings, including post-grant review, inter partes review and derivation proceedings that allow third parties to challenge the validity of issued patents. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending patents or enforcing proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize their technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents and patent applications may be challenged in the courts or patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. An adverse decision in any such challenge may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay incurred by the USPTO in examining the patent application (patent term adjustment). The scope of patent protection may also be limited.

Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product

candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a U.S. patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent.

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

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

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

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

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

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

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

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

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

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

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and future product

candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future product candidates may infringe.

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

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

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

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

Competitors may infringe or otherwise violate our patents or other intellectual property rights, or those of our licensors. To counter infringement or unauthorized use or misappropriations, we or any future licensors may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents or any of our current or future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us, such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review or post-grant review, or

oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours or a future licensor is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our or any future licensors' patent claims do not cover the invention, or decide that the other party's use of our or any future licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our or any future licensors' patents could limit our ability to assert our own or any future licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position and our business, financial condition, results of operations and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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

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

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

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

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our

intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (the “UPC”). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC over the first seven years of the court’s existence and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries that are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents covering OKI-219 and any future product candidate throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions in which we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or any future licensors’ inventions in all countries outside the United States, even in jurisdictions where we or any future licensors do pursue patent protection, or from selling or importing products made using our or any future licensors’ inventions in and into the United States or other jurisdictions. Competitors may use our or any future licensors’ technologies in jurisdictions where we have not obtained patent protection to develop our own products and, further, may export otherwise infringing products to territories where we may have or obtain patent protection, but where patent enforcement is not as strong as in the United States. These unauthorized competitors’ products may compete with our products in such jurisdictions and take away our market share where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products. This could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment.

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

Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of

theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. In addition, some courts inside and outside of the United States may be less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, such lawsuits would consume our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

Monitoring unauthorized disclosure and detection of unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our products, including confidential aspects of sample preparation,

methods of manufacturing, and related processes and software, are based on unpatented trade secrets. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

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

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

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

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

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

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to those of ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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

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

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

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

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

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

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

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

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

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

We may license or otherwise acquire development or commercialization rights to current and future product candidates or data from third parties. If any future licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize future product candidates that may be subject of such licensed rights could be adversely affected. In spite of our efforts, any future licensors might conclude that we are in material breach of obligations under our license agreements. If we breach any material obligations, or 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.

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

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

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

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

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. 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. In September and October 2025, the government announced the first agreements with two major pharmaceutical companies to bring American drug prices in line with the lowest paid by other developed nations, requiring the companies to offer medicines at a deep discount off the list price when selling directly to American patients. Such agreements 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 R&D 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. On June 28, 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; however, this adequacy decision is subject to a four-year “sunset” period, after which it may be renewed. This decision may 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.

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 product 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 the ongoing 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. 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. To the extent that any disruption or security incident were to result in a loss, destruction or alteration of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal or international laws relating to privacy, data protection, and information security. Litigation and governmental investigations 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 development and research programs;
- failure to achieve development, regulatory or commercialization milestones under our collaborations;
- failure or discontinuation of any of our product development and research programs;
- results of preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- the level of expenses related to any of our research programs, clinical development programs or product candidates;
- the results of our efforts to develop additional product candidates;
- regulatory actions with respect to our or our competitors' product candidates or products;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- announced or completed acquisitions of businesses, products or intellectual property by us or our competitors;
- actual or anticipated changes in the financial projections or development timelines we may provide to the public or our failure to meet those projections or timelines;
- market conditions in the biotechnology and pharmaceutical sectors;
- changes in the structure of healthcare payment systems;
- sales of our Class A Common Stock by us or our stockholders, or expectations that such sales may occur, and the expiration of lock-up agreements;
- the recruitment or departure of key personnel;
- the public's reaction to our press releases, other public announcements and our filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- fluctuations in the trading volume of our Class A Common Stock or the size of our public float;
- actual or anticipated changes or fluctuations in our results of operations;
- actual or anticipated developments in our business, our competitors' businesses or changes in the market valuations of similar companies and the competitive landscape generally;
- changes in the market valuations of similar companies;

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

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

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

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

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

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. These

competitors also may provide higher compensation, more diverse opportunities, and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

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

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

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

We will incur significant legal, accounting and other expenses as a public company that Legacy OnKure did not incur as a private company, including costs associated with public company reporting obligations under the Exchange Act. Our management team consists of the executive officers of Legacy OnKure prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our Board 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. As a private company, Legacy OnKure was not required to test its internal controls within a specified period. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

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

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

Our Amended and Restated Certificate of Incorporation 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.

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

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

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

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

Reneo's winddown of its historical operations, the suspension of development activities and the Merger, resulting in the conversion of Legacy OnKure into a public company, 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) limits the ability of holders of restricted securities and any affiliates of the public company to publicly resell Rule 145(c) securities per Rule 145(d), as well as any other of our "restricted" or "control" securities per Rule 144, until one year after the Super 8-K is filed with the SEC. Non-affiliate Reneo stockholders prior the Merger are 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.

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

If existing securityholders sell, or indicate an intention to sell, substantial amounts of our Class A Common Stock in the public market after legal restrictions on resale lapse, the trading price of our Class A Common Stock could decline. Of the outstanding shares of our Class A Common Stock, approximately 6,733,253 shares became available for sale in the public market as a result of the expiration of lock-up agreements. All other outstanding shares of our Class A Common Stock, other than shares held by our affiliates, are also freely tradable, without restriction, in the public market. In addition, shares of our Class A Common Stock that are subject to outstanding options or warrants will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our Class A Common Stock could decline.

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

As of September 30, 2025, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 36.1% 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, 2024, we had U.S. federal net operating loss carryforwards of \$219.4 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 Concurrent Financing. 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 Financing 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	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated December 9, 2020.	S-1	3/19/2021	4.2	
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

<u>Exhibit Number</u>	<u>Description</u>	<u>Form</u>	<u>Filing Date</u>	<u>Number</u>	<u>Filed Herewith</u>
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: November 6, 2025

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)

**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 September 30, 2025, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 6, 2025

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

Date: November 6, 2025

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.

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 06, 2025

OnKure Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40315
(Commission File Number)

47-2309515
(IRS Employer
Identification No.)

6707 Winchester Circle, #400
Boulder, Colorado
(Address of Principal Executive Offices)

80301
(Zip Code)

Registrant's Telephone Number, Including Area Code: (720) 307-2892

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, \$0.0001 par value per share	OKUR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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.

Item 1.01 Entry into a Material Definitive Agreement.

On November 6, 2025, OnKure Therapeutics, Inc. (the “Company”), entered into a sales agreement (the “Sales Agreement”) with Leerink Partners LLC (“Leerink Partners”) to sell shares (the “Placement Shares”) of the Company’s Class A common stock, \$0.0001 par value per share (the “Common Stock”), from time to time, through an “at the market offering” program under which Leerink Partners will act as sales agent.

Under the Sales Agreement, the Company will set the parameters for the sale of Placement Shares, including the maximum number or dollar amount of Placement Shares to be sold, the time period during which sales are requested to be made, any limitation on the number or dollar amount of Placement Shares that may be sold in any one trading day, and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, unless otherwise specified by the Company, Leerink Partners may sell Placement Shares by any method permitted by law deemed to be an “at-the-market offering” as defined in Rule 415 of the Securities Act of 1933, as amended, including sales made directly on or through the Nasdaq Global Market, on or through any other existing trading market for the Common Stock or to or through a market maker. If expressly authorized by the Company, the Leerink Partners may also sell Placement Shares in negotiated transactions. Leerink Partners has agreed to use commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of The Nasdaq Stock Market LLC to sell such Placement Shares up to the number or amount specified in, and otherwise in accordance with, the terms of a placement notice given to Leerink Partners. As specified in the Sales Agreement, the Sales Agreement may be terminated by the Company upon 10 days’ prior notice to Leerink Partners in its sole discretion at any time, or by Leerink Partners upon 10 days’ prior notice to the Company in its sole discretion at any time or immediately upon notice to the Company under certain circumstances, including in the event of a material adverse change in the Company.

The Sales Agreement provides that Leerink Partners will be entitled to compensation for its services of up to 3.0% of the gross proceeds from the sales of Placement Shares through Leerink Partners under the Sales Agreement. The Company has no obligation to sell any Placement Shares under the Sales Agreement, and may at any time suspend sales of shares under the Sales Agreement. The Sales Agreement contains customary representations, warranties, and agreements by the Company, indemnification obligations of the Company and Leerink Partners, other obligations of the parties, and termination provisions.

The Placement Shares will be offered and sold pursuant to the Company’s shelf registration statement on Form S-3 (the “Registration Statement”), including the prospectus supplement contained therein, to be filed with the Securities and Exchange Commission (the “Commission”) on November 6, 2025, once the Registration Statement becomes effective, and no sales may be made until such time as the Registration Statement becomes effective.

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which is filed as Exhibit 1.1 to this Current Report on Form 8-K (“Current Report”) and incorporated herein by reference.

This Current Report shall not constitute an offer to sell or the solicitation of an offer to buy the securities discussed herein, nor shall there be any sale of such securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
1.1	Sales Agreement by and between OnKure Therapeutics, Inc. and Leerink Partners LLC, dated as of November 6, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

ONKURE THERAPEUTICS, INC.

Date: November 6, 2025

By: /s/ Jason Leverone

Name: Jason Leverone

Title: Chief Financial Officer

ONKURE THERAPEUTICS, INC.
Shares of Class A Common Stock
(\$0.0001 par value per share)

SALES AGREEMENT

November 6, 2025

LEERINK PARTNERS LLC
1301 Avenue of the Americas, 5th Floor
New York, New York 10019

Ladies and Gentlemen:

OnKure Therapeutics, Inc., a Delaware corporation (the “**Company**”), confirms its agreement (this “**Agreement**”) with Leerink Partners LLC (the “**Agent**”), as follows:

1. **Issuance and Sale of Shares.** The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through the Agent shares of Class A common stock, \$0.0001 par value per share, of the Company (the “**Common Stock**”), subject to the limitations set forth in Section 5(c) (the “**Placement Shares**”). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this Section 1 on the aggregate gross sales price of Placement Shares that may be issued and sold under this Agreement from time to time shall be the sole responsibility of the Company, and that the Agent shall have no obligation in connection with such compliance. The issuance and sale of Placement Shares through the Agent will be effected pursuant to the Registration Statement (as defined below) to be filed by the Company with the Securities and Exchange Commission (the “**Commission**”) on November 6, 2025 and to become effective or to be declared effective by the Commission, although nothing in this Agreement shall be construed as requiring the Company to issue any Placement Shares.

The Company has prepared and will file, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the “**Securities Act**”), with the Commission a registration statement on Form S-3, including (a) a base prospectus (the “**Base Prospectus**”), relating to certain securities, including the Common Stock, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the “**Exchange Act**”), and (b) a prospectus supplement to the Base Prospectus specifically relating to the Placement Shares to be issued from time to time pursuant to this Agreement (the “**Prospectus Supplement**”). The Company will furnish to the Agent, for use by the Agent, copies of the Base Prospectus at the time such registration statement becomes effective, as supplemented by the Prospectus Supplement. Except where the context otherwise requires, such registration statement, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration

statement pursuant to Rule 430B or Rule 462(b) under the Securities Act, is herein called the “**Registration Statement**.” The Base Prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by the Prospectus Supplement, in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any “issuer free writing prospectus” (as used herein, as defined in Rule 433 under the Securities Act (“**Rule 433**”)), relating to the Placement Shares that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case, in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g), is herein called the “**Prospectus**.”

Any reference herein to the Registration Statement, the Prospectus Supplement, the Prospectus or any issuer free writing prospectus shall be deemed to refer to and include the documents, if any, that are or are deemed to be incorporated by reference therein (the “**Incorporated Documents**”), including, unless the context otherwise requires, the documents, if any, filed as exhibits to such Incorporated Documents. Any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement, the Prospectus Supplement, the Prospectus or any issuer free writing prospectus shall be deemed to refer to and include the filing of any document under the Exchange Act on or after the most-recent effective date of the Registration Statement, or the respective dates of the Prospectus Supplement, Prospectus or such issuer free writing prospectus, as the case may be, and incorporated therein by reference. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to include the most recent copy filed with the Commission pursuant to its Electronic Data Gathering Analysis and Retrieval System or, if applicable, the Interactive Data Electronic Application system when used by the Commission (collectively, “**EDGAR**”).

2. **Placements.** Each time that the Company wishes to issue and sell any Placement Shares through the Agent hereunder (each, a “**Placement**”), it will notify the Agent by email notice (or other method mutually agreed to in writing by the parties) (each such notice, a “**Placement Notice**”) containing the parameters in accordance with which it desires such Placement Shares to be sold, which at a minimum shall include the maximum number or dollar amount of Placement Shares to be sold, the time period during which sales are requested to be made, any limitation on the number or dollar amount of Placement Shares that may be sold in any one Trading Day (as defined in Section 3) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters is attached hereto as **Schedule 1**. The Placement Notice must originate from one of the individuals authorized to act on behalf of the Company and set forth on **Schedule 2** (with a copy to each of the other individuals from the Company listed on such **Schedule 2**), and shall be addressed to each of the recipients from the Agent set forth on **Schedule 2**, as such **Schedule 2** may be updated by either party from time to time by sending a written notice containing a revised **Schedule 2** to the other party in the manner provided in Section 12 (including by email correspondence to each of the individuals of the Company set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply). The Placement Notice shall be effective upon receipt by the Agent unless and until (i) in accordance with the notice requirements set forth in Section 4, the Agent declines to accept the terms contained therein for any reason, in its sole discretion, within two Trading Days of the date the Agent receives the Placement Notice, (ii) in accordance with the notice requirements set forth in Section 4, the Agent suspends sales under the Placement Notice for any reason in its sole discretion, (iii) the entire amount of the Placement Shares has been sold pursuant to this Agreement, (iv) in accordance with the notice requirements set forth in Section 4, the Company suspends sales under or terminates the Placement Notice for any reason in its sole discretion, (v) the Company issues a subsequent Placement Notice and explicitly indicates that its parameters supersede those contained in the earlier dated Placement Notice or (vi) this Agreement has been terminated pursuant to the provisions of Section 11. The amount of any

discount, commission or other compensation to be paid by the Company to the Agent in connection with the sale of the Placement Shares effected through the Agent shall be calculated in accordance with the terms set forth in **Schedule 3**. It is expressly acknowledged and agreed that neither the Company nor the Agent will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to the Agent and the Agent does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control with respect to the matters covered thereby.

3. **Sale of Placement Shares by the Agent.** On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, including Section 5(c), upon the Agent's acceptance of the terms of a Placement Notice as provided in Section 2, and unless the sale of the Placement Shares described therein has been declined, suspended or otherwise terminated in accordance with the terms of this Agreement, the Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Global Market ("**Nasdaq**") to sell such Placement Shares up to the number or amount specified in, and otherwise in accordance with the terms of, such Placement Notice. The Agent will provide written confirmation to the Company (including by email correspondence to each of the individuals of the Company set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number or amount of Placement Shares sold on such Trading Day, the volume-weighted average price of the Placement Shares sold and the Net Proceeds (as defined below) payable to the Company. Unless otherwise specified by the Company in a Placement Notice, the Agent may sell Placement Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including sales made directly on or through Nasdaq, on or through any other existing trading market for the Common Stock or to or through a market maker. If expressly authorized by the Company (including in a Placement Notice), the Agent may also sell Placement Shares in negotiated transactions. Notwithstanding the provisions of Section 6(tt), except as may be otherwise agreed by the Company and the Agent, the Agent shall not purchase Placement Shares on a principal basis pursuant to this Agreement unless the Company and the Agent enter into a separate written agreement setting forth the terms of such sale. The Company acknowledges and agrees that (i) there can be no assurance that the Agent will be successful in selling Placement Shares, (ii) the Agent will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by the Agent to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of Nasdaq to sell such Placement Shares as required under this Agreement and (iii) the Agent shall be under no obligation to purchase Placement Shares on a principal basis pursuant to this Agreement unless the Company and the Agent enter into a separate written agreement setting forth the terms of such sale. For the purposes hereof, "**Trading Day**" means any day on which the Common Stock is purchased and sold on Nasdaq.

4. **Suspension of Sales.**

(a) The Company or the Agent may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by email correspondence to each of the individuals of the other party set forth on **Schedule 2**), suspend any sale of Placement Shares; *provided, however*, that such suspension shall not affect or

impair either party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. While a suspension pursuant to this Section 4(a) is in effect, any obligation under Section 7(m), 7(n), 7(o), and 7(p) with respect to the delivery of certificates, opinions, or comfort letters to the Agent, shall be waived; provided, that upon delivery of a Placement Notice following a Representation Date (as defined below), the Company shall be subject to the obligations set forth in Section 7(m), 7(n), 7(o), and 7(p), as applicable. Each of the parties agrees that no such notice under this Section 4 shall be effective against the other party unless such notice is sent by one of the individuals named on **Schedule 2** hereto to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply).

(b) Notwithstanding any other provision of this Agreement, during any period in which the Company is, or could be deemed to be, in possession of material non-public information, the Company and the Agent agree that (i) no sale of Placement Shares will take place, (ii) the Company shall not request the sale of any Placement Shares and shall cancel any effective Placement Notices instructing the Agent to make any sales and (iii) the Agent shall not be obligated to sell or offer to sell any Placement Shares.

5. Settlement and Delivery of the Placement Shares.

(a) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the first Trading Day (or such other day as is industry practice or as is required for regular-way trading) following the date on which such sales are made (each, a "**Settlement Date**"). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "**Net Proceeds**") will be equal to the aggregate gross sales price received by the Agent at which such Placement Shares were sold, after deduction of (i) the Agent's commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, (ii) any other amounts due and payable by the Company to the Agent hereunder pursuant to Section 7(g) hereof and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(b) Delivery of Placement Shares. On or before each Settlement Date, the Company will issue the Placement Shares being sold on such date and will, or will cause its transfer agent to, electronically transfer such Placement Shares by crediting the Agent's or its designee's account (provided the Agent shall have given the Company written notice of such designee prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System ("**DWAC**") or by such other means of delivery as may be mutually agreed upon by the parties hereto, which in all cases shall be duly authorized, freely tradeable, transferable, registered shares of Common Stock in good deliverable form. On each Settlement Date, the Agent will deliver the related Net Proceeds in same day funds to an account designated by the Company on or prior to the Settlement Date. The Agent shall be responsible for providing DWAC instructions or other instructions for delivery by other means with regard to the transfer of the Placement Shares being sold. In addition to and in no way limiting the rights and obligations set forth in Section 9(a) hereto, the Company agrees that if the Company or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized, freely tradeable, transferable, registered Placement Shares in good deliverable form by 2:30 P.M., New York City time, on a Settlement Date (other than as a result of a failure by the Agent to provide instructions for delivery), the Company will (i) take all necessary action to cause the full amount of any Net Proceeds that were delivered to the Company's account with respect to such settlement, together

with any costs incurred by the Agent and/or its clearing firm in connection with recovering such Net Proceeds, to be immediately returned to the Agent or its clearing firm no later than 5:00 P.M., New York City time, on such Settlement Date, by wire transfer of immediately available funds to an account designated by the Agent or its clearing firm, (ii) indemnify and hold the Agent and its clearing firm harmless against any loss, claim, damage, or expense (including reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company or its transfer agent (if applicable) and (iii) pay to the Agent any commission, discount or other compensation to which it would otherwise have been entitled absent such default. Certificates for the Placement Shares, if any, shall be in such denominations and registered in such names as the Agent may request in writing one Business Day (as defined below) before the applicable Settlement Date. Certificates for the Placement Shares, if any, will be made available by the Company for examination and packaging by the Agent in New York City not later than 12:00 P.M., New York City time, on the Business Day prior to the applicable Settlement Date.

(c) Limitations on Offering Size. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares if, after giving effect to the sale of such Placement Shares, the aggregate number or gross sales proceeds of Placement Shares sold pursuant to this Agreement would exceed the lesser of: (i) the number or dollar amount of shares of Common Stock registered pursuant to, and available for offer and sale under, the Registration Statement pursuant to which the offering of Placement Shares is being made, (ii) the number of authorized but unissued shares of Common Stock of the Company (less shares of Common Stock issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized capital stock), (iii) the number or dollar amount of shares of Common Stock permitted to be offered and sold by the Company under Form S-3 (including General Instruction I.B.6. thereof, if such instruction is applicable), (iv) the number or dollar amount of shares of Common Stock that the Company's board of directors or a duly authorized committee thereof is authorized to issue and sell from time to time, and notified to the Agent in writing, or (v) the dollar amount of shares of Common Stock for which the Company has filed the Prospectus Supplement. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Company's board of directors or a duly authorized committee thereof, and notified to the Agent in writing. Notwithstanding anything to the contrary contained herein, the parties hereto acknowledge and agree that compliance with the limitations set forth in this Section 5(c) on the number or dollar amount of Placement Shares that may be issued and sold under this Agreement from time to time shall be the sole responsibility of the Company, and that the Agent shall have no obligation in connection with such compliance.

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with, the Agent that as of the date of this Agreement, and as of (i) each Representation Date (as defined in Section 7(m)) for which no waiver is in effect, (ii) each date on which a Placement Notice is given, (iii) the date and time of each sale of any Placement Shares pursuant to this Agreement and (iv) each Settlement Date (each such time or date referred to in clauses (i) through (iv), an "**Applicable Time**"):

(a) The Company and the transactions contemplated by this Agreement meet the requirements for and comply with the conditions for the use of Form S-3 (including General Instructions I.A and I.B.1.) under the Securities Act. The Registration Statement will be filed with the Commission and will become effective or be declared effective by the Commission under the Securities Act prior to the issuance of any Placement Notices by the Company. At the time the Registration Statement becomes effective or is declared effective and as of each Applicable Time,

the Company meets the applicable requirements for use of Form S-3 (including General Instructions I.A and I.B.1.) under the Securities Act. The Registration Statement meets, and the offering and sale of Placement Shares as contemplated hereby comply with, the requirements of Rule 415(a)(1)(x) under the Securities Act. The Agent is named as the agent engaged by the Company in the section entitled “Plan of Distribution” in the Prospectus Supplement. The Company has not received, and has no notice from the Commission of, any notice pursuant to Rule 401(g)(1) under the Securities Act objecting to the use of the shelf registration statement form. No stop order of the Commission preventing or suspending the use of the base prospectus, the Prospectus Supplement or the Prospectus, or the effectiveness of the Registration Statement, has been issued, and no proceedings for such purpose are pending before or, to the knowledge of the Company, threatened by the Commission. At the time of the initial filing of the Registration Statement, the Company paid the required Commission filing fees relating to the securities covered by the Registration Statement, including the Placement Shares that may be sold pursuant to this Agreement, in accordance with Rule 457(o) under the Securities Act. Copies of the Registration Statement, the Prospectus, any such amendments or supplements to any of the foregoing and all Incorporated Documents that were filed with the Commission on or prior to the date of this Agreement have been delivered, or are available through EDGAR, to the Agent and its counsel.

(b) Each of the Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective, at each deemed effective date with respect to the Agent pursuant to Rule 430B(f)(2) under the Securities Act and as of each Applicable Time, complied, complies and will comply in all material respects with the requirements of the Securities Act and did not, does not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, except that the representations and warranties set forth in this sentence do not apply to Agent’s Information (as defined below). The Prospectus and any amendment or supplement thereto, when so filed with the Commission under Rule 424(b) under the Securities Act, complied, complies and as of each Applicable Time will comply in all material respects with the requirements of the Securities Act, and each Prospectus Supplement, Prospectus or issuer free writing prospectus (or any amendments or supplements to any of the foregoing) furnished to the Agent for use in connection with the offering of the Placement Shares was identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T. Neither the Prospectus nor any amendment or supplement thereto, as of its date and as of each Applicable Time, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, except that the representations and warranties set forth in this sentence do not apply to Agent’s Information. Each Incorporated Document heretofore filed, when it was filed (or, if any amendment with respect to any such document was filed, when such amendment was filed), conformed in all material respects with the requirements of the Exchange Act and was filed on a timely basis with the Commission, and any further Incorporated Documents so filed and incorporated into the Prospectus after the date of this Agreement will be filed on a timely basis and, when so filed, will conform in all material respects with the requirements of the Exchange Act; no such Incorporated Document when it was filed (or, if an amendment with respect to any such document was filed, when such amendment was filed), contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and no such Incorporated Document, when it is filed, will contain an untrue statement of a material fact or will omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(c) Except as disclosed in the Registration Statement, the Company was not and is not an “ineligible issuer” (as defined in Rule 405), without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.

(d) Reneo Pharmaceuticals, Inc. (“**Reneo**”), the Company’s predecessor entity, was, and since April 13, 2021 had been, an “emerging growth company,” as defined in Section 2(a) of the Securities Act (an “**Emerging Growth Company**”). The Company is, and since the consummation of the merger of Radiate Merger Sub I, Inc., Reneo’s direct and wholly-owned subsidiary, with and into OnKure, Inc. on October 4, 2024, has been, an Emerging Growth Company.

(e) Each issuer free writing prospectus, as of its issue date and as of each Applicable Time, did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any Incorporated Document deemed to be a part thereof that has not been superseded or modified. Each issuer free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433 or that was prepared by or on behalf of or used by the Company complies or will comply in all material respects with the requirements of the Securities Act.

(f) The Company has not distributed and, prior to the later to occur of each Settlement Date and completion of the Agent’s distribution of the Placement Shares under this Agreement, will not distribute any offering material in connection with the offering and sale of the Placement Shares other than the Registration Statement, the Prospectus or any Permitted Free Writing Prospectus (as defined below).

(g) The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement and the Prospectus fairly presents the information called for in all material respects and has been prepared in accordance with the Commission’s rules and guidelines applicable thereto.

(h) The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is listed on Nasdaq, and the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from Nasdaq, nor has the Company received any notification that the Commission or Nasdaq is contemplating terminating such registration or listing. The Company is in compliance with the current listing standards of Nasdaq. The Company has filed a Notification of Listing of Additional Shares with Nasdaq with respect to the Placement Shares.

(i) No person (as such term is defined in Rule 1-02 of Regulation S-X promulgated under the Securities Act) has the right to act as an underwriter or as a financial advisor to the Company in connection with the offer and sale of the Placement Shares hereunder, whether as a result of the filing or effectiveness of the Registration Statement or the sale of the Placement Shares as contemplated hereby or otherwise. Except for the Agent, there is no broker, finder or other party that is entitled to receive from the Company or any of its Subsidiaries (as defined below) any brokerage or finder’s fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(j) The Company has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware, with full corporate power and authority to acquire, own, lease and operate its properties, and to lease the same to others, and to conduct its business as described in

the Registration Statement and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified to transact business as a foreign corporation and is in good standing in the State of Colorado and under the laws of each other jurisdiction that requires such qualification, whether by reason of the ownership or leasing of property or the conduct of business, except to the extent that the failure to be so qualified or in good standing would not reasonably be expected, individually or in the aggregate, to have a material adverse effect on the condition (financial or otherwise), earnings, results of operations, business, properties, operations, assets, liabilities or prospects of the Company and its Subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business (a “**Material Adverse Effect**”).

(k) Each subsidiary of the Company that is a “significant subsidiary” (as such term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission) (each, a “**Subsidiary**” and collectively, the “**Subsidiaries**”) has been duly organized and is validly existing in good standing (where such concept exists) under the laws of the jurisdiction of its organization and has full power and authority to acquire, own, lease and operate its properties, and to conduct its business as described in the Registration Statement and the Prospectus. Each Subsidiary is duly qualified to transact business and is in good standing (where such concept exists) under the laws of each jurisdiction that requires such qualification, whether by reason of the ownership or leasing of property or the conduct of business, except to the extent that the failure to be so qualified or in good standing would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. All of the issued and outstanding share capital or other equity or ownership interests of each Subsidiary has been duly authorized and validly issued, is fully paid and nonassessable, has been issued in compliance with federal state and securities laws and is owned by the Company, directly or through other wholly-owned Subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. The Company does not own or control, directly or indirectly, any corporation, association or other entity, other than the Subsidiaries listed on Exhibit 21.1 to the Company’s most recent Annual Report on Form 10-K filed with the Commission. No Subsidiary is prohibited or restricted, directly or indirectly, from paying dividends to the Company, from making any other distribution with respect to such Subsidiary’s equity securities, from repaying to the Company or any other Subsidiary any amounts that may from time to time become due under any loans or advances to such Subsidiary from the Company or from transferring any property or assets to the Company or to any other Subsidiary.

(l) The Company has the authorized and outstanding capitalization as set forth in the Company’s Annual Report on Form 10-K for the most recent fiscal year or, if later, the Company’s Quarterly Report on Form 10-Q for the most recent fiscal quarter, as of the dates referred to therein (subject, in each case, to the issuance of Placement Shares under this Agreement, the issuance of shares of Common Stock upon exercise of stock options and settlement of restricted stock units, in each case disclosed as outstanding as of the date hereof in the Registration Statement and the Prospectus and the grant of options and restricted stock units under existing Stock Plans (as defined below) described in the Registration Statement and the Prospectus). The Common Stock conforms in all material respects to the description thereof contained in the Registration Statement and the Prospectus, including under the heading “Description of Capital Stock.” All of the issued and outstanding share capital or other equity or ownership interest of the Company (including the Common Stock) has been duly authorized and validly issued and is fully paid and nonassessable, has been issued in compliance with all federal, state and local securities laws and is free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. None of the outstanding shares of capital stock of the Company were issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. Except as described in the Registration Statement and Prospectus, there are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase or subscribe for, or equity or debt securities convertible into or exchangeable or exercisable for, any share capital of the Company or any of its Subsidiaries or to which the Company or any of its

Subsidiaries is a party or by which any of them may be bound. The descriptions of the Company's equity incentive plan, stock option plans and other stock plans or arrangements described in the Prospectus and in effect as of the date hereof (collectively, the "**Stock Plans**") and the options or other rights granted thereunder, set forth in the Registration Statement and the Prospectus accurately and fairly present the information required to be shown with respect to such Stock Plans and the options or other rights granted thereunder.

(m) The Placement Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable and will conform in all material respects to the description thereof contained in the Prospectus. The issuance and sale of the Placement Shares as contemplated hereby shall not be subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Placement Shares. When issued and delivered by the Company against payment therefor pursuant to this Agreement, the purchasers of the Placement Shares issued and sold hereunder will acquire good, marketable and valid title to such Placement Shares, free and clear of all pledges, liens, security interests, charges, claims or encumbrances. The issuance and sale of the Placement Shares as contemplated hereby will not cause any holder of any share capital, securities convertible into or exchangeable or exercisable for share capital or options, warrants or other rights to purchase share capital or any other securities of the Company to have any right to acquire any preferred shares of the Company. There are no restrictions upon the voting or transfer of the Common Stock under the Company's amended and restated certificate of incorporation or amended and restated bylaws or any agreement or other instrument to which the Company is a party or otherwise filed as an exhibit to the Registration Statement.

(n) There is no statute, regulation, contract, agreement or other document required to be described in the Registration Statement, Prospectus or in any Incorporated Document, or to be filed as an exhibit to the Registration Statement or any Incorporated Document which is not described or filed as required. The statements set forth or incorporated by reference in the Prospectus, insofar as they purport to constitute summaries of the terms of the statutes, regulations, contracts, agreements or other documents described and filed, constitute accurate summaries of the terms thereof in all material respects. The statements set forth or incorporated by reference in the Prospectus under the headings "Risk Factors," "Business—Intellectual Property," "Business—Government Regulation," "Business—Other U.S. Regulatory Matters," "Legal Proceedings," and "Description of Capital Stock," insofar as such statements summarize legal matters, agreements, documents or proceedings discussed therein, are accurate and fair summaries of such legal matters, agreements, documents or proceedings. Neither the Company nor any of its Subsidiaries has sent or received any communication regarding termination of, or intent not to renew or render performance under, any of the contracts or agreements referred to or described in the Prospectus or any free writing prospectus, or referred to or described in, or filed as an exhibit to, the Registration Statement, or any Incorporated Document, and no such termination or non-renewal has been threatened by the Company or any of its Subsidiaries or, to the Company's knowledge, any other party to any such contract or agreement, which threat of termination or non-renewal has not been rescinded as of the date hereof.

(o) This Agreement has been duly and validly authorized, executed and delivered by the Company and constitutes a valid and legally binding obligation of the Company, enforceable against the Company in accordance with its terms, except as enforceability, including rights of indemnification, may be limited by bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar laws relating to or affecting creditors' rights generally and by general principles of equity. This Agreement conforms in all material respects to the descriptions thereof in the Registration Statement and the Prospectus.

(p) The Company is not and, after giving effect to the offering and sale of the Placement Shares and the application of the proceeds thereof as described in the Prospectus, will not be an “investment company” as defined in the Investment Company Act of 1940, as amended.

(q) No consent, approval, license, permit, qualification, authorization or other order or decree of, or registration or filing with, any court or other governmental, taxing or regulatory authority or agency, is required for the Company’s execution, delivery and performance of this Agreement or consummation of the transactions contemplated hereby or by the Registration Statement and the Prospectus (including the issuance and sale of the Placement Shares hereunder), except such as have been already obtained or made or as may be required under the Securities Act, applicable state securities or Blue Sky laws, applicable rules of Nasdaq, or Rule 5110 of the Financial Industry Regulatory Authority, Inc. (“**FINRA**”).

(r) Neither the execution and delivery by the Company of, nor the performance of the Company of its obligations under, this Agreement will conflict with, result in a breach or violation of, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its Subsidiaries pursuant to: (i) the certificate or articles of incorporation, charter, bylaws, articles of association, limited liability company agreement, certificate or agreement of limited or general partnership or other similar organizational documents, as the case may be, of such entity, (ii) the terms of any indenture, contract, license, lease, mortgage, deed of trust, note agreement, agreement or other instrument, obligation, condition, covenant or instrument to which it is a party or bound or to which its property or assets is subject or (iii) any statute, law, rule, regulation, judgment, order or decree applicable to the Company or any of its Subsidiaries of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company, any of its Subsidiaries or any of their respective properties or assets, as applicable, except, in the case of clauses (ii) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have a Material Adverse Effect.

(s) Subsequent to the respective dates as of which information is given in the Registration Statement and the Prospectus: (i) there has been no Material Adverse Effect, or any development that would reasonably be expected to result in a Material Adverse Effect, in the condition (financial or otherwise), earnings, results of operations, business, properties, operations, assets, liabilities or prospects of the Company and its Subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business; (ii) neither the Company nor its Subsidiaries has (A) incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with its business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company and its Subsidiaries, considered as one entity, (B) entered into any material transactions not in the ordinary course of business or (C) issued or granted any shares of the Company’s capital stock or securities convertible into or exchangeable or exercisable for or that represent the right to receive shares of the Company’s capital stock other than under the Stock Plans; and (iii) there has not been any material decrease in the share capital or any material increase in any short-term or long-term indebtedness of the Company or any of its Subsidiaries and there has been no dividend or distribution of any kind declared, paid or made by the Company or, except for dividends paid to the Company or another Subsidiary, by any Subsidiary on any class of shares, or any repurchase or redemption by the Company or any of its Subsidiaries of any class of shares.

(t) There are no persons (as such term is defined in Rule 1-02 of Regulation S-X promulgated under the Securities Act) with registration or other similar rights to have any equity or debt

securities of the Company registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived in a writing previously furnished to the Agent.

(u) The financial statements included or incorporated by reference in the Registration Statement and the Prospectus, together with the related notes and schedules, present fairly in all material respects the consolidated financial position of the Company and the Subsidiaries as of the dates indicated and the consolidated results of operations, cash flows and changes in stockholders' equity of the Company and the Subsidiaries for the periods specified and have been prepared in compliance in all material respects with the requirements of the Securities Act and Exchange Act and in conformity with United States generally accepted accounting principles ("**GAAP**") applied on a consistent basis during the periods involved. To the extent applicable, any pro forma financial statements, information or data included or incorporated by reference in the Registration Statement and the Prospectus comply in all material respects with the requirements of Regulation S-X of the Securities Act, including, without limitation, Article 11 thereof, fairly present in all material respects the information set forth herein, and the assumptions used in the preparation of such pro forma financial statements and data are reasonable, the pro forma adjustments used therein are appropriate to give effect to the circumstances referred to therein and the pro forma adjustments have been properly applied to the historical amounts in the compilation of those statements and data. The other financial data set forth or incorporated by reference in the Registration Statement and the Prospectus is accurately and fairly presented and prepared on a basis consistent with the financial statements and books and records of the Company. There are no financial statements (historical or pro forma) that are required to be included or incorporated by reference in the Registration Statement or the Prospectus that are not included or incorporated by reference therein as required. The Company and the Subsidiaries do not have any material liabilities or obligations, direct or contingent (including any off-balance sheet obligations or any "variable interest entities" as that term is used in Accounting Standards Codification Paragraph 810-10-25-20), not disclosed in the Registration Statement and the Prospectus. All disclosures contained in the Registration Statement or the Prospectus that contain "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply, in all material respects, with Regulation G under the Exchange Act and Item 10 of Regulation S-K under the Securities Act, to the extent applicable. The statistical, industry-related and market-related data included or incorporated by reference in the Registration Statement and the Prospectus were obtained or derived from sources which the Company reasonably and in good faith believes are reliable and accurate, such data agree with the sources from which they are derived, and the Company has obtained the written consent to the use of such data from such sources to the extent required. To the Company's knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the Public Company Accounting Oversight Board ("**PCAOB**"), has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement and the Prospectus.

(v) There are no actions, suits, claims, investigations or proceedings pending or, to the Company's knowledge, threatened to which the Company or any of the Subsidiaries is or would be a party, or of which any of the respective properties or assets of the Company and the Subsidiaries is or would be subject, at law or in equity, before any court or arbitral body or by or before any federal, state, local or foreign governmental or regulatory commission, board, body, authority or agency, that (i) are required to be described in the Registration Statement or the Prospectus and are not so described, (ii) would reasonably be expected to have a material adverse effect on the ability of the Company to perform its obligations under this Agreement or on the consummation of any of the transactions contemplated hereby or (iii) would reasonably be expected to have a Material Adverse Effect. The aggregate of all pending legal or governmental proceedings to which the Company or any of its Subsidiaries is a party or

of which any of their respective properties or assets is the subject which are not described in the Prospectus, including ordinary routine litigation incidental to the Company's business, would not reasonably be expected to (A) result in a Material Adverse Effect or (B) have a material adverse effect on the ability of the Company to perform its obligations under this Agreement or the consummation of any of the transactions contemplated hereby.

(w) The Company owns or leases all such real properties as are necessary to the conduct of its operations as presently conducted in all material respects.

(x) Neither the Company nor any Subsidiary is in violation or default of (i) any provision of its certificate or articles of incorporation, charter, bylaws, articles of association, limited liability company agreement, certificate or agreement of limited or general partnership, or other similar organizational documents, as the case may be, of such entity, (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which it is a party or bound or to which its property or assets is subject, or (iii) any statute, law, rule, regulation, judgment, order or decree of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company, any of its Subsidiaries or any of their respective properties or assets, as applicable, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, have a Material Adverse Effect.

(y) KPMG LLP, whose report on the consolidated financial statements of the Company is filed with the Commission as part of the Company's most recent Annual Report on Form 10-K filed with the Commission and incorporated by reference in the Registration Statement and the Prospectus, is (i) an independent registered public accounting firm as required by the Securities Act, the Exchange Act and the rules of the PCAOB, (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn. KPMG LLP has not been engaged by the Company to perform any "prohibited activities" (as defined in Section 10A of the Exchange Act).

(z) There are no transfer taxes or other similar fees or charges under federal law, the laws of any state, any foreign law, or any political subdivision thereof, required to be paid in connection with the execution and delivery of this Agreement or the issuance by the Company or sale by the Company of the Placement Shares.

(aa) All United States federal income tax returns of the Company and its Subsidiaries required by law to be filed have been filed or extensions thereof have been requested, and all taxes shown by such returns or otherwise assessed, which are due and payable, have been paid, except where the failure to pay or file would not, individually or in the aggregate, have a Material Adverse Effect or assessments that are being contested in good faith and as to which adequate reserves have been provided under GAAP. The Company has no knowledge of any material tax deficiency which has been or is likely to be threatened or asserted against the Company or its Subsidiaries. Each of the Company and its Subsidiaries has filed all foreign, state, provincial, local or other tax returns that are required to have been filed pursuant to applicable foreign, state, provincial, local or other law except insofar as the failure to file such returns would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, and paid all taxes due pursuant to such returns or pursuant to any assessment received by the Company and its Subsidiaries, except for such taxes, if any, as are being contested in good faith and as to which adequate reserves have been provided and except for such taxes or assessments the nonpayment of which would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

The charges, accruals and reserves on the books of the Company and its Subsidiaries in respect of any income or other tax liability for any years not finally determined are adequate to meet any assessments or re-assessments for additional tax for any years not finally determined, except to the extent of any inadequacy that would not reasonably be expected to result in a Material Adverse Effect. All material taxes which the Company and its Subsidiaries are required by law to withhold or to collect for payment have been duly withheld and collected and have been paid to the appropriate governmental authority or agency or have been accrued, reserved against and entered on the books of the Company and its Subsidiaries.

(bb) No labor dispute with the employees of the Company or any of its Subsidiaries exists or, to the Company's knowledge, is threatened or imminent, and the Company is not aware of any existing, threatened or imminent labor disturbance by the employees of any of its or any of its Subsidiaries' principal suppliers, manufacturers, contractors or customers, in each case that would have a Material Adverse Effect. None of the employees of the Company or any of its Subsidiaries is represented by a union and, to the knowledge of the Company, no union organizing activities are taking place. Neither the Company nor any of its Subsidiaries has violated (or received notice of any violation of) any federal, state or local law or foreign law relating to the discrimination in hiring, promotion or pay of employees, nor any applicable wage or hour laws, or the rules and regulations thereunder, or analogous foreign laws and regulations, which would, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(cc) Each of the Company and its Subsidiaries are insured by recognized and reputable institutions with policies in such amounts and with such deductibles and covering such risks as are generally deemed adequate and customary for their businesses including, but not limited to, policies covering real and personal property owned or leased by the Company and its Subsidiaries against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company and its Subsidiaries for clinical trial liability claims. The Company has no reason to believe that it or any of its Subsidiaries will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its Subsidiaries has been denied any material insurance coverage which it has sought or for which it has applied.

(dd) The Company and each of its Subsidiaries has good and marketable title in fee simple to all real property owned by them and good and marketable title to all personal property owned by them that is material to their business (except with respect to intellectual property, which is addressed exclusively in Section 6(pp) and Section 6(ggg) below), in each case free and clear of all liens, encumbrances and defects except such as do not materially affect the value of such property and do not interfere in any material respect with the use made and proposed to be made of such property by the Company or any Subsidiary; and any real property and buildings held under lease by the Company or any of its Subsidiaries are held by them under valid, subsisting and enforceable leases (subject to the effects of (A) bankruptcy, insolvency, fraudulent conveyance, fraudulent transfer, reorganization, moratorium or other similar laws relating to or affecting the rights or remedies of creditors generally; (B) the application of general principles of equity (including, without limitation, concepts of materiality, reasonableness, good faith and fair dealing, regardless of whether enforcement is considered in proceedings at law or in equity); and (C) applicable law and public policy with respect to rights to indemnity and contribution) with such exceptions as are not material and do not interfere in any material respect with the use made and proposed to be made of such property and buildings by the Company or such Subsidiary.

(ee) The Company and its Subsidiaries possess and are operating in compliance with such valid and current material certificates, authorizations or permits required by United States federal, state or foreign regulatory agencies or bodies to conduct their respective businesses as currently conducted and as described in the Registration Statement and the Prospectus (collectively, “Permits”). Except as described in the Registration Statement and Prospectus, neither the Company nor any of its Subsidiaries is in violation of, or in default under, any of the Permits or has received any written notice of proceedings relating to the revocation or material modification of, or non-compliance with, any such certificate, authorization or permit, which, individually or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to result in a Material Adverse Effect

(ff) The Company and each of its Subsidiaries make and keep accurate books and records and maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management’s general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement and the Prospectus fairly presents the information called for in all material respects and is prepared in accordance with the Commission’s rules and guidelines applicable thereto.

(gg) The Company and each of its Subsidiaries have established and maintain disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which (i) are designed to ensure that information relating to the Company, including its consolidated Subsidiaries, is made known to the Company’s principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company’s most recent fiscal quarter; and (iii) are effective in all material respects to perform the functions for which they were established. Since the end of the Company’s most recent audited fiscal year, there has been no material weakness in the Company’s internal control over financial reporting (whether or not remediated) and no change in the Company’s internal control over financial reporting, including any corrective actions with regard to significant deficiencies or material weaknesses. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

(hh) Neither the Company, nor any of its Subsidiaries, nor to the knowledge of the Company, any of its or their respective directors, officers or controlling persons has taken, directly or indirectly, without giving effect to any actions taken by the Agent, (i) any action designed to or that might constitute or reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares or (ii) any action designed to or that might constitute or reasonably be expected to cause or result in a violation of Regulation M under the Exchange Act.

(ii) Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect: (i) neither the Company nor any of its Subsidiaries is in violation of any United States federal, state or local, or any foreign, statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the

environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the emissions, discharges, release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, "**Hazardous Materials**") or otherwise related to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "**Environmental Laws**"), which violation includes, but is not limited to, noncompliance with any permits or other governmental authorizations required for the operation of the business of the Company or any of its Subsidiaries under applicable Environmental Laws, or noncompliance with the terms and conditions thereof, nor has the Company or any of its Subsidiaries received any written communication, whether from a governmental authority, citizens group, employee or otherwise, that alleges that the Company or any of its Subsidiaries is in violation of any Environmental Law; (ii) the Company and its Subsidiaries have all material permits, authorizations and approvals required under any applicable Environmental Laws and are in compliance with their requirements; (iii) there are no pending or, to the Company's knowledge, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its Subsidiaries, or any investigation with respect to which the Company or any of its Subsidiaries has received written notice or any written notice by any person or entity alleging potential liability for investigatory costs, cleanup costs, governmental responses costs, natural resources damages, property damages, personal injuries, attorneys' fees or penalties arising out of, based on or resulting from the presence, or release into the environment, of any Hazardous Materials at any location owned, leased or operated by the Company or any of its Subsidiaries, now or in the past; and (iv) to the Company's knowledge, there are no past or present actions, activities, events, conditions, incidents or circumstances that might reasonably be expected to result in a violation of any Environmental Law or form the basis of an order for clean-up or remediation, or an action, suit, investigation or proceeding by any private party or governmental body or agency, against or affecting the Company or any of its Subsidiaries relating to Hazardous Materials or any Environmental Laws.

(jj) The Company and any "employee benefit plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, "**ERISA**")) established or maintained by the Company, or its "ERISA Affiliates" (as defined below) are in compliance in all material respects with ERISA. "ERISA Affiliates" means, with respect to the Company, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "**Code**") of which the Company is a member. No "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any "employee benefit plan" established or maintained by the Company, or any of its ERISA Affiliates. No "employee benefit plan" established or maintained by the Company or any of its ERISA Affiliates, if such "employee benefit plan" were terminated, would have any "amount of unfunded benefit liabilities" (as defined under ERISA). Neither the Company nor any of its ERISA Affiliates has incurred or reasonably expects to incur any liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any "employee benefit plan" or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each "employee benefit plan" established or maintained by the Company or any of its ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification.

(kk) The Company is in compliance with, and there is and has been no failure on the part of the Company and, to the Company's knowledge, any of the Company's directors or officers, in their capacities as such, to comply with, any provision of the Sarbanes-Oxley Act of 2002 and all rules and regulations promulgated thereunder or implementing the provisions thereof (the "**Sarbanes-Oxley Act**")

and the rules and regulations promulgated in connection therewith, including Section 402 relating to loans.

(ll) None of the Company, any of its Subsidiaries, or, to the knowledge of the Company, any of their respective directors, officers, agents, employees or affiliates, has taken or will take any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the unlawful payment or giving of money, property, gifts or anything else of value, directly or indirectly, to any “government official” (including any officer or employee of a government or government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office) to influence official action or secure an improper advantage; and the Company, each of its Subsidiaries and, to the Company’s knowledge, each of their respective affiliates have conducted their businesses in compliance with applicable anti-corruption laws.

(mm) None of the Company, any of its Subsidiaries, any of their respective directors, officers or employees, or, to the knowledge of the Company, any of their respective affiliates, agents, representatives or other persons acting on behalf of the Company or any of its Subsidiaries or affiliates, is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of any applicable anti-corruption laws, including the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the “**FCPA**”), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any “foreign official” (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office or otherwise took any action (or failed to fully disclose any action) in contravention of the FCPA; and the Company, its Subsidiaries and each of their respective affiliates have conducted their businesses in compliance with the FCPA and have instituted and maintain, and will continue to maintain, policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(nn) The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements and the money laundering statutes and the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “**Money Laundering Laws**”) and no action, suit, investigation or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries with respect to the Money Laundering Laws is pending or, to the Company’s knowledge, threatened.

(oo) Neither the Company nor any of its Subsidiaries, nor any director or officer thereof, nor, to the Company’s knowledge, any employee, agent, affiliate or representative of the Company or any of its Subsidiaries, is currently or is owned or controlled by an individual or entity that is subject to any sanctions administered or enforced by the United States government (including, without limitation, the Office of Foreign Assets Control of the United States Department of the Treasury), the United Nations Security Council, the European Union, His Majesty’s Treasury or other relevant sanctions authority (collectively, “**Sanctions**”) or is located, organized or resident in a country or territory that is the subject or target of Sanctions; and the Company will not directly or indirectly use the proceeds of the sale of the Placement Shares, or lend, contribute or otherwise make available such proceeds to any Subsidiary, or any joint venture partner or other person or entity, for the purpose of financing or facilitating the activities of or business of any person or entity, or in any country or territory, that currently or at the time of such

financing or facilitation is the subject of any Sanctions or in any other manner that will result in a violation by any person or entity (including any person participating in the transactions contemplated by this Agreement) of any Sanctions. For the past five years, the Company and its Subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person or entity, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(pp) The Company and its Subsidiaries own or possess the right to use all inventions, patent applications, patents, trademarks, trade names, service names, domain names, copyrights, trade secrets, know-how and other intellectual property (collectively, “**Intellectual Property**”) as are (i) necessary or material for the conduct of their respective businesses as currently conducted or as currently proposed to be conducted and as described in the Registration Statement and the Prospectus and (ii) necessary or material for the commercialization of the products described in the Registration Statement and the Prospectus as being under development. There is no pending or, to the Company’s knowledge, threatened (I) action, suit, proceeding, or claim by others challenging the rights of the Company or any of its Subsidiaries in or to any such Intellectual Property that, if decided adversely to the Company or such Subsidiary would, individually or in the aggregate, have a Material Adverse Effect, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (II) action, suit, proceeding, or claim by others that the Company or any of its Subsidiaries infringes, misappropriates, or otherwise violates any Intellectual Property of others that, if decided adversely to the Company or such Subsidiary would, individually or in the aggregate, have a Material Adverse Effect, and the Company is unaware of any facts which would form a reasonable basis for any such claim; or (III) action, suit, proceeding, or claim by others challenging the validity, scope, or enforceability of any such Intellectual Property owned or licensed by the Company or its Subsidiaries and the Company is unaware of any facts which would form a reasonable basis for any such claim. To the Company’s knowledge, the operation of the business of the Company and its Subsidiaries as now conducted, and as described in the Prospectus, and in connection with the development and commercialization of the products described in the Prospectus does not infringe, misappropriate, conflict with or otherwise violate any claim of any patent or published patent application of any other person or entity. There is no prior art of which the Company or any of its Subsidiaries is aware that may render any patent owned or licensed by the Company or its Subsidiaries invalid or any patent application owned or licensed by the Company or its Subsidiaries unpatentable which has not been disclosed to the applicable government patent office. The Company’s granted or issued patents, registered trademarks and registered copyrights have been duly maintained and are in full force and effect, and none of the patents, trademarks and copyrights have been adjudged invalid or unenforceable in whole or in part. The Company knows of no infringement, misappropriation or violation by others of any Intellectual Property owned or licensed by the Company or its Subsidiaries which would reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its Subsidiaries is a party to or bound by any options, licenses or agreements with respect to the Intellectual Property of any other person or entity that are required to be set forth in the Prospectus and that are not described therein in all material respects. The Company and its Subsidiaries have taken all reasonable steps necessary to secure their interests in the Intellectual Property of the Company and its Subsidiaries from their employees and contractors and to protect the confidentiality of all of their confidential information and trade secrets. None of the technology or intellectual property used by the Company and its Subsidiaries in its business has been obtained or is being used by the Company or its Subsidiaries in violation of any contractual obligation binding on the Company or its Subsidiaries, or, to the Company’s knowledge, any of its officers, directors or employees or otherwise in violation of the rights of any persons. No third party has been granted by the Company or its Subsidiaries rights to the Intellectual Property of the Company or its Subsidiaries, including any rights that, if exercised, would enable such party to develop products competitive to those of the Company as described in the Registration Statement and the Prospectus, and excluding any rights granted in the ordinary course of business and that would not reasonably be expected to have a Material Adverse Effect on the Company

and its Subsidiaries taken as a whole. All Intellectual Property owned or exclusively licensed by the Company or its Subsidiaries is free and clear of all liens, encumbrances, defects or other restrictions (other than non-exclusive licenses granted in the ordinary course of business), except those that would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company and its Subsidiaries are not subject to any judgment, order, writ, injunction or decree of any court or any federal, state, local, foreign or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, or any arbitrator, nor has it entered into or is it a party to any agreement made in settlement of any pending or threatened litigation, which materially restricts or impairs their use of any Intellectual Property.

(qq) The Company and each of its Subsidiaries (i) are and have at all times been in compliance with all laws, statutes, rules, regulations or guidance applicable to the Company and its Subsidiaries and the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, advertising, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any pharmaceuticals or biohazardous substances, materials or any other products developed, manufactured or distributed by the Company (including, without limitation, from the United States Food and Drug Administration (“**FDA**”), European Medicines Agency (“**EMA**”) and any local or other governmental or regulatory authority performing functions similar to those performed by the FDA or EMA) (collectively, “**Applicable Laws**”), except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, (ii) have not received any notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the FDA or any other federal, state or foreign governmental authority having authority over the Company, any of its Subsidiaries or their activities alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws (collectively, the “**Governmental Permits**”), (iii) have made all filings with, the appropriate local, or other governmental or regulatory agencies or bodies that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Registration Statement and the Prospectus, except where any failures to possess or make the same would not, singularly or in the aggregate, have a Material Adverse Effect, (iv) possess all material Governmental Permits necessary to conduct their respective businesses as described in the Registration Statement and the Prospectus, and such Governmental Permits are valid and in full force and effect and are not in violation of any term of any such Governmental Permits, (v) have filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Governmental Permits and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct in all material respects on the date filed (or were corrected or supplemented by a subsequent submission), and (vi) are not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders or similar agreements with or imposed by any governmental authority. All Governmental Permits are valid and in full force and effect, except where the validity or failure to be in full force and effect would not, singularly or in the aggregate, have a Material Adverse Effect. Neither the Company nor any Subsidiary has received notification of any revocation, modification, suspension, termination or invalidation (or proceedings related thereto) of any such Governmental Permit and the Company has no reason to believe that any such Governmental Permit will not be renewed. None of the Company, any of its Subsidiaries or, to the Company’s knowledge, any of their respective directors, officers, employees or agents has been convicted of any crime under any Applicable Laws or has been the subject of an FDA debarment proceeding. Neither the Company nor any of its Subsidiaries has been nor is now subject to the FDA’s Application Integrity Policy. To the Company’s knowledge, none of the Company, any of its Subsidiaries, or any of its directors, officers, employees or agents has made, or caused the making of, any false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other governmental authority.

(rr) There is no legal or governmental proceeding to which the Company or any of its Subsidiaries is a party or of which any property or assets of the Company or any of its Subsidiaries is the subject, including any proceeding before the FDA, the EMA or any foreign, local, national or other governmental agency with jurisdiction over the types of products being developed by the Company that is required to be described in the Registration Statement or the Prospectus and is not described therein, or which, singularly or in the aggregate, if determined adversely to the Company or any of its Subsidiaries, would reasonably be expected to have a Material Adverse Effect; and no such proceedings are threatened or contemplated by governmental or regulatory authorities or threatened by others. The Company and its Subsidiaries (i) have not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Governmental Permits and have no knowledge that any such governmental authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding and (ii) have not received notice that any governmental authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Governmental Permits and the Company has no knowledge that any such governmental authority is considering such action.

(ss) The research, non-clinical, pre-clinical studies and clinical studies and tests conducted or being conducted by or on behalf of the Company or any of its Subsidiaries or in which any of their respective product candidates have participated and, to the Company's knowledge, the preclinical studies and clinical trials directed or sponsored by the Company's collaborators (collectively, the "**Studies**") that are described in, or the results of which are referred to in, the Registration Statement and the Prospectus were and, if still pending, are being conducted with reasonable care and in all material respects in accordance with the protocols, procedures and controls pursuant to all Applicable Laws and Governmental Permits and with standard medical and scientific research procedures; each description of the results of such Studies is accurate and complete in all material respects and fairly presents the data derived from such Studies, and the Company and its Subsidiaries have no knowledge of any other research, non-clinical studies or tests the results of which are materially inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement and the Prospectus; the Company and its Subsidiaries have made all such filings and obtained all such approvals as may be required by the EMA, the FDA or any committee thereof or from any other United States or foreign government agency with jurisdiction over the types of products being developed by the Company; neither the Company nor any of its Subsidiaries has received any notice of, or correspondence from, any governmental authority requiring the termination, suspension or modification of any Study; and the Company and its Subsidiaries have each operated and currently are in compliance in all material respects with all applicable rules, regulations and policies of all governmental authorities. There have been no material serious adverse events resulting from any Study. To the Company's knowledge, the manufacturing facilities and operations of its suppliers are operated in compliance in all material respects with all Applicable Laws and Governmental Permits.

(tt) The Company acknowledges and agrees that the Agent has informed the Company that the Agent may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell shares of Common Stock for its own account while this Agreement is in effect; *provided*, that (i) no such purchase or sales shall take place while a Placement Notice is in effect (except to the extent the Agent may engage in sales of Placement Shares purchased or deemed purchased from the Company as a "riskless principal" or in a similar capacity) and (ii) the Company shall not be deemed to have authorized or consented to any such purchases or sales by the Agent, except as may be otherwise agreed by the Company and the Agent.

(uu) The Company is not a party to any agreement with an agent or underwriter for any other “at the market” or continuous equity transaction.

(vv) The Company is not required to register as a “broker” or “dealer” in accordance with the provisions of the Exchange Act and does not, directly or indirectly through one or more intermediaries, control or have any other association with (within the meaning of Article I of the By-laws of FINRA) any member firm of FINRA. No relationship, direct or indirect, exists between or among the Company, on the one hand, and the directors, officers or shareholders of the Company, on the other hand, which is required by the rules of FINRA to be described in the Registration Statement and the Prospectus, which is not so described. All of the information (including, but not limited to, information regarding affiliations, security ownership and trading activity) provided to the Agent or its counsel by the Company, its officers and directors and the holders of any securities (debt or equity) or warrants, options or rights to acquire any securities of the Company in connection with the filing to be made and other supplemental information to be provided to FINRA pursuant to FINRA Rule 5110 in connection with the transactions contemplated by this Agreement is true, complete and correct.

(ww) As of the close of trading on Nasdaq on November 5, 2025, the aggregate market value of the outstanding voting and non-voting common equity (as defined in Rule 405) of the Company held by persons other than affiliates of the Company (pursuant to Rule 144 of the Securities Act, those that directly, or indirectly through one or more intermediaries, control, or are controlled by, or are under common control with, the Company) (the “**Non-Affiliate Shares**”), was approximately \$15,986,792 (calculated by multiplying (x) the price at which the common equity of the Company was last sold on Nasdaq on October 27, 2025 by (y) the number of Non-Affiliate Shares outstanding on September 30, 2025). The Company is not a shell company (as defined in Rule 405) and has not been a shell company for at least 12 calendar months previously.

(xx) Neither the issuance, sale and delivery of the Placement Shares nor the application of the proceeds thereof by the Company as described in the Registration Statement and the Prospectus will violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

(yy) Each of the independent directors (or independent director nominees, once appointed, if applicable) named in the Registration Statement and Prospectus satisfies the independence standards established by Nasdaq and, with respect to members of the Company’s audit committee, the enhanced independence standards contained in Rule 10A-3(b)(1) promulgated by the Commission under the Exchange Act.

(zz) Neither the Company nor, to the Company’s knowledge, any of its affiliates (within the meaning of Rule 144 under the Securities Act) has, prior to the date hereof, made any offer or sale of any securities which could be “integrated” (within the meaning of the Securities Act) with the offer and sale of the Placement Shares hereunder.

(aaa) Neither the Company nor any of its Subsidiaries has (i) failed to pay any dividend or sinking fund installment on preferred stock or (ii) defaulted on any installment or payment due on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would reasonably be expected to result in a Material Adverse Effect.

(bbb) Each financial or operational projection or other “forward-looking statement” (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained in the Registration Statement or the Prospectus (i) was so included by the Company in good faith and with reasonable basis

after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) as required, is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was made with the knowledge of a director or senior manager of the Company that was false or misleading.

(ccc) There are no relationships, direct or indirect, or related party transactions involving the Company or any of its Subsidiaries or any other person (including any director, officer, stockholder, customer or supplier of the Company or any of its Subsidiaries) required to be described in the Registration Statement or the Prospectus that have not been described as required. There are no material outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees of indebtedness by the Company or any of its Subsidiaries to or for the benefit of any of the officers or directors of the Company or any of its Subsidiaries, or any of the family members of any of such persons.

(ddd) The Company is not in or subject to a bankruptcy or insolvency proceeding in any jurisdiction.

(eee) The Company and its Subsidiaries (i) are in compliance, in all material respects, with any and all applicable foreign, federal, state and local laws, rules, regulations, treaties, statutes and codes promulgated by any and all governmental authorities (including pursuant to the Occupational Health and Safety Act) relating to the protection of human health and safety the workplace (“**Occupational Laws**”); (ii) have received all material permits, licenses or other approvals required of it under applicable Occupational Laws to conduct their respective businesses as currently conducted; and (iii) are in compliance, in all material respects, with all terms and conditions of such permit, license or approval. No action, proceeding, revocation proceeding, writ, injunction or claim is pending or, to the Company’s knowledge, threatened against the Company or any of its Subsidiaries relating to Occupational Laws, and the Company does not have knowledge of any facts, circumstances or developments relating to its operations or cost accounting practices that would reasonably be expected to form the basis for or give rise to such actions, suits, investigations or proceedings.

(fff) No director or officer of the Company or any of its Subsidiaries is subject to any non-competition agreement or non-solicitation agreement with any employer or prior employer which would materially affect each director’s or officer’s ability to be and act in the capacity of a director or officer of the Company or a Subsidiary.

(ggg) The Company has duly and properly filed or caused to be filed with the U.S. Patent and Trademark Office (the “**PTO**”) and applicable foreign and international patent and trademark authorities all patents, trademarks, copyrights and applications relating to the same owned by the Company and its Subsidiaries (the “**Company Patent and Trademark Applications**”). To the knowledge of the Company, the Company has complied with the PTO’s duty of candor and disclosure for the Company Patent and Trademark Applications and has made no material misrepresentation in the Company Patent and Trademark Applications. To the Company’s knowledge, the Company Patent and Trademark Applications disclose patentable subject matter. The Company has not been notified of any inventorship challenges nor has any interference been declared or provoked nor is any material fact known by the Company that would preclude the issuance of patents with respect to the Company Patent and Trademark Applications or would render such patents, if issued, invalid or unenforceable. Except as would not have a Material Adverse Effect, neither the Company nor any of its Subsidiaries has breached and is currently in breach of any provision of any license, contract or other agreement governing the use by the Company or its Subsidiaries of Intellectual Property owned by third parties (collectively, the “**Licenses**”) and no third

party has alleged any such breach and the Company is unaware of any facts that would form a reasonable basis for such a claim. To the Company's knowledge, no other party to the Licenses has breached or is currently in breach of any provision of the Licenses. Each of the Licenses is in full force and effect and constitutes a valid and binding agreement between the parties thereto, enforceable in accordance with its terms, and there has not occurred any breach or default under any such Licenses or any event that, with the giving of notice or lapse of time, would constitute a breach or default thereunder. Except as would not have a Material Adverse Effect, neither the Company nor any of its Subsidiaries has been and is currently involved in any disputes regarding the Licenses. To the Company's knowledge, all patents licensed to the Company pursuant to the Licenses are valid, enforceable and being duly maintained. To the Company's knowledge, all patent applications licensed to the Company pursuant to the Licenses are being duly prosecuted.

Any certificate signed by any officer of the Company and delivered to the Agent or its counsel in connection with the offering of the Placement Shares shall be deemed a representation and warranty by the Company, as to matters covered thereby, to the Agent.

7. Covenants of the Company. The Company covenants and agrees with the Agent that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which the Prospectus relating to any Placement Shares is required to be delivered by the Agent under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act or a similar rule); (i) the Company will notify the Agent promptly of the time when any subsequent amendment to the Registration Statement, other than Incorporated Documents, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus, other than Incorporated Documents, has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information (in each case, insofar as it relates to the transactions contemplated hereby); (ii) the Company will prepare and file with the Commission, promptly upon the Agent's reasonable request, any amendments or supplements to the Registration Statement or Prospectus that, in the Agent's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by the Agent (provided, however, that the failure of the Agent to make such request shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement and provided, further, that the only remedy the Agent shall have with respect to the failure by the Company to make such filing (but without limiting the Agent's rights under Section 9 hereof) will be to cease making sales under this Agreement until such amendment or supplement is filed); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus, other than Incorporated Documents, relating to the Placement Shares or a security convertible into or exchangeable or exercisable for the Placement Shares unless a copy thereof has been submitted to the Agent within a reasonable period of time before the filing and the Agent has not reasonably objected thereto (provided, however, that the failure of the Agent to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement and provided, further, that the only remedy the Agent shall have with respect to the Company's making such filing notwithstanding the Agent's objection (but without limiting the Agent's rights under Section 9 hereof) will be to cease making sales under this Agreement) and the Company will furnish to the Agent at the time of filing thereof a copy of any Incorporated Document, except for those documents available via EDGAR; and (iv) the Company will cause each amendment or supplement to the Prospectus, other than Incorporated Documents, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act and, in the case of any Incorporated Document, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed.

(b) Notice of Commission Stop Orders. The Company will advise the Agent, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued. The Company will advise the Agent promptly after it receives any request by the Commission for any amendments to the Registration Statement or any amendment or supplements to the Prospectus or for additional information related to the offering of the Placement Shares or for additional information related to the Registration Statement or the Prospectus.

(c) Delivery of Prospectus; Subsequent Changes. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by the Agent under the Securities Act with respect to the offer and sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act or a similar rule), the Company will comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and will file on or before their respective due dates (taking into account any extensions available under the Exchange Act) all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify the Agent to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance. If the Company has omitted any information from the Registration Statement pursuant to Rule 430B under the Securities Act, it will use its best efforts to comply with the provisions thereof and make all requisite filings with the Commission pursuant to said Rule 430B and to notify the Agent promptly of all such filings if not available on EDGAR.

(d) Listing of Placement Shares. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by the Agent under the Securities Act with respect to the offer and sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act or a similar rule), the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on Nasdaq. The Company will timely file with Nasdaq all material documents and notices required by Nasdaq of companies that have or will issue securities that are traded on Nasdaq.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to the Agent and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all Incorporated Documents) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which the Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all Incorporated Documents filed with the Commission during such period), in each case as soon as reasonably practicable and in such quantities as the Agent may from time to time reasonably request and, at the Agent's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided, however*, that the Company shall not be required to

furnish any document (other than the Prospectus) to the Agent to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders and to the Agent as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) of and Rule 158 under the Securities Act.

(g) Expenses. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated in accordance with the provisions of Section 11 hereunder, will pay all expenses incident to the performance of its obligations hereunder, including expenses relating to (i) the preparation, printing and filing of the Registration Statement and each amendment and supplement thereto, of the Prospectus and of each amendment and supplement thereto and of this Agreement and such other documents as may be required in connection with the offering, purchase, sale, issuance or delivery of the Placement Shares, (ii) the preparation, issuance, sale and delivery of the Placement Shares and any taxes due or payable in connection therewith, (iii) the qualification of the Placement Shares under securities laws in accordance with the provisions of Section 7(w) of this Agreement, including filing fees (provided, however, that any fees or disbursements of counsel for the Agent in connection therewith shall be paid by the Agent except as set forth in clauses (vii) and (viii) below), (iv) the printing and delivery to the Agent and its counsel of copies of the Prospectus and any amendments or supplements thereto, and of this Agreement, (v) the fees and expenses incurred in connection with the listing or qualification of the Placement Shares for trading on Nasdaq, (vi) the filing fees and expenses, if any, owed to the Commission or FINRA and the fees and expenses of any transfer agent or registrar for the Placement Shares, (vii) the fees and associated expenses of the Agent's outside legal counsel for filings with the FINRA Corporate Financing Department in an amount not to exceed \$15,000 (excluding FINRA filing fees referred to in clause (vi) above and in addition to the fees and disbursements referred to in clause (viii) below), and (viii) the reasonable fees and disbursements of the Agent's outside legal counsel (A) in an amount not to exceed \$75,000 arising out of executing this Agreement and the Company's delivery of the initial certificate pursuant to Section 7(m) and (B) in an amount not to exceed \$25,000 in connection with each Representation Date (as defined below) on which the Company is required to provide a certificate pursuant to Section 7(m) (in addition to the fees and associated expenses referred to in clause (vii) above).

(h) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(i) Notice of Other Sales. Without the prior written consent of the Agent, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any shares of Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable or exercisable for shares of Common Stock, warrants or any rights to purchase or acquire shares of Common Stock during the period beginning on the third Trading Day immediately prior to the date on which any Placement Notice is delivered to Agent hereunder and ending on the first Trading Day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice (or, if the Placement Notice has been terminated or suspended prior to the sale of all Placement Shares covered by a Placement Notice, the date of such suspension or termination) (such period, the "Lock-up Period"); and will not directly or indirectly in any other "at the market offering" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any shares of Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable or exercisable for shares of Common Stock, warrants or any rights to purchase or acquire, shares of Common Stock

prior to the later of the termination of this Agreement and the thirtieth day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice; *provided, however*, that such restrictions will not be required in connection with the Company's issuance or sale of (i) shares of Common Stock, options to purchase shares of Common Stock, other securities under the Company's existing equity incentive plans, or shares of Common Stock issuable upon the exercise of options or other equity awards or vesting of other securities, pursuant to any employee or director stock option or benefits plan, stock ownership plan, dividend reinvestment plan (but not shares of Common Stock subject to a waiver to exceed plan limits in its dividend reinvestment plan), inducement award under Nasdaq rules or other compensation plan of the Company whether now in effect or hereafter implemented, (ii) shares of Common Stock issuable upon the exchange, conversion or redemption of securities or the exercise or vesting of warrants, options or other rights in effect or outstanding, and disclosed in filings by the Company available on EDGAR or otherwise in writing to the Agent and (iii) shares of Common Stock or securities convertible into or exchangeable for shares of Common Stock as consideration for mergers, acquisitions, other business combinations, joint ventures, collaborations, licensing arrangements, manufacturing, distribution, marketing, supply, sponsored research, technology transfer or development or third party service arrangements or strategic alliances occurring after the date of this Agreement which are not issued for capital raising purposes.

(j) Change of Circumstances. The Company will, at any time during a fiscal quarter in which the Company intends to tender a Placement Notice or sell Placement Shares, advise the Agent promptly after it shall have received notice or obtained knowledge of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided or required to be provided to the Agent pursuant to this Agreement.

(k) Due Diligence Cooperation. During the term of this Agreement, the Company will cooperate with any reasonable due diligence review conducted by the Agent, its affiliates agents and counsel from time to time in connection with the transactions contemplated hereby, including providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as the Agent may reasonably request.

(l) Required Filings Relating to Placement of Placement Shares. The Company agrees that on or prior to such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act, which prospectus supplement will set forth, within the relevant period, the number or amount of Placement Shares sold through the Agent, the Net Proceeds to the Company and the compensation payable by the Company to the Agent with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market; *provided*, that, unless a prospectus supplement containing such information is required to be filed under the Securities Act, the requirement of this Section 7(l) may be satisfied by Company's inclusion in the Company's Form 10-K or Form 10-Q, as applicable, of the number or amount of Placement Shares sold through the Agent, the Net Proceeds to the Company and the compensation payable by the Company to the Agent with respect to such Placement Shares during the relevant period.

(m) Representation Dates; Certificate. On or prior to the date on which the Company first delivers a Placement Notice pursuant to this agreement (the "**First Placement Notice Date**") and each time the Company:

(i) amends or supplements the Registration Statement or the Prospectus relating to the Placement Shares (other than a prospectus supplement filed in accordance with Section 7(l) of this

Agreement) by means of a post-effective amendment, sticker or supplement but not by means of incorporation of document(s) by reference into the Registration Statement or the Prospectus relating to the Placement Shares;

(ii) files an Annual Report on Form 10-K under the Exchange Act (including any Form 10-K/A containing amended financial information or a material amendment to the previously filed Form 10-K);

(iii) files a Quarterly Report on Form 10-Q under the Exchange Act; or

(iv) files a Current Report on Form 8-K containing amended financial information (other than an earnings release that is “furnished” pursuant to Item 2.02 or Item 7.01 of Form 8-K) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a “**Representation Date**”),

the Company shall furnish the Agent (but in the case of clause (iv) above only if (1) a Placement Notice is pending or in effect and (2) the Agent requests such certificate within three Business Days after the filing of such Form 8-K with the Commission) with a certificate, in the form attached hereto as **Exhibit 7(m)** (modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented), within two Trading Days of any Representation Date. The requirement to provide a certificate under this Section 7(m) shall be waived for any Representation Date occurring at a time at which no Placement Notice is pending or in effect, which waiver shall continue until the earlier to occur of (1) the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date) and (2) the next occurring Representation Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date on which the Company relied on the waiver referred to in the previous sentence and did not provide the Agent with a certificate under this Section 7(m), then before the Company delivers a Placement Notice or the Agent sells any Placement Shares pursuant thereto, the Company shall provide the Agent with a certificate, in the form attached hereto as **Exhibit 7(m)**, dated the date of such Placement Notice. Within two Trading Days of each Representation Date, the Company shall have furnished to the Agent such further information, certificates and documents as the Agent may reasonably request.

(n) **Legal Opinions.** On or prior to the First Placement Notice Date and on any date which the Company is obligated to deliver a certificate pursuant to Section 7(m) for which no waiver is applicable, the Company shall cause to be furnished to the Agent the written opinion and negative assurance letter of Wilson Sonsini Goodrich & Rosati, Professional Corporation, counsel to the Company, or such other counsel satisfactory to the Agent (“**Company Counsel**”), in form and substance satisfactory to the Agent and its counsel, dated the date that the opinion and negative assurance letter are required to be delivered, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided, however*, that in lieu of such opinion and negative assurance letter for subsequent Representation Dates, Company Counsel may furnish the Agent with a letter to the effect that the Agent may rely on a prior opinion or negative assurance letter delivered by such counsel under this Section 7(n) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion or negative assurance letter shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented at such Representation Date).

(o) **Intellectual Property Opinion.** On or prior to the First Placement Notice Date and on any date which the Company is obligated to deliver a certificate pursuant to Section 7(m) for which no waiver is applicable, the Company shall cause to be furnished to the Agent the written opinion of Buchanan Ingersoll & Rooney PC, counsel for the Company with respect to intellectual property matters, or such

other intellectual property counsel satisfactory to the Agent (“**Intellectual Property Counsel**”), in form and substance satisfactory to the Agent and its counsel, dated the date that the opinion letter is required to be delivered, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided, however*, that in lieu of such written opinion for subsequent Representation Dates, Intellectual Property Counsel may furnish the Agent with a letter to the effect that the Agent may rely on a prior opinion letter delivered by such counsel under this Section 7(o) to the same extent as if it were dated the date of such opinion letter (except that statements in such prior opinion letter shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented at such Representation Date).

(p) **Comfort Letter**. On or prior to the First Placement Notice Date and on any date which the Company is obligated to deliver a certificate pursuant to Section 7(m) for which no waiver is applicable, the Company shall cause its independent registered public accounting firm (and any other independent accountants whose report is included in the Registration Statement or the Prospectus) to furnish the Agent letters (the “**Comfort Letters**”), dated the date the Comfort Letter is delivered, which shall meet the requirements set forth in this Section 7(p); *provided*, that if requested by the Agent, the Company shall cause a Comfort Letter to be furnished to the Agent within 10 Trading Days of the occurrence of any material transaction or event that necessitates the filing of additional, pro forma, amended or revised financial statements (including any restatement of previously issued financial statements). Each Comfort Letter shall be in form and substance satisfactory to the Agent and each Comfort Letter from the Company’s independent registered public accounting firm shall (i) confirm that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) state, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants’ “comfort letters” to underwriters in connection with registered public offerings (the first such letter, the “**Initial Comfort Letter**”) and (iii) update the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(q) **Market Activities**. The Company will not, directly or indirectly, and will cause its officers, directors and Subsidiaries not to (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of shares of Common Stock or (ii) sell, bid for, or purchase shares of Common Stock in violation of Regulation M, or pay anyone any compensation for soliciting purchases of the Placement Shares other than the Agent; *provided, however*, that the Company may bid for and purchase shares of Common Stock in accordance with Rule 10b-18 under the Exchange Act.

(r) **Insurance**. The Company and, if applicable, its Subsidiaries, shall maintain, or cause to be maintained, insurance in such amounts and covering such risks as is reasonable and customary for the business for which it is engaged.

(s) **Compliance with Laws**. The Company and each of its Subsidiaries shall maintain, or cause to be maintained, all material environmental certificates, authorizations or permits required by federal, state and local law in order to conduct their businesses as described in the Prospectus (collectively, “**Permits**”), and the Company and each of its Subsidiaries shall conduct their businesses, or cause their businesses to be conducted, in substantial compliance with such Permits and with applicable Environmental Laws, except where the failure to maintain or be in compliance with such Permits would not reasonably be expected to result in a Material Adverse Effect.

(t) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor any of its Subsidiaries will be or become, at any time prior to the termination of this Agreement, an “investment company,” as such term is defined in the Investment Company Act.

(u) Securities Act and Exchange Act. The Company will use its best efforts to comply with all requirements imposed upon it by the Securities Act and the Exchange Act as from time to time in force, so far as necessary to permit the sales of, or dealings in, the Placement Shares as contemplated by the provisions hereof and the Prospectus.

(v) No Offer to Sell. Other than a free writing prospectus (as defined in Rule 405 under the Securities Act) approved in advance by the Company and the Agent, neither the Agent nor the Company (including its agents and representatives, other than the Agent in its capacity as agent) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Placement Shares hereunder.

(w) Blue Sky and Other Qualifications. The Company will use its commercially reasonable efforts, in cooperation with the Agent, to qualify the Placement Shares for offering and sale, or to obtain an exemption for the Placement Shares to be offered and sold, under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Agent may designate and to maintain such qualifications and exemptions in effect for so long as required for the distribution of the Placement Shares (but in no event for less than one year from the date of this Agreement); *provided, however*, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject. In each jurisdiction in which the Placement Shares have been so qualified or exempt, the Company will file such statements and reports as may be required by the laws of such jurisdiction to continue such qualification or exemption, as the case may be, in effect for so long as required for the distribution of the Placement Shares (but in no event for less than one year from the date of this Agreement).

(x) Sarbanes-Oxley Act. The Company will maintain and keep accurate books and records reflecting its assets and maintain internal accounting controls in a manner designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and including those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of the Company’s financial statements in accordance with GAAP, (iii) that receipts and expenditures of the Company are being made only in accordance with management’s and the Company’s directors’ authorization, and (iv) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company’s assets that could have a material effect on its financial statements. The Company will maintain such controls and other procedures, including, without limitation, those required by Sections 302 and 906 of the Sarbanes-Oxley Act, and the applicable regulations thereunder that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission’s rules and forms, including, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to

allow timely decisions regarding required disclosure and to ensure that material information relating to the Company is made known to it by others within the Company, particularly during the period in which such periodic reports are being prepared.

(y) Emerging Growth Company. The Company will promptly notify the Agent if the Company ceases to be an Emerging Growth Company at any time prior to the completion of the Agent's distribution of the Placement Shares pursuant to this Agreement.

(z) Renewal of Registration Statement. If, immediately prior to the third anniversary of the initial effective date of the Registration Statement (the "**Renewal Date**"), any of the Placement Shares remain unsold and this Agreement has not been terminated, the Company will, prior to the Renewal Date, file a new shelf registration statement or, if applicable, an automatic shelf registration statement relating to the Common Stock that may be offered and sold pursuant to this Agreement (which shall include a prospectus reflecting the number or amount of Placement Shares that may be offered and sold pursuant to this Agreement), in a form satisfactory to the Agent and its counsel, and, if such registration statement is not an automatic shelf registration statement, will use its reasonable best efforts to cause such registration statement to be declared effective within 180 days after the Renewal Date. The Company will take all other reasonable actions necessary or appropriate to permit the public offer and sale of the Placement Shares to continue as contemplated in the expired registration statement and this Agreement. From and after the effective date thereof, references herein to the "Registration Statement" shall include such new shelf registration statement or such new automatic shelf registration statement, as the case may be.

(aa) General Instruction I.B.6. of Form S-3. If, from and after the date of this Agreement, the Company is no longer eligible to use Form S-3 (including pursuant to General Instruction I.B.6.) at the time it files with the Commission an Annual Report on Form 10-K or any post-effective amendment to the Registration Statement, then it shall promptly notify the Agent and, within two Business Days after the date of filing of such Annual Report on Form 10-K or amendment to the Registration Statement, the Company shall file a new prospectus supplement with the Commission reflecting the number of shares of Common Stock available to be offered and sold by the Company under this Agreement pursuant to General Instruction I.B.6. of Form S-3; *provided, however*, that the Company may delay the filing of any such prospectus supplement for up to 30 days if, in the reasonable judgment of the Company, it is in the best interest of the Company to do so, provided that no Placement Notice is in effect or pending during such time. Until such time as the Company shall have corrected such misstatement or omission or effected such compliance, the Company shall not notify the Agent to resume the offering of Placement Shares.

(bb) Tax Indemnity. The Company will indemnify and hold harmless the Agent against any documentary, stamp or similar issue tax, including any interest and penalties, on the issue and sale of the Placement Shares.

(cc) Transfer Agent. The Company has engaged and will maintain, at its sole expense, a transfer agent and registrar for the Common Stock.

8. Conditions to the Agent's Obligations. The obligations of the Agent hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by the Agent of a due diligence review satisfactory to the Agent in its reasonable judgment, and to the continuing satisfaction (or waiver by the Agent in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall be effective and shall be available for all offers and sales of Placement Shares (i) that have been issued pursuant to all prior Placement Notices and (ii) that will be issued pursuant to any Placement Notice.

(b) Prospectus Supplement. The Company shall have filed with the Commission the Prospectus Supplement pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second Business Day following the date of this Agreement.

(c) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material Incorporated Document untrue in any material respect or that requires the making of any changes in the Registration Statement, the Prospectus or Incorporated Documents so that, in the case of the Registration Statement, it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, in the case of the Prospectus, so that it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(d) No Misstatement or Material Omission. The Agent shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's opinion is material, or omits to state a fact that in the Agent's opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(e) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Effect or any development that would reasonably be expected to result in a Material Adverse Effect, or any downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities), if any, by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), if any, the effect of which, in the judgment of the Agent (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(f) Company Counsel Legal Opinions. The Agent shall have received the opinions and negative assurance letters, as applicable, of Company Counsel and Intellectual Property Counsel required to be delivered pursuant to Section 7(n) and Section 7(o), as applicable, on or before the date on which such delivery of such opinions and negative assurance letters are required pursuant to Section 7(n) and Section 7(o), as applicable.

(g) Agent's Counsel Legal Opinion. The Agent shall have received from Covington & Burling LLP, counsel for the Agent, such opinion or opinions, on or before the date on which the delivery of the Company Counsel legal opinion is required pursuant to Section 7(n), with respect to such matters as the Agent may reasonably require, and the Company shall have furnished to such counsel such documents as they may request to enable them to pass upon such matters.

(h) Comfort Letter. The Agent shall have received the Comfort Letter required to be delivered pursuant to Section 7(p) on or before the date on which such delivery of such Comfort Letter is required pursuant to Section 7(p).

(i) Representation Certificate. The Agent shall have received the certificate required to be delivered pursuant to Section 7(m) on or before the date on which delivery of such certificate is required pursuant to Section 7(m).

(j) Secretary's Certificate. On or prior to the First Placement Notice Date, the Agent shall have received a certificate, signed on behalf of the Company by the Secretary of the Company and attested to by an executive officer of the Company, dated as of such date and in form and substance satisfactory to the Agent and its counsel, certifying as to (i) the amended and restated certificate of incorporation of the Company, (ii) the amended and restated bylaws of the Company, (iii) the resolutions of the board of directors of the Company or duly authorized committee thereof authorizing the execution, delivery and performance of this Agreement and the issuance and sale of the Placement Shares and (iv) the incumbency of the officers of the Company duly authorized to execute this Agreement and the other documents contemplated by this Agreement (including each of the officers set forth on Schedule 2).

(k) No Suspension. The Common Stock shall be duly listed, and admitted and authorized for trading, subject to official notice of issuance, on Nasdaq. Trading in the Common Stock shall not have been suspended on, and the Common Stock shall not have been delisted from, Nasdaq.

(l) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(m), the Company shall have furnished to the Agent such appropriate further information, opinions, certificates, letters and other documents as the Agent may have reasonably requested. All such information, opinions, certificates, letters and other documents shall have been in compliance with the provisions hereof. The Company shall have furnished the Agent with conformed copies of such opinions, certificates, letters and other documents as the Agent may have reasonably requested.

(m) Securities Act Filings Made. All filings with the Commission required by Rule 424(b) or Rule 433 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424(b) (without reliance on Rule 424(b)(8) of the Securities Act) or Rule 433, as applicable.

(n) Approval for Listing. Either (i) the Placement Shares shall have been approved for listing on Nasdaq, subject only to notice of issuance, or (ii) the Company shall have filed an application for listing of the Placement Shares on Nasdaq at, or prior to, the First Placement Notice Date and Nasdaq shall have reviewed such application and not provided any objections thereto.

(o) FINRA. FINRA shall have raised no objection to the terms of the offering contemplated hereby and the amount of compensation allowable or payable to the Agent as described in the Prospectus.

(p) No Termination Event. There shall not have occurred any event that would permit the Agent to terminate this Agreement pursuant to Section 11(a).

9. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless the Agent, its affiliates and their respective partners, members, directors, officers, employees and agents, and each person, if any, who (i) controls the Agent within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Agent, in each case from and against any and all losses, claims, liabilities, expenses and damages (including any and all investigative, legal and other expenses reasonably incurred in connection with, and any and all amounts paid in settlement (in accordance with this Section 9), any action, suit, investigation or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party (including any governmental or self-regulatory authority, or otherwise, or any claim asserted or threatened), as and when incurred, to which the Agent, or any such other person may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise), insofar as such losses, claims, liabilities, expenses or damages arise out of or are based, directly or indirectly, on (x) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or the Prospectus (or any amendment or supplement to the Registration Statement or the Prospectus) or in any free writing prospectus or in any application or other document executed by or on behalf of the Company or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Common Stock under the securities laws thereof or filed with the Commission, (y) the omission or alleged omission to state in any such document a material fact required to be stated therein or necessary to make the statements therein (solely with respect to the Prospectus, in light of the circumstances under which they were made) not misleading or (z) any breach by any of the indemnifying parties of any of their respective representations, warranties or agreements contained in this Agreement; *provided, however*, that this indemnity agreement shall not apply to the extent that such loss, claim, liability, expense or damage arises from the sale of the Placement Shares pursuant to this Agreement and is caused, directly or indirectly, by an untrue statement or omission, or alleged untrue statement or omission, made in reliance upon and in conformity with the Agent's Information. This indemnity agreement will be in addition to any liability that the Company might otherwise have.

(b) Agent Indemnification. The Agent agrees to indemnify and hold harmless the Company and its directors and each officer of the Company who signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 9(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Agent's Information.

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 9 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 9, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 9 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 9

unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any other legal expenses except as provided below and except for the reasonable documented costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel reasonably satisfactory to the indemnified party to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm (plus local counsel) admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly after the indemnifying party receives a written invoice relating to such fees, disbursements and other charges in reasonable detail. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 9 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (1) includes an unconditional release of each indemnified party, in form and substance reasonably satisfactory to such indemnified party, from all liability arising out of such claim, action or proceeding and (2) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) Settlement Without Consent if Failure to Reimburse. If an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for reasonable fees and expenses of counsel for which it is entitled to be reimbursed under this Section 9, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 9(a) effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

(e) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 9 is applicable in accordance with its terms but for any reason is held to be unavailable or insufficient from the Company or the Agent, the Company and the Agent will contribute to the total losses, claims, liabilities, expenses and

damages (including any documented investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit, investigation or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than the Agent, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and the Agent may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Agent on the other hand. The relative benefits received by the Company on the one hand and the Agent on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by the Agent from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action, suit, investigation or proceeding in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Agent, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Agent agree that it would not be just and equitable if contributions pursuant to this Section 9(e) were to be determined by *pro rata* allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense or damage, or action, suit, investigation or proceeding in respect thereof, referred to above in this Section 9(e) shall be deemed to include, for the purpose of this Section 9(e), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action, suit, investigation, proceeding or claim to the extent consistent with this Section 9. Notwithstanding the foregoing provisions of this Section 9(e), the Agent shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 9(e), any person who controls a party to this Agreement within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, any affiliates of the Agent, any partners, members, directors, officers, employees and agents of the Agent and each person that is controlled by or under common control with the Agent will have the same rights to contribution as that party, and each officer and director of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 9(e), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 9(e) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 9(c) hereof or pursuant to Section 9(d) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 9(c) hereof.

10. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 9 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates,

regardless of (i) any investigation made by or on behalf of the Agent, any controlling persons, or the Company (or any of their respective officers, directors, employees or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

11. Termination.

(a) The Agent shall have the right, by giving notice as hereinafter specified, at any time to terminate this Agreement if (i) any Material Adverse Effect, or any development that would reasonably be expected to result in a Material Adverse Effect, has occurred that, in the judgment of the Agent, may materially impair the ability of the Agent to sell the Placement Shares hereunder, (ii) the Company shall have failed, refused or been unable to perform any agreement on its part to be performed hereunder; *provided, however*, in the case of any failure of the Company to deliver (or cause another person to deliver) any certification, opinion or letter required under Section 7(m), Section 7(n), Section 7(o) or Section 7(p), the Agent's right to terminate shall not arise unless such failure to deliver (or cause to be delivered) continues for more than 15 calendar days from the date such delivery was required, (iii) any other condition of the Agent's obligations hereunder is not fulfilled, (iv) any suspension or limitation of trading in the Placement Shares or in securities generally on Nasdaq shall have occurred, (v) a general banking moratorium shall have been declared by any of United States federal or New York authorities, or (vi) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States or international political, financial or economic conditions that, in the judgment of the Agent, may materially impair the ability of the Agent to sell the Placement Shares hereunder or to enforce contracts for the sale of securities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 11(f), Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination. If the Agent elects to terminate this Agreement as provided in this Section 11(a), the Agent shall provide the required notice as specified in Section 12.

(b) The Company shall have the right, by giving 10 days' prior notice as hereinafter specified, to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 11(f), Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(c) The Agent shall have the right, by giving 10 days' prior notice as hereinafter specified, to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 11(f), Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 11, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through the Agent on the terms and subject to the conditions set forth herein; *provided* that the provisions of Section 7(g), Section 9, Section 10, Section 11(f), Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 11(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; *provided, however*,

that any such termination by mutual agreement shall in all cases be deemed to provide that Section 7(g), Section 9, Section 10, Section 11(f), Section 16 and Section 17 shall remain in full force and effect.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided, however*, that such termination shall not be effective until the close of business on the date of receipt of such notice by the Agent or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement. Upon termination of this Agreement, the Company shall not be required to pay to the Agent any discount or commission with respect to any Placement Shares not otherwise sold by the Agent under this Agreement; *provided, however*, that the Company shall remain obligated to reimburse the Agent's expenses pursuant to Section 7(g).

12. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified in this Agreement, and if sent to the Agent, shall be delivered to:

Leerink Partners LLC
1301 Avenue of the Americas, 5th Floor
New York, New York 10019
Attention: Peter M. Fry
E-mail: [***]

with copies (which shall not constitute notice) to:

Leerink Partners LLC
1301 Avenue of the Americas, 5th Floor
New York, New York 10019
Attention: Legal Department
E-mail: [***]

and:

Covington & Burling LLP
30 Hudson Yards
New York, New York 10001
Attention: Brian K. Rosenzweig
E-mail: [***]

and if to the Company, shall be delivered to:

OnKure Therapeutics, Inc.
6707 Winchester Circle, Suite 400
Boulder, CO 80301
Attention: Nicholas A. Saccomano
E-mail: [***]

with a copy (which shall not constitute notice) to:

Wilson Sonsini Goodrich & Rosati, Professional Corporation
1155 Canyon Blvd., Suite 400

Boulder, CO 80302
Attention: Jennifer Knapp
E-mail: [***]

Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally on or before 4:30 P.M., New York City time, on a Business Day, or, if such day is not a Business Day, on the next succeeding Business Day, (ii) by Electronic Notice as set forth in the next paragraph, (iii) on the next Business Day after timely delivery to a nationally-recognized overnight courier or (iv) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, “**Business Day**” shall mean any day on which the Nasdaq and commercial banks in the City of New York are open for business.

An electronic communication (“**Electronic Notice**”) shall be deemed written notice for purposes of this Section 12 if sent to the electronic mail address specified by the receiving party in Section 12. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives actual acknowledgment of receipt from the person whom the notice is sent, other than via auto-reply. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form (“**Nonelectronic Notice**”), which shall be sent to the requesting party within 10 days of receipt of the written request for Nonelectronic Notice.

13. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and the Agent and their respective successors and the affiliates, controlling persons, officers, directors and other persons referred to in Section 9 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of each such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto, the persons referred to in the preceding sentence and their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided, however*, that the Agent may assign its rights and obligations hereunder to an affiliate of the Agent without obtaining the Company’s consent, so long as such affiliate is a registered broker-dealer.

14. Adjustments for Share Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share split, share dividend or similar event effected with respect to the Common Stock.

15. Entire Agreement; Amendment; Severability; Waiver. This Agreement (including all schedules (as amended pursuant to this Agreement) and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and the Agent; *provided, however*, that **Schedule 2** of this Agreement may be amended by either party from time to time by sending a notice containing a revised **Schedule 2** to the other party in the manner provided in Section 12 and, upon such amendment, all references herein to **Schedule 2** shall automatically be deemed to refer to such amended **Schedule 2**. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent

jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement. No implied waiver by a party shall arise in the absence of a waiver in writing signed by such party. No failure or delay in exercising any right, power, or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any right, power, or privilege hereunder.

16. GOVERNING LAW AND TIME; WAIVER OF JURY TRIAL. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAWS. SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME. EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

17. Consent to Jurisdiction. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any of the transactions contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum, or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy (certified or registered mail, return receipt requested) to such party at the address in effect for notices under Section 12 of this Agreement and agrees that such service shall constitute good and sufficient notice of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

18. Construction.

(a) The section and exhibit headings herein are for convenience only and shall not affect the construction hereof.

(b) Words defined in the singular shall have a comparable meaning when used in the plural, and vice versa.

(c) The words “hereof,” “hereto,” “herein” and “hereunder” and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement.

(d) Wherever the word “include,” “includes” or “including” is used in this Agreement, it shall be deemed to be followed by the words “without limitation.”

(e) References herein to any gender shall include each other gender.

(f) References herein to any law, statute, ordinance, code, regulation, rule or other requirement of any governmental authority shall be deemed to refer to such law, statute, ordinance, code,

regulation, rule or other requirement of any governmental authority as amended, reenacted, supplemented or superseded in whole or in part and in effect from time to time and also to all rules and regulations promulgated thereunder.

19. Permitted Free Writing Prospectuses. Each of the Company and the Agent represents, warrants and agrees that, unless it obtains the prior written consent of the other party, which consent shall not be unreasonably withheld, conditioned or delayed, it has not made and will not make any offer relating to the Placement Shares that would constitute an issuer free writing prospectus, or that would otherwise constitute a free writing prospectus (as defined in Rule 405), required to be filed with the Commission. Any such free writing prospectus consented to by the Agent or by the Company, as the case may be, is hereinafter referred to as a “**Permitted Free Writing Prospectus**.” The Company represents and warrants that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an issuer free writing prospectus, and that it has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping.

20. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) the Agent has been retained to act as sales agent in connection with the sale of the Placement Shares, the Agent has acted at arms’ length and no fiduciary or advisory relationship between the Company or any of its respective affiliates, stockholders (or other equity holders), creditors or employees or any other party, on the one hand, and the Agent, on the other hand, has been or will be created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Agent has advised or is advising the Company on other matters and the Agent has no duties or obligations to the Company with respect to the transactions contemplated by this Agreement except the obligations expressly set forth herein;

(b) the Company is capable of evaluating, and understanding and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) neither the Agent nor its affiliates have provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated by this Agreement and it has consulted its own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate;

(d) the Company has been advised and is aware that the Agent and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that the Agent and its affiliates have no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship or otherwise; and

(e) the Company waives, to the fullest extent permitted by law, any claims it may have against the Agent or its affiliates for breach of fiduciary duty or alleged breach of fiduciary duty in connection with the transactions contemplated by this Agreement and agrees that the Agent and its affiliates shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders (or other equity holders), creditors or employees of the Company.

21. Recognition of the U.S. Special Resolution Regimes. In the event that the Agent is a Covered Entity (as defined below) and becomes subject to a proceeding under a U.S. Special Resolution Regime (as defined below), the transfer from the Agent of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under

the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

In the event that the Agent is a Covered Entity and the Agent or a BHC Act Affiliate (as defined below) of the Agent becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights (as defined below) under this Agreement that may be exercised against the Agent are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Agreement, (A) “BHC Act Affiliate” has the meaning assigned to the term “affiliate” in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k); (B) “Covered Entity” means any of the following: (i) a “covered entity” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a “covered bank” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a “covered FSI” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b); (C) “Default Right” has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable; and (D) “U.S. Special Resolution Regime” means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

22. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile or electronic transmission. Counterparts may be delivered via facsimile, electronic mail (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

23. Use of Information. The Agent may not provide any information gained in connection with this Agreement and the transactions contemplated by this Agreement, including due diligence, to any third party other than its legal counsel advising it on this Agreement and the transactions contemplated by this Agreement unless expressly approved by the Company in writing.

24. Agent’s Information. As used in this Agreement, “Agent’s Information” means solely the following information in the Registration Statement and the Prospectus: the last sentence of the eighth paragraph under the heading “Plan of Distribution” in the Prospectus Supplement.

All references in this Agreement to the Registration Statement, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to EDGAR. All references in this Agreement to financial statements and schedules and other information that is “contained,” “included” or “stated” in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information that is incorporated by reference in the Registration Statement or the Prospectus, as the case may be.

All references in this Agreement to “supplements” to the Prospectus shall include any supplements, “wrappers” or similar materials prepared in connection with any offering, sale or private placement of any Placement Shares by the Agent outside of the United States.

[Remainder of Page Intentionally Blank]

If the foregoing correctly sets forth the understanding between the Company and the Agent, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and the Agent.

Very truly yours,

ONKURE THERAPEUTICS, INC.

By: /s/ Nicholas A. Saccomano

Name: Nicholas A. Saccomano

Title: President and Chief Executive Officer

**ACCEPTED as of the date
first-above written:**

LEERINK PARTNERS LLC

By: /s/ Peter M. Fry

Name: Peter M. Fry

Title: Senior Managing Director, Head of
Alternative Equities

FORM OF PLACEMENT NOTICE

From: Nicholas A. Saccomano
President and Chief Executive Officer
OnKure Therapeutics, Inc.
Cc: Rogan Nunn, General Counsel and Secretary
To: Leerink Partners LLC
Subject: Leerink Partners —At the Market Offering—Placement Notice

Ladies and Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement, dated November 6, 2025 (the “**Agreement**”), by and between OnKure Therapeutics, Inc., a Delaware corporation (the “**Company**”), and Leerink Partners LLC (“**Leerink Partners**”), I hereby request on behalf of the Company that Leerink Partners sell up to [] shares of Class A common stock, \$0.0001 par value per share, of the Company (the “**Shares**”), at a minimum market price of \$ per share[; *provided* that no more than [] Shares shall be sold in any one Trading Day (as such term is defined in Section 3 of the Agreement)]. Sales should begin [on the date of this Placement Notice] and end on [DATE] [until all Shares that are the subject of this Placement Notice are sold].

The Company

Nicholas A. Saccomano
[***]

Leerink Partners

Dan Dubin ([***)
Sean Pitt ([***)
[***]

Compensation

The Company shall pay Leerink Partners compensation in cash up to 3.0% of the gross proceeds from the sales of Placement Shares pursuant to the terms of the Sales Agreement of which this **Schedule 3** forms a part.

OFFICERS' CERTIFICATE

Each of Nicholas A. Saccomano, the duly qualified and elected President and Chief Executive Officer of OnKure Therapeutics, Inc., a Delaware corporation (the "**Company**"), and Jason Leverone, the duly qualified and elected Chief Financial Officer of the Company, does hereby certify in his respective capacity and on behalf of the Company, pursuant to Section 7(m) of the Sales Agreement, dated November 6, 2025 (the "**Sales Agreement**"), by and between the Company and Leerink Partners LLC, that, after due inquiry, to the best of the knowledge of the undersigned:

(i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Effect, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions relating to materiality or Material Adverse Effect, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date.

(ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

(iii) As of the date hereof, (A) the Registration Statement complies in all material respects with the requirements of the Securities Act and does not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading, (B) the Prospectus complies in all material respects with the requirements of the Securities Act and does not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading and (C) no event has occurred as a result of which it is necessary to amend or supplement the Registration Statement or the Prospectus in order to make the statements therein not untrue or misleading or for clauses (A) and (B) above, to be true and correct.

(iv) There has been no material adverse change, or any development that would reasonably be expected to result in a material adverse change, in the condition (financial or otherwise), earnings, results of operations, business, properties, operations, assets, liabilities or prospects of the Company and its Subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business, since the date as of which information is given in the Prospectus, as amended or supplemented to the date hereof.

(v) The Company does not possess any material non-public information.

(vi) The maximum amount of Placement Shares that may be sold pursuant to the Sales Agreement has been duly authorized by the Company's board of directors or a duly authorized committee

thereof pursuant to a resolution or unanimous written consent in accordance with the Company's amended and restated certificate of incorporation, amended and restated bylaws and applicable law.

Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Sales Agreement.

Each of Wilson Sonsini Goodrich & Rosati, Professional Corporation and Covington & Burling LLP are entitled to rely on this certificate in connection with the respective opinions such firms are rendering pursuant to the Sales Agreement.

IN WITNESS WHEREOF, each of the undersigned, in such individual's respective capacity as Chief Executive Officer or Chief Financial Officer of the Company, has executed this Officers' Certificate on behalf of the Company.

By: _____
Name: Nicholas A. Saccomano
Title: President and Chief Executive Officer
Date:

By: _____
Name: Jason Leverone
Title: Chief Financial Officer
Date:

[Company Signature Page to Officers' Certificate]
