

PROSPECTUS

## 2,938,005 Shares of Class A Common Stock



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This prospectus relates to the resale by certain of the selling securityholders named in this 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 a private placement on October 4, 2024 (the “PIPE Financing”). This prospectus also covers any additional securities that may become issuable by reason of stock splits, stock dividends or other similar transactions.

We are registering the offer and sale of these securities to satisfy certain registration rights we have granted. We will not receive any of the proceeds from the sale of the securities by the selling securityholders. We will pay the expenses associated with registering the sales by the selling securityholders, as described in more detail in the section titled “Use of Proceeds” appearing elsewhere in this prospectus.

The selling securityholders may sell the securities described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling securityholders may sell their securities in the section titled “Plan of Distribution” appearing elsewhere in this prospectus.

The selling securityholders may sell any, all or none of the securities and we do not know when or in what amount the selling securityholders may sell their securities hereunder following the effective date of this registration statement.

Our Common Stock is listed on The Nasdaq Global Market (“Nasdaq”) under the symbol “OKUR.” On October 29, 2024, the last quoted sale price for our Common Stock as reported on Nasdaq was \$17.87.

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 7 of this prospectus.**

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

**Neither the Securities 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.**

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*The date of this prospectus is October 30, 2024.*

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You should rely only on the information contained in this prospectus or in any free writing prospectus prepared by us or on our behalf. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission (the “SEC”) using the “shelf” registration process. Under this shelf registration process, the selling securityholders hereunder may, from time to time, sell the securities offered by them described in this prospectus. We will not receive any proceeds from the sale by such selling securityholders of the securities offered by them described in this prospectus.

Neither we nor the selling securityholders have authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus or any applicable prospectus supplement or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. Neither we nor the selling securityholders take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor the selling securityholders will make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted.

We may also provide a prospectus supplement or post-effective amendment to the registration statement to add information to, or update or change information contained in, this prospectus. You should read both this prospectus and any applicable prospectus supplement or post-effective amendment to the registration statement together with the additional information to which we refer you in the section of this prospectus titled “*Where You Can Find Additional Information.*”

## MARKET AND INDUSTRY DATA

This prospectus includes industry and market data that we have obtained from industry publications, third-party studies and surveys, filings of public companies in their respective industries and related industry and internal company surveys. These sources include government and industry sources, which generally state that the information contained therein has been obtained from sources believed to be reliable. Although we believe the industry and market data to be reliable as of the date of this prospectus, this information could prove to be inaccurate. Industry and market data could be wrong because of the method by which sources obtained their data and because information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. We do not know all of the assumptions regarding general economic conditions or growth that were used in preparing the forecasts from the sources relied upon or cited herein. Assumptions and estimates of future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “*Risk Factors.*” These and other factors could cause future performance to differ materially from our assumptions and estimates. See “*Cautionary Statement Concerning Forward-Looking Statements.*”

## TRADEMARKS

We have proprietary rights to trademarks, trade names and service marks appearing in this prospectus that are important to our business. This prospectus may also contain trade names, trademarks and service marks belonging to other companies that are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks may appear in this prospectus without the ™ and ® symbols, but such references, or their failure to appear, should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights or the rights of the applicable licensors with respect thereto.

## PROSPECTUS SUMMARY

*This summary highlights information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should read the entire prospectus carefully before making an investment in our Common Stock. You should carefully consider, among other things, our consolidated financial statements and the related notes and the sections titled “Risk Factors,” “Business,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this prospectus.*

### ONKURE THERAPEUTICS, INC.

#### Overview

OnKure Therapeutics, Inc. (“OnKure”, “we”, “us” 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 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 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, OnKure aims 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. OnKure believes 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. OnKure designed its current product candidates utilizing x-ray crystallography and computational chemistry to inhibit specified mutated versions of phosphoinositide 3 kinase alpha (“PI3K $\alpha$ ”), a key mediator in cancer growth signaling. OnKure’s lead product candidate, OKI-219, is a highly selective inhibitor of PI3K $\alpha$  harboring the H1047R mutation (“PI3K $\alpha$ <sup>H1047R</sup>”) that has a much smaller impact on wild-type PI3K $\alpha$  (“PI3K $\alpha$ <sup>WT</sup>”). OnKure plans to initially focus on the development of OKI-219 in patients with advanced breast cancer of genetic subtypes that are (a) both hormone receptor positive (“HR+”) and human epidermal growth factor receptor 2 negative (“HER2-”); and (b) human epidermal growth factor receptor 2 positive (“HER2+”). OnKure believes it 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 1 monotherapy dose-escalation trial in H1074R-mutated advanced solid tumors including breast cancer. Early clinical data are anticipated in the fourth quarter of 2024.

Genetic analysis of tumors has become standard of care in oncology and has enabled oncologists to characterize tumors much more precisely than simple segmentation based on the tissue of origin. A more precise understanding of the genetic alterations driving the growth of specific tumors has also created an opportunity for the industry to develop drugs that are intended to target mutated or oncogenic forms of proteins that drive cancer growth and survival. In a number of notable cases, this approach has profoundly changed how these tumors are treated and has significantly improved outcomes for patients with cancers that depend on these oncogenes for survival. However, in many cases, it has been challenging to effectively target the mutated oncogenic form of a target protein. In particular, non-selective inhibition of the wild-type protein in normal tissues often leads to toxic effects that can limit effective target inhibition of the intended oncogenic protein in cancers and, therefore, offers suboptimal clinical benefit. One such challenging target is the oncogene PI3K $\alpha$ .

PI3K $\alpha$  is an attractive target for cancer drugs because it is one of the most commonly mutated oncogenes in cancers and is a key mediator of abnormal cell growth. Furthermore, PI3K $\alpha$  kinase mutations are clinically correlated with drug resistance and poor clinical outcomes. Single amino acid mutations such as E542K, E545K, H1047R, H1047L, and H1047Y account for over 70% of PI3K $\alpha$  mutations. Notably, the PI3K $\alpha$ <sup>H1047R</sup> mutation

is very common in breast cancer, being identified in approximately 13% of breast cancer cases. The PI3K $\alpha$  inhibitor alpelisib has been approved to treat patients with advanced breast cancers harboring PI3K $\alpha$  mutations. Alpelisib is non-selective for the key mutations, and its inhibition of not only mutant but also wild-type PI3K $\alpha$  leads to significant toxicities in patients, such as hyperglycemia, rash and diarrhea. These toxicities can present significant challenges to optimal dosing and use in this patient population. OnKure is focused on addressing the shortcomings of alpelisib and other first-generation PI3K $\alpha$  inhibitors by developing product candidates that target these genetic alterations selectively while sparing the wild-type PI3K $\alpha$ .

OnKure has shown preclinical data supporting the selectivity of its lead product candidate, OKI-219. OKI-219 targets the H1047R mutated PI3K $\alpha$  with approximately 80-fold selectivity over the wild-type PI3K $\alpha$ . OnKure designed this mutant-specific approach in order to minimize or eliminate potential toxicities and enable potentially higher and more continuous target coverage than has been achievable with drugs that also inhibit wild-type PI3K $\alpha$ . OnKure is currently conducting a Phase 1 dose-escalation trial to test the efficacy and tolerability of OKI-219 in patients with solid tumors harboring the H1047R mutation.

OnKure is also developing next-generation product candidates designed to selectively target not just H1047R, but also to inhibit H1047L and H1047K mutations, providing an opportunity to potentially broaden the patient population and address possible resistance mechanisms. Additional programs at OnKure include targeting other highly prevalent PI3K $\alpha$  mutations such as E542K and E545K. Over time, OnKure aims to design and develop product candidates that effectively target all of the key oncogenic mutations in PI3K $\alpha$ .

### OnKure’s Development Pipeline

OnKure is focused on the discovery and development of precision oncology therapies that target biologically validated drivers of cancers underserved by available therapies. OnKure is currently advancing OKI-219 in a Phase 1 clinical trial and has two other programs targeting PI3K $\alpha$  in the early stages of development.

### OnKure’s Clinical Pipeline

Program/Target	Initial Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Current Status	Next Anticipated Milestone
OKI-219 PI3K $\alpha$ <sup>H1047R</sup> selective inhibitor	Breast cancer	PIKture-01 Trial					Phase 1 enrolling	Early phase 1 data (Q4 2024)

### CORPORATE INFORMATION

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

Pursuant to the Merger Agreement, on the Closing Date, (i) Reneo effected a reverse stock split of Reneo’s issued common stock at a ratio of 1:10, (ii) Reneo changed its name to “OnKure Therapeutics, Inc.”, (iii) Reneo

reclassified all of its common stock as “Class A Common Stock”, and (iv) Radiate 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 becoming a wholly-owned subsidiary of OnKure Therapeutics, Inc. (together with its consolidated subsidiary, “OnKure” or the “Combined Company”). As of the open of trading on October 7, 2024, the Class A Common Stock of the Combined Company (the “Common Stock”), formerly those of Reneo, began trading on The Nasdaq Global Market (“Nasdaq”) under the symbol “OKUR.”

Our principal executive offices are located at 6707 Winchester Circle, Suite 400, Boulder, CO 80301, and our telephone number is (720) 307-2892.

Our website address is [www.onkuretherapeutics.com](http://www.onkuretherapeutics.com). The information on, or that can be accessed through, our website is not part of this prospectus, and you should not consider information contained on our website in deciding whether to purchase shares of our Common Stock. We have included our website address in this prospectus solely as an inactive textual reference.

We use the OnKure logo and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without a trademark symbol, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). We will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year in which we have more than \$1.235 billion in annual revenues; the date we qualify as a “large accelerated filer,” with at least \$700 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; and the last day of the fiscal year ending after the fifth anniversary of Reneo’s initial public offering (i.e., December 31, 2026).

Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the “Securities Act”), for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with certain other public companies difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We may continue to be a smaller reporting company in any given year if either (i) the market value of our stock held by non-affiliates is less than \$250 million as of June 30th in the most recently completed fiscal year, or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million as of June 30th in the most recently completed fiscal year.

Unless expressly indicated or the context requires otherwise, the terms “OnKure,” the “Combined Company,” the “Company,” the “Registrant,” “we,” “us” and “our” in this prospectus refer to OnKure

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Therapeutics, Inc., the parent entity formerly named Reneo Pharmaceuticals, Inc., after giving effect to the Merger, and as renamed OnKure Therapeutics, Inc., and where appropriate, our wholly-owned subsidiaries (including Legacy OnKure).

### The Offering

Shares of Common Stock Offered Hereunder	We are registering the resale by the selling securityholders named in this prospectus, or their permitted transferees, of an aggregate of 2,839,005 shares of Class A Common Stock (the “Common Stock”) issued in a private placement of securities by the Company on October 4, 2024 (the “PIPE Financing”).
Use of Proceeds	We will not receive any proceeds from the sale of our shares of Common Stock offered by the selling securityholders under this prospectus (the “Securities”). See the section titled “ <i>Use of Proceeds</i> ” appearing elsewhere in this prospectus for more information.
Class A Common Stock Outstanding	12,652,890
Combined Class A Common Stock and Non-Voting Class B Common Stock Outstanding	13,339,417
Risk Factors	See the section titled “ <i>Risk Factors</i> ” and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our Common Stock.
Nasdaq Symbol	“OKUR”

The number of shares of Common Stock outstanding is based on as of 12,652,890 shares of Common Stock as of October 4, 2024 and excludes the following, in each case as of October 4, 2024 and adjusted for the reverse stock split and applicable exchange ratios:

- 221 shares of our Common Stock issuable upon the exercise of outstanding options under the Legacy OnKure 2011 Stock Incentive Plan, which were assumed by the Company in connection with the Merger, with a weighted average exercise price of \$4.24 per share;
- 194,694 shares of our Common Stock issuable upon the exercise of outstanding options under the Legacy OnKure 2021 Stock Incentive Plan, which were assumed by the Company in connection with the Merger, with a weighted average exercise price of \$16.53 per share;
- 213,254 shares of our Common Stock issuable upon the vesting of restricted stock units issued under the Legacy OnKure 2023 RSU Equity Incentive Plan, which were assumed by the Company in connection with the Merger;
- 217,619 shares of our Common Stock issuable upon the exercise of outstanding options under the Reneo Pharmaceuticals, Inc. 2014 Equity Incentive Plan and UK Sub-Plan, with a weighted average exercise price of \$45.25 per share;
- 231,481 shares of our Common Stock issuable upon the exercise of outstanding options under the Reneo Pharmaceuticals, Inc. 2021 Equity Incentive Plan, with a weighted average exercise price of \$46.20 per share;
- 18,000 shares of our Common Stock issuable upon the exercise of outstanding options that were not issued pursuant to a Reneo Equity Plan, with a weighted average exercise price of \$88.50 per share;
- 26,591 shares of our Common Stock issuable upon the vesting of restricted stock units issued under under the Reneo Pharmaceuticals, Inc. 2021 Equity Incentive Plan;



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- 3,000 shares of our Common Stock issuable upon the vesting of restricted stock units not issued pursuant to a Reneo Equity Plan;
- 1,733,150 shares of our Common Stock issuable upon the exercise of outstanding options under our 2024 Equity Incentive Plan (the “2024 Plan”), with an exercise price of \$18.20 per share;
- 746,850 shares of our Common Stock reserved for future issuance under the 2024 Plan, as well as any automatic increases in the number of shares of Common Stock reserved for future issuance under this plan;
- 137,500 shares of our Common Stock reserved for future issuance under our 2024 Employee Stock Purchase Plan (the “2024 ESPP”), as well as any automatic increases in the number of shares of Common Stock reserved for future issuance under this plan; and
- 686,527 shares of our non-voting Class B Common Stock, which are convertible into shares of our Common Stock on a 1:1 basis, subject to customary beneficial ownership limitations.

## RISK FACTORS

*An investment in our Class A Common Stock involves a high degree of risk. In addition to the risk and uncertainties described under the section titled “Cautionary Note Regarding Forward-Looking Statements,” you should consider carefully the risks and uncertainties described below, together with all of the other information contained in this prospectus, including our consolidated financial statements and related notes, before deciding to invest in our Class A Common Stock. If any of the following events occur, our business, financial condition and operating results may be materially adversely affected. In that event, the trading price of our Class A Common Stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business or results of operations.*

### Summary Risk Factors

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company, as more fully described below. The principal factors and uncertainties that make investing in our company risky include, among others:

- 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.

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- If we are unable to obtain and maintain sufficient intellectual property protection for our technology and products and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and, if approved, commercialize our product candidates may be adversely affected.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct, supervise and monitor certain aspects of our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements and meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.
- The market price of our Class A Common Stock is expected to be volatile.
- We expect to incur losses for the foreseeable future and might never achieve profitability.
- 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 and the Amended Bylaws and provisions under Delaware law could make an acquisition of our company more difficult and may prevent attempts by our stockholders to replace or remove our management.
- As a result of the Merger, we are subject to the SEC requirements applicable to reporting shell company business combinations. As a result, we are subject to more stringent reporting requirements, offering limitations and resale restrictions.
- An active trading market for our Class A Common Stock may not develop, and the holders of our Class A Common Stock may not be able to resell their shares of our Class A Common Stock for a profit, if at all.
- We could be subject to securities class action litigation, which is expensive and could divert management attention.
- Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

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

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

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

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

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

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

We have incurred significant net losses in each reporting period since inception, have not generated any revenue from the sale of products, and have funded our operations primarily from the sale and issuance of equity securities and convertible debt. Legacy OnKure's net losses were \$35.3 million and \$29.5 million for the years ended December 31, 2023 and 2022, respectively. As of June 30, 2024, Legacy OnKure had an accumulated deficit of \$125.7 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;

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

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

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

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

### **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

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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;

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- 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.



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

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

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

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

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

Trials may be subject to delays as a result of patient withdrawal or patient enrollment taking longer than anticipated. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of subjects to participate to such trials' conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. While our Phase 1 dose-escalation and expansion cohort trial, OKI-219-101, known as PIKture-01, has begun enrollment, future difficulties we experience relating to enrollment in our clinical trials, or complications in the PIKture-01 trial or future clinical trials, could delay regulatory approval for OKI-219 or our future product candidates.

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

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

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

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

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

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

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

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

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

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

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. For example, we previously decided to cease developing another product candidate, known as OKI-179, despite promising early data. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

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

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

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

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

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

- changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials for various reasons, including non-compliance with regulatory requirements, a finding that a product candidate has undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate and we may not have funds to cover the costs;
- the supply or quality of product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

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

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

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

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program or the approvability or commercialization of the particular product candidate, and could have a material adverse effect on the success of our business. In addition, the information we choose to disclose publicly regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determines 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

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

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects or are more convenient or less

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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 Risk Evaluation Mitigation Strategy (“REMS”), if any, which may not be required of alternative treatments and competitor products;
- the cost of treatment in relation to alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of doctors to prescribe these therapies;
- the strength of our marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of an approved product candidate for use as a combination therapy;
- the potential for our competitors to limit our access to the market through anti-competitive contracts or other arrangements;
- unfavorable publicity relating to our product candidates;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

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

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

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



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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 the Company, 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.



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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

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of the United States. As such, we expect that we will be subject to additional risks related to operating in foreign countries if we or such partners obtain the necessary approvals, including:

- differing regulatory requirements and drug pricing regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act (“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.

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

### **Risks Related to Our Intellectual Property**

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

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our development programs and product candidates. Our success

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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

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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

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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



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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

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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 the Company, 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;

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- 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



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

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

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

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

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

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



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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;

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

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. It is difficult to predict how current and future legislation, executive actions and litigation, including the executive orders, will be implemented, and the extent to which they will impact our business and clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including the FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. To the extent any executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown or other disruption occurs, or if global health or other concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities in a timely manner, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, the FDA announced its intention to postpone most inspections of foreign and domestic manufacturing facilities at various points. Even though the FDA has since

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resumed standard inspection operations of domestic facilities, if a prolonged government shutdown occurs, either for global health related reasons or other reasons, preventing the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material effect on our business.

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

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

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

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

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

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

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from

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

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control prescription drug pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage bulk purchasing and importation from other countries. A number of states are considering or have recently enacted drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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

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

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

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure to what extent these legislative and regulatory proposals will be implemented by the federal and state governments, whether additional legislative changes will be enacted, whether FDA regulations, guidance or interpretations will be changed or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In

addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

Our current and future arrangements with healthcare professionals, clinical investigators, CROs and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we plan to market, sell and distribute products for which we obtain marketing approval.

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

- the federal Anti-Kickback Statute (the "AKS"), which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Violations are subject to civil and criminal fines and penalties, plus up to three times the remuneration involved, imprisonment and exclusion from government healthcare programs;
- federal civil and criminal false claims laws, including the False Claims Act ("FCA"), which can be enforced through civil "qui tam" or "whistleblower" actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting or causing to be presented claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare

benefits, items or services relating to healthcare matters. Similar to the AKS, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

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

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



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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, or hazardous materials.

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

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

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value



to or from recipients in the public or private sector. Violations of such trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials or to obtain necessary permits, licenses, patent registrations and other regulatory approvals, and we may be held liable for the corrupt or other illegal activities of our personnel, agents or partners even if we do not explicitly authorize or have prior knowledge of such activities.

### **Risks Related to Our Reliance on Third Parties**

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

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

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

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

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In many cases, our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third parties terminates, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

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

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

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of their agreements with us;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of their agreements with us;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of third parties to manufacture product candidates according to our specifications;

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- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

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

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

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

**Risks Related to Our Business Operations**

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

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

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

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

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

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

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

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

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

The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and such an event could disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay clinical development of our product candidates.

**Risks Related to Ownership of Our Class A Common Stock**

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

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

- price and volume fluctuations in the overall stock market from time to time;
- the timing and results of clinical trials for our current product candidates and any future product candidates that we may develop;
- commencement or termination of collaborations for our product development and research programs;
- failure to achieve development, regulatory or commercialization milestones under our collaborations;
- failure or discontinuation of any of our product development and research programs;
- results of preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- the level of expenses related to any of our research programs, clinical development programs or product candidates;
- the results of our efforts to develop additional product candidates;
- regulatory actions with respect to our or our competitors' product candidates or products;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- announced or completed acquisitions of businesses, products or intellectual property by us or our competitors;
- actual or anticipated changes in the financial projections or development timelines we may provide to the public or our failure to meet those projections or timelines;
- market conditions in the biotechnology and pharmaceutical sectors;

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- 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 the Company, 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 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

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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.

### ***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 this prospectus and 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.



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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.

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***The unaudited pro forma condensed combined financial data for Reneo and Legacy OnKure included as an exhibit to this prospectus are preliminary, and our actual financial position and operations after the Merger may differ materially from the unaudited pro forma financial data included in this prospectus.***

The unaudited pro forma financial data for Reneo and Legacy OnKure included elsewhere in this prospectus are presented for illustrative purposes only and are not necessarily indicative of our actual financial condition or results of operations of future periods, or the financial condition or results of operations that would have been realized had the entities been combined during the periods presented. The unaudited pro forma financial statements have been derived from the historical financial statements of Reneo and OnKure, and adjustments and assumptions have been made after giving effect to the transaction. The information upon which these adjustments and assumptions have been made is preliminary, and these kinds of adjustments and assumptions are difficult to make with accuracy. Moreover, the unaudited pro forma financial statements do not reflect all costs that are expected to be incurred by us in connection with the Proposed Transactions or that have been incurred since the date of such unaudited pro forma financial statements. The assumptions used in preparing the unaudited pro forma financial information may not prove to be accurate, and other factors may affect our financial condition following the Merger. Our actual results and financial position after the Merger may differ materially and adversely from the unaudited pro forma financial data included in this prospectus. For more information see the section beginning on page 65 entitled “*Unaudited Pro Forma Condensed Combined Financial Information.*”

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

Provisions in the Company’s Amended Certificate of Incorporation and the 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 Class A Common Stock might otherwise receive a premium price for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Class A Common Stock, thereby depressing the market price of our Class A Common Stock. In addition, because 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 Class A Common Stock to amend specified provisions of our Amended Certificate of Incorporation and the Amended Bylaws.

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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 the outstanding voting stock of the Company from merging or combining with the Company. 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 behalf of the Company; (ii) any claim or cause of action for breach of a fiduciary duty owed by any current or former director, officer or other employee of the Company, to the Company or the stockholders of the Company; (iii) any claim or cause of action against the Company or any current or former director, officer or other employee of the Company, 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 the Company or any current or former director, officer or other employee of the Company, 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 the Company.***

The Company's 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 of directors 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.

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

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

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

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

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

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

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

***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 discussed in this prospectus 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 will be available for sale in the public market beginning 180 days after the closing of the Merger as a result of the expiration of lock-up agreements between Reneo and OnKure on the one hand and certain securityholders of Reneo and OnKure on the other hand. All other outstanding shares of our Class A Common Stock, other than shares held by our affiliates and shares of our Class A Common Stock issued in the PIPE Financing, are currently freely tradable, without restriction, in the public market. In addition, shares of our Class A Common Stock that are subject to outstanding options or warrants will become eligible for sale in

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the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our Class A Common Stock could decline.

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

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

***If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the Company, 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 the Company 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 the Company or fails to publish reports on it regularly, demand for our Class A Common Stock could decrease, which in turn could cause our stock price or trading volume to decline.

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

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

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

As of December 31, 2023 and 2022, Reneo had U.S. federal net operating loss carryforwards of \$110.9 million and \$74.7 million, respectively (which are not subject to expiration other than the net operating

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loss carryforwards generated prior to 2018 of \$1.6 million, which will begin to expire in 2034), and state net operating loss carryforwards of \$1.8 million and \$1.6 million, respectively (which begin to expire in various amounts in 2034). In addition, as of December 31, 2023, Legacy OnKure had approximately \$36.7 million of federal and state net operating loss carryforwards. Approximately \$1.5 million federal net operating loss carryforwards expire through 2037 and approximately \$35.2 million have an indefinite life. Legacy OnKure's state net operating loss carryforwards are subject to similar survival periods.

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.



## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains or incorporates statements that constitute forward-looking statements within the meaning of the federal securities laws. Any express or implied statements that do not relate to historical or current facts or matters are forward-looking statements. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. These forward-looking statements include, but are not limited to, express or implied statements regarding our expectations, hopes, beliefs, intentions or strategies regarding the future. In some cases, you can identify forward-looking statements by terminology such as “may,” “might,” “will,” “could,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “seeks,” “target,” “endeavor,” “possible,” “potential,” “continue,” “contemplate” or the negative of these terms or other comparable terminology, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. In addition to other factors and matters contained in or incorporated by reference in this document, we believe the following factors could cause actual results to differ materially from those discussed in the forward-looking statements:

- risks related to our early stage of development; the uncertainties associated with our product candidates, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the completion of clinical trials;
- the significant net losses we have incurred since inception;
- our ability to initiate and complete ongoing and planned preclinical studies and clinical trials and advance our product candidates through clinical development;
- the timing of the availability of data from our clinical trials;
- the outcome of preclinical testing and clinical trials of our product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements;
- our plans to research, develop and commercialize our current and future product candidates;
- the clinical utility, potential benefits and market acceptance of our product candidates;
- the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all;
- our ability to attract, hire, and retain skilled executive officers and employees;
- our ability to protect our intellectual property and proprietary technologies;
- our reliance on third parties, contract manufacturers, and contract research organizations;
- the possibility that we may be adversely affected by other economic, business, or competitive factors; risks associated with changes in applicable laws or regulations;
- the risks and uncertainties identified from time to time in documents filed or to be filed with the SEC; and
- other risks.

Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. There may be additional risks that we consider immaterial or which are unknown. You are urged to carefully review the disclosures we make concerning these risks and other factors that may affect our business and



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operating results under the section entitled “*Risk Factors*” beginning on page 7 of this prospectus. Additional factors that could cause actual results to differ materially from those expressed in the forward-looking statements are discussed in reports filed with the SEC and incorporated by reference herein. Please see the section entitled “*Where You Can Find Additional Information*” beginning on page 181 of this prospectus.

If any of these risks or uncertainties materialize or any of these assumptions prove incorrect, our results could differ materially from the forward-looking statements. Any public statements or disclosures by us following this prospectus that modify or impact any of the forward-looking statements contained in this prospectus will be deemed to modify or supersede such statements in this prospectus. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus and are qualified in their entirety by reference to the cautionary statements herein. We do not intend, and undertake no obligation, to update any forward-looking information to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events, unless required by law to do so.

This prospectus also concerns product candidates that are under clinical investigation and which have not yet been approved for marketing by the FDA. Such product candidates are currently limited by federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

## USE OF PROCEEDS

All of the securities offered by the selling securityholders pursuant to this prospectus will be sold by the selling securityholders for their respective accounts. We will not receive any of the proceeds from the sale of the securities hereunder.

With respect to the registration of shares of our Class A Common Stock offered by the selling securityholders pursuant to this prospectus, the selling securityholders will pay any underwriting discounts and commissions and expenses incurred by them for brokerage, accounting, tax or legal services or any other expenses incurred by them in disposing of the securities. We will bear all other costs, fees and expenses incurred in effecting the registration of the securities covered by this prospectus, including, without limitation, all registration and filing fees, Nasdaq listing fees, and fees of our counsel and our independent registered public accountants.

## **MARKET PRICE OF AND DIVIDENDS ON THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

### **Market Information and Holders**

Our Class A Common Stock (the "Common Stock") is currently listed on The Nasdaq Global Market ("Nasdaq") under the symbol "OKUR." Prior to the consummation of the Merger, Reneo's common stock was historically quoted on The Nasdaq Global Market under the symbol "RPHM."

As of October 4, 2024, there were approximately 12,652,890 shares of Common Stock issued and outstanding held of record by approximately 98 holders.

There are also 686,527 shares of non-voting Class B Common Stock outstanding and held of record by one holder. The Class B Common Stock is convertible into Common Stock on a 1:1 basis at the election of such holder, subject to customary beneficial ownership limitations.

### **Dividend Policy**

We have never declared or paid any cash dividends on our capital stock. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Investors should not purchase our Common Stock with the expectation of receiving cash dividends.

Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

## UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

On May 10, 2024, Reneo entered into the Merger Agreement with Merger Sub I, Merger Sub II and Legacy OnKure, pursuant to which, on the Closing Date, (i) Reneo changed its name to “OnKure Therapeutics, Inc.” and (ii) Merger Sub I merged with and into Legacy OnKure in the Merger, with Legacy OnKure surviving the Merger as a wholly owned subsidiary of OnKure Therapeutics, Inc. On October 4, 2024, the Merger was consummated and the Combined Company’s shares began trading on Nasdaq on October 7, 2024 under the ticker symbol “OKUR”.

On October 4, 2024, in connection with the closing of transactions contemplated by the Merger Agreement, Reneo effected the Reverse Stock Split, whereby each ten shares of Reneo’s common stock was combined into one share of Reneo’s Class A Common Stock.

Also on October 4, 2024:

- each then-outstanding share of Legacy OnKure common stock was converted into the right to receive 0.023596 shares of common stock of Reneo, which was reclassified as Class A common stock of the Combined Company (“Class A Common Stock”) immediately prior to the Effective Time, based on the Common Exchange Ratio calculated in accordance with the Merger Agreement;
- 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 the Preferred Exchange Ratio calculated in accordance with the Merger Agreement; provided that a holder of Legacy OnKure preferred stock chose to receive a portion of the Merger Consideration that they would otherwise receive in the form of 686,527 shares of Class A Common Stock in an equal number of shares of Class B common stock of the Company (“Class B Common Stock”);
- the then-outstanding awards of RSUs corresponding to shares of Legacy OnKure preferred stock issued pursuant to the Legacy OnKure equity plans that were outstanding immediately prior to the Effective Time were assumed by the Combined Company and converted into RSUs covering Class A Common Stock equal to the Preferred Exchange Ratio, subject to adjustments set forth in the Merger Agreement; and
- each then-outstanding option to purchase shares of Legacy OnKure common stock was assumed by the Combined Company and converted into an option to purchase Class A Common Stock based on the Common Exchange Ratio, subject to adjustments set forth in the Merger Agreement.

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

Immediately after the Effective Time, following the consummation of the Concurrent PIPE Investments, Legacy OnKure stockholders owned approximately 53.6%, pre-Merger Reneo stockholders owned approximately 25.1%, and the PIPE Investors owned approximately 21.3% of the Combined Company’s outstanding common stock.

In addition, a majority of Reneo Options and Reneo RSUs outstanding as of immediately prior to the Effective Time were accelerated in full as of immediately prior to the Effective Time and remain outstanding

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following the Merger. These Reneo Options and Reneo RSUs generally will be subject to the same terms and conditions as were applicable to such Reneo Options and Reneo RSUs as of immediately prior to the Effective Time, except that as of the Effective Time, such Reneo Options and Reneo RSUs cover shares of Class A Common Stock instead of Reneo common stock. However, Reneo Options held by directors and executive officers have extended periods of exercisability and Reneo RSUs held by directors and executive officers are subject to a lock-up for 90 days after the Closing.

The unaudited pro forma condensed combined financial statements include adjustments to reflect the amendment and/or termination of multiple operating leases as required by the Merger Agreement, as well as the abandonment and/or disposal of tenant improvements, furniture and equipment (see Notes to the unaudited pro forma condensed combined financial statements).

The unaudited pro forma condensed combined financial information gives effect to the Merger, which has been accounted for as a reverse recapitalization under GAAP. Legacy OnKure is considered to be the accounting acquirer for financial reporting purposes because on the Closing Date, the pre-combination assets of Reneo were primarily cash, cash equivalents, short-term investments, and other non-operating assets. In addition, this determination is based on the expectation that, immediately following the Merger: (i) Legacy OnKure stockholders will own a substantial majority of the voting rights of the Combined Company; (ii) Legacy OnKure will designate a majority (six of eight) of the initial members of the board of directors of the Combined Company; and (iii) Legacy OnKure's management team will continue as the management team of the Combined Company. The Combined Company was renamed "OnKure Therapeutics, Inc." and is headquartered in Boulder, Colorado. Accordingly, the Merger is treated for accounting purposes as the equivalent of Legacy OnKure issuing stock to acquire the net assets of Reneo. As a result of Legacy OnKure being treated as the accounting acquirer, Legacy OnKure's assets and liabilities was recorded at their pre-combination carrying amounts and Reneo's assets and liabilities was measured and recognized at their fair values as of the Effective Time. At completion of the Merger, the historical financial statements of Legacy OnKure became the historical consolidated financial statements of the Combined Company.

The unaudited pro forma condensed combined balance sheet data assumes that the Merger took place on June 30, 2024 and combines the historical balance sheets of Reneo and Legacy OnKure as of such date. The unaudited pro forma condensed combined statements of operations and comprehensive loss for the six-month period ended June 30, 2024 and for the year ended December 31, 2023 assume that the Merger took place as of January 1, 2023 and combines the historical results of Reneo and Legacy OnKure for the periods then ended. The unaudited proforma condensed combined financial information was prepared pursuant to the rules and regulations of Rule 8-05 and Article 11 of SEC Regulation S-X.

The unaudited pro forma condensed combined financial statements have been derived from and should be read in connection with:

- the accompanying notes to the unaudited pro forma condensed combined financial statements;
- the historical unaudited consolidated financial statements of Reneo as of and for the three and six months ended June 30, 2024 and the related notes set forth in Reneo's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024;
- the historical unaudited financial statements of Legacy OnKure as of and for the three and six months ended June 30, 2024 and the related notes;
- the historical audited consolidated financial statements of Reneo as of and for the year ended December 31, 2023 and the related notes thereto set forth in Reneo's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as amended by Amendment No. 1 thereto;
- the historical audited financial statements of Legacy OnKure as of and for the year ended December 31, 2023 and the related notes;

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- the section entitled “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in Reneo’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as amended by Amendment No. 1 thereto, and in Reneo’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2024;
- the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations”; and
- other financial information relating to Reneo and Legacy OnKure included elsewhere in this prospectus.

The unaudited pro forma condensed combined financial information is provided for illustrative purposes only, does not necessarily reflect what the actual consolidated results of operations and financial position would have been had the Merger occurred on the dates assumed and may not be useful in predicting the future consolidated results of operations or financial position of the Combined Company.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary accounting conclusions and estimates and the final accounting conclusions and amounts may occur as a result of, among other reasons, (i) changes in initial assumptions in the determination of the accounting acquirer and related accounting, (ii) changes in the amount of cash used in Reneo’s operations, and (iii) other changes in Reneo’s assets and liabilities, which are expected to be completed after the Closing, and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the Combined Company’s future results of operations and financial position.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in conjunction with the separate historical financial statements of Reneo and Legacy OnKure, and their respective management’s discussion and analysis of financial condition and results of operations included elsewhere in this prospectus.

The accounting policies of Reneo may materially vary from those of Legacy OnKure. During preparation of the unaudited pro forma condensed combined financial information, management has performed a preliminary analysis and is not aware of any material differences, and accordingly, this unaudited pro forma condensed combined financial information assumes no material differences in accounting policies. Following the Merger, management is conducting a final review of Reneo’s accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Reneo’s results of operations or reclassification of assets or liabilities to conform to Legacy OnKure’s accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on these unaudited pro forma condensed combined financial statements.

**Unaudited Pro Forma Condensed Combined Balance Sheets**  
**As of June 30, 2024**  
(In thousands)

	<u>Historical</u>		<u>Transaction Accounting Adjustments</u>	Note 4	<u>Pro Forma Combined Total</u>
	<u>OnKure</u>	<u>Reneo</u>			
<b>Assets</b>					
Current assets:					
Cash and cash equivalents	\$ 18,633	\$ 35,970	\$ 54,927	(a)	\$ 108,741
	—	—	(789)	(b)	
Short-term investments	—	40,704	—		40,704
Prepaid expenses and other current assets	5,163	1,316	(253)	(a)	5,451
	—	—	(119)	(c)	
	—	—	(656)	(e)	
Total current assets	<u>23,796</u>	<u>77,990</u>	<u>53,110</u>		<u>154,896</u>
Property and equipment, net	1,223	81	(81)	(d)	1,223
Right-of-use assets	405	493	(493)	(b)	405
Other non-current assets	49	153	(89)	(a)	49
	—	—	(64)	(b)	
Total assets	<u>\$ 25,473</u>	<u>\$ 78,717</u>	<u>\$ 52,383</u>		<u>\$ 156,573</u>
<b>Liabilities, convertible preferred stock and stockholders' equity (deficit)</b>					
Current liabilities:					
Accounts payable	\$ 8,261	\$ 64	\$ —		\$ 8,325
Accrued expenses	4,507	953	5,604	(e)	17,376
	—	—	1,267	(e)	
	—	—	5,045	(g)	
Operating lease liabilities, current portion	216	331	(331)	(b)	216
Total current liabilities	<u>12,984</u>	<u>1,348</u>	<u>11,585</u>		<u>25,917</u>
Convertible note payable	5,858	—	(5,858)	(f)	—
Operating lease liabilities, less current portion	357	492	(492)	(b)	357
Other long-term liabilities	26	—	—		26
Performance award	—	8	—		8
Total liabilities	<u>19,225</u>	<u>1,848</u>	<u>5,235</u>		<u>26,308</u>
Commitments and contingencies					
Series C convertible preferred stock	129,825	—	(129,825)	(h)	—
Stockholders' equity (deficit):					
Common stock	1	—	—	(l)	—
Additional paid-in capital	2,148	309,143	54,581	(a)	261,918
	—	—	(1,923)	(e)	
	—	—	6,000	(f)	
	—	—	129,824	(h)	
	—	—	(312,819)	(k)	
	—	—	74,944	(k)	
	—	—	10	(i)	
Accumulated deficit	(125,726)	(232,261)	(523)	(b)	(131,646)
	—	—	(119)	(c)	
	—	—	(81)	(d)	
	—	—	(5,604)	(e)	
	—	—	(142)	(f)	
	—	—	(5,045)	(g)	
	—	—	237,865	(k)	
	—	—	(10)	(i)	
Accumulated other comprehensive loss	—	(13)	13	(k)	—
Total stockholders' equity (deficit)	<u>(123,577)</u>	<u>76,869</u>	<u>176,971</u>		<u>130,263</u>
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 25,473</u>	<u>\$ 78,717</u>	<u>\$ 52,381</u>		<u>\$ 156,571</u>

**Unaudited Pro Forma Condensed Combined Statements of Operations and Comprehensive Loss**  
**For the Six Month Period Ended June 30, 2024**  
(In thousands, except share and per share amounts)

	<u>Historical</u>		Transaction Accounting Adjustments	Note 4	Pro Forma Combined Total
	<u>OnKure</u>	<u>Renco</u>			
Operating expenses:					
Research and development	\$ 19,318	\$ 5,533	\$ —		\$ 24,851
General and administrative	4,857	10,396	(3,735)	(e)	11,395
	—	—	(32)	(d)	
	—	—	(91)	(i)	
Total operating expenses	<u>24,175</u>	<u>15,929</u>	<u>(3,858)</u>		<u>36,246</u>
Loss from operations	(24,175)	(15,929)	3,858		(36,246)
Other income	500	2,142	—		2,642
Net loss	(23,675)	(13,787)	3,858		(33,604)
Unrealized losses on short-term investments	—	(21)	—		(21)
Comprehensive loss	<u>\$ (23,675)</u>	<u>\$ (13,808)</u>	<u>\$ 3,858</u>		<u>\$ (33,625)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.77)</u>	<u>\$ (4.13)<sup>(1)</sup></u>			<u>\$ (2.52)<sup>(1)</sup></u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>13,339,473</u>	<u>3,342,080<sup>(1)</sup></u>		(j)	<u>13,338,933<sup>(1)</sup></u>

(1) As effected by the Reverse Stock Split



**Unaudited Pro Forma Condensed Combined Statements of Operations and Comprehensive Loss**

**For the Year Ended December 31, 2023**

**(In thousands, except share and per share amounts)**

	Historical		Transaction Accounting Adjustments	Note 4	Pro Forma Combined Total
	OnKure	Reneo			
Operating expenses:					
Research and development	\$ 32,115	\$ 56,613	—		\$ 88,728
General and administrative	4,819	26,440	—		31,259
Restructuring and other charges	—	—	9,339	(e)	15,219
	—	—	523	(b)	
	—	—	77	(c)	
	—	—	134	(d)	
	—	—	101	(i)	
	—	—	5,045	(g)	
Total operating expenses	<u>36,934</u>	<u>83,053</u>	<u>15,219</u>		<u>135,206</u>
Loss from operations	<u>(36,934)</u>	<u>(83,053)</u>	<u>(15,219)</u>		<u>(135,206)</u>
Other income	1,623	5,665	—		7,288
Interest expense on convertible loan	—	—	(142)		(142)
Net loss	<u>(35,311)</u>	<u>(77,388)</u>	<u>(15,219)</u>		<u>(128,060)</u>
Unrealized gain on short-term investments	—	51	—		51
Comprehensive loss	<u>\$ (35,311)</u>	<u>\$ (77,337)</u>	<u>\$ (15,219)</u>		<u>\$ (128,009)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (2.93)</u>	<u>\$ (25.23)<sup>(1)</sup></u>			<u>\$ (9.83)<sup>(1)</sup></u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>12,043,375</u>	<u>3,067,645<sup>(1)</sup></u>		(j)	<u>13,033,915<sup>(1)</sup></u>

(1) As effected by the Reverse Stock Split

## NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

### 1. Description of the Transaction

On May 10, 2024, Reneo entered into the Merger Agreement by and among Reneo, Merger Sub I, Merger Sub II and Legacy OnKure pursuant to which, Merger Sub I merged with and into Legacy OnKure, with Legacy OnKure surviving the Merger as a wholly-owned subsidiary of OnKure Therapeutics, Inc. On October 4, 2024, the Merger and other transactions contemplated by the Merger Agreement were consummated.

On October 4, 2024, in connection with the transactions contemplated by the Merger Agreement, Reneo effected a reverse stock split of Reneo's common stock, par value \$0.0001 per share, at a ratio of 1-for-10 (the "Reverse Stock Split"). Unless otherwise noted, the Reverse Stock Split has not been reflected in the historical share and per share disclosures of Reneo. Defined terms used in this "Notes to the Unaudited Pro Forma Condensed Combined Financial Information" section shall be used as defined in this section.

At the Effective Time and upon filing an amendment to the Reneo Certificate of Incorporation to reclassify the Reneo common stock, each share of Reneo common stock existing and outstanding immediately prior thereto was recapitalized and remain outstanding as a share of Class A Common Stock. The unaudited pro forma condensed combined financial information assume that, upon the Effective Time, all shares of Legacy OnKure common stock outstanding as of June 30, 2024, after giving effect to the Common Exchange Ratio of 0.023596 to one and the Preferred Exchange Ratio of 0.144794, to one were converted into the right to receive approximately 7,156,808 shares of common stock of the Combined Company in the aggregate, which is subject to adjustment as set forth in the Merger Agreement. Only 6,470,287 shares of common stock of the Combined Company was issued following the election of one holder to receive 686,527 shares of Class B Common Stock of the Combined Company in lieu of shares such holder would have otherwise received as shares of common stock of the Combined Company.

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

Immediately after the Effective Time, pre-Merger Reneo stockholders owned approximately 31.8%, and Legacy OnKure stockholders owned approximately 68.2% of the Combined Company's outstanding common stock before the Concurrent PIPE Investments. Following the consummation of the Concurrent PIPE Investments, Legacy OnKure stockholders owned approximately 53.6%, pre-Merger Reneo stockholders owned approximately 25.1%, and the PIPE Investors owned approximately 21.3% of the Combined Company's outstanding common stock.

### 2. Basis of Pro Forma Presentation

The unaudited pro forma condensed combined financial information has been prepared in accordance with Rule 8-05 and Article 11 of SEC Regulation S-X. The unaudited pro forma condensed combined statements of operations and comprehensive loss for the six-month period ended June 30, 2024 and for the year ended December 31, 2023, give effect to the Merger and the Concurrent PIPE Investments as if they had been completed on January 1, 2023, and combine the historical statements of operations and comprehensive loss of Reneo and Legacy OnKure as of such dates.

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The unaudited pro forma condensed combined balance sheet as of June 30, 2024 gives effect to the Merger and the Concurrent PIPE Investments and combines the historical balance sheets of Reneo and Legacy OnKure as of such date. Based on Legacy OnKure's preliminary review of Legacy OnKure's and Reneo's summary of significant accounting policies and preliminary discussions between management teams of Legacy OnKure and Reneo, the nature and amount of any adjustments to the historical financial statements of Reneo to conform its accounting policies to those of Legacy OnKure are not expected to be material. Upon completion of the Merger, further review of Reneo's accounting policies may result in additional revisions to Reneo's accounting policies and classifications to conform to those of Legacy OnKure.

Unless otherwise noted, the Reverse Stock Split has not been reflected in the historical share and per share disclosures of Reneo within this unaudited pro forma condensed combined financial information.

For purposes of these unaudited pro forma condensed combined financial statements, the preliminary total estimated purchase price is summarized as follows (in thousands, except share and per share amounts):

Estimated number of shares of Class A Common Stock to be owned by Reneo stockholders <sup>(1)</sup>	3,398,841
Multiplied by the assumed price per share of Reneo common stock <sup>(2)</sup>	\$ 18.20
Total	\$ 61,859
Estimated fair value of assumed Reneo equity awards based on pre-combination service <sup>(3)</sup>	3,679
Total estimated purchase price	\$ 65,538

- (1) Reflects the number of shares of Class A Common Stock that Reneo stockholders owned as of the Effective Time of the Merger pursuant to the Merger Agreement. This amount is calculated, for purposes of this unaudited pro forma condensed combined financial information, based on the number of shares of Reneo common stock outstanding at October 3, 2024 and outstanding equity instruments as effected by the Reverse Stock Split, and contemplation of equity instruments that are in-the-money and expected to be net exercised using the treasury stock method.
- (2) Reflects the price per share of Reneo common stock, which is the closing trading price of Reneo common stock as reported by Nasdaq on October 4, 2024, as effected by the Reverse Stock Split (See Note 1).
- (3) Reflects the estimated acquisition date fair value of the assumed Reneo's equity awards attributable to pre-combination service.

For accounting purposes, Legacy OnKure is considered to be the acquiring company and the Merger is accounted for as a reverse recapitalization of Reneo by Legacy OnKure because, on the Closing Date, the pre-combination assets of Reneo are primarily cash, cash equivalents, short-term investments, and other non-operating assets.

Under reverse recapitalization accounting, the assets and liabilities of Reneo were recorded, as of the completion of the Merger, at their fair value, which is the carrying value of the pre-combination assets. The difference between the final fair value of the consideration transferred and the fair value of the net assets of Reneo following determination of the actual purchase price consideration for Reneo was reflected as an adjustment to additional paid-in capital. The subsequent financial statements of Legacy OnKure will reflect the operations of Legacy OnKure, the acquirer for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the stockholders of the legal acquirer, Reneo, immediately prior to the Effective Time, and a recapitalization of the equity of the accounting acquirer, Legacy OnKure.

The accompanying unaudited pro forma condensed combined financial information is derived from the historical financial statements of Reneo and Legacy OnKure and include adjustments to give pro forma effect to reflect the

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accounting for the transactions contemplated by the Merger Agreement and other events in accordance with GAAP. The historical financial statements of Legacy OnKure shall become the historical financial statements of the Combined Company.

Legacy OnKure and Reneo may incur significant costs associated with integrating the operations of Legacy OnKure and Reneo after the Merger is completed. The unaudited pro forma condensed combined financial information does not reflect the costs of any integration activities or benefits that may result from realization of future cost savings from operating efficiencies expected to result.

The unaudited pro forma condensed combined financial information may differ from the final recapitalization accounting for a number of reasons, including the fact that the estimate of the fair value of Reneo's net assets at the Closing is preliminary and subject to change up to the Closing. The differences that may occur between the preliminary estimate and the final purchase accounting could have a material impact on the accompanying unaudited pro forma condensed combined financial information.

### **3. Shares of Common Stock of the Combined Company Issued to OnKure Stockholders upon the Closing**

At the Closing, (i) each then-outstanding share of Legacy OnKure common stock was converted into the right to receive a number of shares of Class A Common Stock equal to the Common Exchange Ratio of 0.023596 and (ii) each then-outstanding share of OnKure preferred stock was converted into a number of shares of Class A Common Stock equal to the Preferred Exchange Ratio of 0.144794. The Exchange Ratios were derived on a fully-diluted basis using the treasury stock method as of October 4, 2024 using a negotiated value of Reneo of approximately \$77.8 million, and of Legacy OnKure of approximately \$170.0 million.

The estimated number of shares of common stock of the Combined Company that Reneo issued to Legacy OnKure stockholders as effected by the Reverse Stock Split (ignoring rounding of fractional shares) as of October 4, 2024 is determined as follows:

	<u>Common Stock Shares</u>
Shares of OnKure common stock outstanding	13,401,523
Common Exchange Ratio	0.023596
Estimated shares of Class A Common Stock to be issued to holders of Legacy OnKure common stock upon the Closing	<u>316,222</u>
	<u>Preferred Stock Shares</u>
Shares of OnKure preferred stock outstanding	47,243,806
Preferred Exchange Ratio	0.144794
Estimated shares of common stock of the Combined Company to be issued to holders of Legacy OnKure preferred stock upon the Closing	<u>6,840,620</u>
Total estimated shares of common stock of the Combined Company to be issued to Legacy OnKure stockholders upon the Closing	<u>7,156,842</u>

### **4. Adjustments to Unaudited Pro Forma Condensed Combined Financial Statements**

Adjustments included in the column under the heading "Transaction Accounting Adjustments" reflect the application of the required accounting to the Merger, applying the effects of the Merger to Legacy OnKure's and

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Reneo's historical financial information. Further analysis will be performed after the completion of the Merger to confirm these estimates and make adjustments in the final purchase price allocation, as necessary.

Both Legacy OnKure and Reneo have a history of generating net operating losses and maintain a full valuation allowance against their net deferred tax assets, and management has not identified any changes to the income tax positions due to the Merger that would result in an incremental tax expense or benefit. Accordingly, management assumed a statutory tax rate of 0% and no tax-related adjustments have been reflected for the pro forma adjustments.

The pro forma adjustments included in the unaudited pro forma condensed combined financial information are as follows:

### **Transaction Accounting Adjustments:**

- (a) To reflect the sale and issuance of approximately 2,839,005 shares of common stock of the Combined Company with a par value of \$0.0001, at a per share price of \$22.895, by Reneo as a result of the Concurrent PIPE Investments and conversion of convertible notes and interest payable of approximately \$65.0 million, less an estimated \$4.3 million in issuance costs. Legacy OnKure has incurred \$0.3 million and Reneo has incurred \$0.1 million of the estimated issuance costs as of June 30, 2024, which are reflected as a reclass to additional paid-in capital.
- (b) To reflect the write-off of Reneo's operating leases that are expected to be early terminated at Closing. The operating lease right-of-use assets of \$0.5 million, operating lease liabilities, current of \$0.3 million and operating lease liabilities, non-current of \$0.5 million are written off, resulting in a \$0.5 million in losses on termination of the lease. Reneo is expected to pay an aggregate \$0.9 million in rent through the end of the lease term. In addition, \$0.1 million security deposit was reclassified from other non-current assets to cash upon termination of lease.
- (c) To write-off \$0.1 million of Reneo's prepaid expenses related to software subscriptions no longer in use.
- (d) To reflect the abandonment and/or disposal of tenant improvements, furniture and equipment totaling \$0.1 million.
- (e) To reflect Reneo's estimated transaction costs of \$9.3 million, not yet accrued for as of December 31, 2023, which are expected to be incurred in connection with the Merger, such as advisor fees, legal, and directors' and officers' liability insurance expenses, as an increase in general and administrative expense in the unaudited pro forma combined statements of operations and comprehensive loss for the year ended December 31, 2023.

As of June 30, 2024, Reneo has incurred approximately \$3.7 million of the estimated transactions costs, which the adjustment is reflected in the unaudited pro forma condensed combined statements of operation for the six-month period ended June 30, 2024. The remaining estimated transaction costs of \$5.6 million is reflected as accrued expenses as of June 30, 2024.

To reflect Legacy OnKure's estimated transaction costs of \$1.3 million, not yet accrued for as of June 30, 2024, which are expected to be incurred in connection with the Merger, such as advisor fees, legal and accounting expenses as an increase to accrued expenses and a reduction to additional paid-in capital of \$1.3 million in the unaudited pro forma combined balance sheet as of June 30, 2024. Legacy OnKure recorded approximately \$0.6 million of the estimated transaction costs on its balance sheet as deferred costs as of June 30, 2024. As the Merger will be accounted for as a reverse recapitalization, Legacy OnKure's direct transaction costs are treated as a reduction of the net proceeds received within additional paid-in capital.

- (f) To reflect the conversion of Legacy OnKure's convertible promissory notes as if it occurred at June 30, 2024 and interest expense of \$0.1 million reflected in the unaudited pro forma condensed combined

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statements of operation for the year ended December 31, 2023. The convertible promissory notes automatically convert into shares to be issued in the Concurrent PIPE Investments at the price-per-share paid by the PIPE Investors in the Concurrent PIPE Investments.

- (g) To reflect Reneo's estimated compensation expense of \$5.0 million related to severance, retention, and bonus payments that were negotiated pre-Merger payable upon termination following a change in control, which had not yet been paid or fully accrued for as of June 30, 2024. As such, the \$5.0 million is recorded as an assumed liability within the unaudited pro forma condensed combined balance sheet as of June 30, 2024 and offset to accumulated deficit. As it is considered a preacquisition expense, there is no related adjustment within the unaudited pro forma condensed combined statements of operations and comprehensive loss.
- (h) To reflect the additional paid-in capital related to the exchange of 48,716,766 shares of Legacy OnKure series C preferred stock into shares of common stock of the Combined Company based on the Preferred Exchange Ratio.
- (i) To reflect Legacy OnKure's stock-based compensation expense related to accelerated vesting of options for certain employees.
- (j) The pro forma basic and diluted earnings per share have been adjusted to reflect the pro forma net losses for the six months ended June 30, 2024, and the year ended December 31, 2023. In addition, the number of shares used to calculate the pro forma basic and diluted net loss per share has been adjusted to reflect the estimated total number of shares of common stock of the Combined Company for the respective periods which excludes common stock issuable upon (i) exercise of outstanding options or (ii) settlement of RSUs. For the year ended December 31, 2023 and the six months ended June 30, 2024, pro forma weighted average shares outstanding, as effected by the Reverse Stock Split (ignoring rounding of fractional shares), has been calculated as follows:

	For the Six Months Ended June 30, 2024	For the Year Ended December 31, 2023
OnKure weighted-average common shares outstanding—basic and diluted	13,339,473	12,043,375
Application of Common Exchange Ratio to Legacy OnKure weighted-average shares outstanding	0.023596	0.023596
Adjusted Legacy OnKure weighted-average common shares outstanding	314,758	284,175
OnKure preferred stock outstanding	47,243,806	47,243,806
Application of Preferred Exchange Ratio to Legacy OnKure weighted-average shares outstanding	0.144794	0.144794
Adjusted Legacy OnKure weighted-average preferred shares outstanding assuming conversion at January 1, 2023	6,840,620	6,840,620
Adjusted Legacy OnKure weighted-average common shares outstanding—basic and diluted	7,155,378	7,124,795
Issuance of shares of Class A Common Stock in the Concurrent PIPE Investments	2,839,005	2,839,005
Impact of Reneo common stock awards that accelerated vesting as of January 1, 2023	2,470	2,470
Historical Reneo weighted-average common shares outstanding—basic and diluted	3,342,080	3,067,645
Pro forma combined weighted average number of shares of common stock—basic and diluted	13,338,933	13,033,915

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(k) To reflect the elimination of Reneo’s historical net equity, which represent the net assets acquired in the Merger (in thousands):

	<u>Amount</u>
Pre-combination Reneo additional paid-in capital (“APIC”):	
Pre-combination stock-based compensation for converted awards	\$ (3,679)
Historical APIC	<u>(309,143)</u>
Total pre-combination APIC	(312,819)
Pre-combination Reno accumulated deficit:	
Reneo transaction costs	5,604
accumulated deficit	<u>232,261</u>
Total pre-combination accumulated deficit	237,865
Reneo accumulated other comprehensive loss (“AOCL”)	<u>13</u>
Total adjustment to historical equity (net assets of Reneo)	<u>\$ (74,944)</u>

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(l) The total impact to equity for the above adjustments are reflected in the table below (in thousands, except share amounts):

(in thousands, except share data)	Note	Preferred Stock OnKure		Common Stock				Additional Paid-in- Capital	Accumulated Deficit	AOCI	Total stockholders' equity (deficit)
		Shares	Amount	OnKure		Reneo					
				Shares	Amount	Shares	Amount				
Conversion of outstanding OnKure preferred stock to Class A Common Stock	3	(47,243,806)	\$(129,825)	—	\$ —	6,840,620	\$ 1	\$ 129,818	\$ —	\$ —	\$ 129,825
Elimination of Reneo's historical equity carrying value, after pro forma adjustments	4 (k)	—	—	—	—	—	(3)	(312,819)	237,865	13	(74,944)
Adjustment to Reneo's historical equity	4 (k)	—	—	—	—	—	—	74,944	—	—	74,944
Issuance of Class A Common Stock in the Concurrent PIPE Investments, net of fees	4 (a)	—	—	—	—	2,571,736	—	54,583	—	—	54,583
Reverse recapitalization transaction costs of Legacy OnKure	4 (e)	—	—	—	—	—	—	(1,923)	—	—	(1,923)
Reneo estimated remaining transaction costs	4 (e)	—	—	—	—	—	—	—	(5,604)	—	(5,604)
Conversion of Legacy OnKure convertible promissory notes	4 (f)	—	—	—	—	267,269	—	6,000	—	—	6,000
Stock-based compensation expense recognized by Legacy OnKure related to accelerated vesting of equity awards at the Closing	4 (i)	—	—	—	—	—	—	10	(10)	—	—
Change-in-control, retention, severance and other restructuring costs	4 (b)(c)(d)(f)(g)	—	—	—	—	—	—	—	(5,910)	—	(5,910)
<b>Total adjustment</b>		<b>(47,243,806)</b>	<b>\$(129,825)</b>	<b>—</b>	<b>\$ —</b>	<b>9,679,625</b>	<b>\$ (2)</b>	<b>\$ (49,381)</b>	<b>\$ 226,341</b>	<b>\$ 13</b>	<b>\$ 176,971</b>



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis provides information that our management believes is relevant to an assessment and understanding of our consolidated results of operations and financial condition. The discussion should be read together with the audited financial statements and related notes and unaudited pro forma condensed financial information that are included elsewhere or incorporated by reference in this prospectus. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" as set forth in this prospectus.*

*Unless otherwise indicated or the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "Legacy OnKure," "OnKure," "the Company," "we," "us," "our" and other similar terms refer to the business and operations of OnKure, Inc. prior to the Merger and to OnKure Therapeutics, Inc. and its consolidated subsidiaries following the Merger.*

Management's discussion and analysis of the financial condition and results of operation of Legacy OnKure as of and for the year ended December 31, 2023 is set forth below.

While the legal acquirer in the Merger was Reneo, for financial accounting and reporting purposes under U.S. GAAP, Legacy OnKure was the accounting acquirer and the Merger was accounted for as a "reverse recapitalization." A reverse recapitalization (i.e., a capital transaction involving the issuance of stock by Reneo for Legacy OnKure's stock) does not result in a new basis of accounting, and the consolidated financial statements of the combined entity represent the continuation of the consolidated financial statements of Legacy OnKure in many respects. Accordingly, the consolidated assets, liabilities and results of operations of Legacy OnKure became the historical consolidated financial statements of the Combined Company, and Reneo's assets, liabilities and results of operations were consolidated with those of Legacy OnKure beginning on the acquisition date. Operations prior to the Merger will be presented as those of Legacy OnKure in future reports. Reneo's assets and liabilities will be measured and recognized at their fair values as of the effective time of the Merger.

### Overview

OnKure Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery and development of precision medicines designed to target biologically validated drivers of cancers underserved by available therapies. Using a structure- and computational chemistry-driven drug design platform, we are committed to improving clinical outcomes for patients by building a robust pipeline of small molecule drugs designed to selectively target specific mutations thought to be key drivers of cancer. Our lead product candidate, OKI-219, is a highly selective inhibitor of 3 kinase alpha (PI3K $\alpha$ ), a key mediator in cancer growth signaling, harboring the H1047R mutation (PI3K $\alpha$ <sup>H1047R</sup>) that has a much smaller impact on non-mutated (or wild-type) PI3K $\alpha$  (PI3K $\alpha$ <sup>WT</sup>). OKI-219 is currently in a first-in-human Phase 1 monotherapy dose-escalation trial in H1074R-mutated advanced solid tumors including breast cancer. Early clinical data are anticipated in the fourth quarter of 2024. In addition to OKI-219, we are also pursuing programs designed to selectively target the other specific mutations of PI3K $\alpha$ .

Legacy OnKure was incorporated in the State of Delaware in 2011 and we are headquartered in Boulder, Colorado. Since inception, we have devoted substantially all of our resources to research and development activities, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and

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clinical testing, and expect that we will rely on third parties for commercial manufacturing should any of our product candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates. In addition, we generally expect to rely on third parties for the manufacture of any companion diagnostics we may develop.

Legacy OnKure funded its operations primarily through private placements of OnKure common stock, OnKure preferred stock and convertible debt. As of June 30, 2024, Legacy OnKure had cash and cash equivalents of \$18.6 million. After giving effect to the Merger and the PIPE Financing in October 2024, we believe the resulting cash resources are sufficient to fund our planned operations into the fourth quarter of 2026.

As of June 30, 2024, Legacy OnKure had an accumulated deficit of \$125.7 million. Legacy OnKure has incurred losses and negative cash flows from operations since inception, including net losses of \$35.3 million and \$29.5 million for the years ended December 31, 2023 and 2022, respectively. Legacy OnKure's net losses for the periods ended June 30, 2024 and 2023 were \$23.7 million and \$16.9 million, respectively. We expect that our operating losses and negative operating cash flows will continue for the foreseeable future as we develop our product candidates.

Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on a variety of factors including the timing and scope of our research and development activities. We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities as we:

- advance our OKI-219 program through clinical development;
- advance the development of our other small-molecule research-stage programs;
- expand our pipeline of product candidates through our own research and development efforts;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates;
- contract to manufacture any approved product candidates;
- expand our clinical, scientific, management and administrative teams;
- maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know-how;
- implement operational, financial and management systems; and
- operate as a public company.

We do not have any products approved for commercial sale, have not generated any revenue from product sales or other sources and cannot provide assurance that we will ever generate positive cash flows from operating activities. Our ability to generate product revenue sufficient to achieve and maintain profitability will depend upon the successful development and eventual commercialization of one or more of our product candidates, which is uncertain and expected to take many years. We will therefore require substantial additional capital to develop our product candidates and support our continuing operations. Accordingly, until such time that we can generate a sufficient amount of revenue from product sales or other sources, if ever, we expect to finance our operations through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties. However, we may be unable to raise additional capital from these sources on

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favorable terms, or at all. Our 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.

### **Recent Developments**

#### ***Agreement and Plan of Merger and PIPE Financing***

On May 10, 2024, we entered into the Merger Agreement, pursuant to which Legacy OnKure merged with and into Radiate Merger Sub I at approximately 4:03 ET on October 4, 2024 (the “Effective Time”), with Legacy OnKure continuing after the Merger as the surviving company and a wholly-owned subsidiary of the Combined Company. At the Effective Time, each outstanding share of Legacy OnKure capital stock was converted into the right to receive shares of Reneo Class A Common Stock or Class B Common Stock, as set forth in the Merger Agreement. Upon closing of the Merger, the Combined Company was named “OnKure Therapeutics, Inc.” and has continued to be listed on Nasdaq.

Under the exchange ratio formulas in the Merger Agreement, immediately following the Effective Time, (i) (a) 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 the Common Exchange Ratio, which at the Effective Time was reclassified as Class A Common Stock, and (b) 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 the Preferred Exchange Ratio; provided that a holder of Legacy OnKure preferred stock chose 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, (ii) each then-outstanding option to purchase shares of Legacy OnKure common stock was assumed by the Combined Company and converted into an option to purchase Class A Common Stock based on the Common Exchange Ratio, subject to adjustments set forth in the Merger Agreement, and (iii) each then-outstanding RSU of Legacy OnKure corresponding to shares of Legacy OnKure preferred stock was assumed by the Combined Company and converted into RSUs of the Combined Company covering 213,254 shares of Class A Common Stock based on the Preferred Exchange Ratio, subject to adjustments set forth in the Merger Agreement. Each share of Reneo common stock, each option to purchase shares of Reneo common stock and each RSU award covering shares of Reneo common stock that was issued and outstanding as of immediately prior to the Effective Time remained issued and outstanding in accordance with its terms and such shares, options and RSUs, subject to the Reverse Stock Split, were reclassified as Class A Common Stock but were otherwise unaffected by the Merger; provided that, to the extent not previously vested, all such options and RSUs held by Reneo’s directors and executive officers vested at the Effective Time.

Concurrently with the execution of the Merger Agreement, Reneo entered into the Subscription Agreement with the PIPE Investors, pursuant to which the PIPE Investors subscribed for and purchased 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.

### **Basis of Presentation**

The following discussion highlights Legacy OnKure’s results of operations and the principal factors that have affected its financial condition as well as its liquidity and capital resources for the periods described and provides information that management believes is relevant for an assessment and understanding of the balance sheets and statements of operations and comprehensive loss presented herein. The following discussion and analysis are based on Legacy OnKure’s audited financial statements and related notes and unaudited interim financial statements and related notes contained in this prospectus, which Legacy OnKure has prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”). You should read the discussion and analysis together with such audited financial statements and the related notes thereto and unaudited interim financial statements and related notes thereto.

## **Components of Legacy OnKure's Statements of Operations and Comprehensive Loss**

### ***Revenue***

To date, OnKure has not generated any revenue and it does not expect to generate any revenue from the sale of products or from other sources in the foreseeable future.

### ***Operating Expenses***

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

Research and development expenses account for a significant portion of OnKure's operating expenses and consist primarily of expenses incurred in connection with the discovery and development of its product candidates.

Research and development expenses consist of costs incurred for the research and development of OnKure's programs and product candidates, which include:

- employee-related expenses, including salaries, severance, retention, benefits, insurance and share-based compensation expense;
- expenses incurred under agreements with contract research organizations ("CROs"), which are companies that assist in managing OnKure's 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 contract manufacturing organizations ("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.

OnKure makes 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 OnKure receives or takes ownership of the goods or when the services are performed. At any one time, OnKure is 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, OnKure does not track its 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 OnKure initiates new clinical trials, its 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, OnKure expects that its research and development expenses will increase substantially over the next several years as it advances product candidates through preclinical studies into and through clinical trials, continues to discover and develop additional product candidates, undertakes activities to expand, maintain, protect and enforce its intellectual property portfolio, and hires 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. OnKure anticipates that it 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 its 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. OnKure will need to raise additional capital and may seek strategic alliances in the future to advance its various programs.

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### *Selling, 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 OnKure's 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. OnKure recognizes general and administrative expenses in the periods in which they are incurred.

OnKure expects that its general and administrative expenses will increase over the next several years as it hires additional personnel to support the growth of its business. In addition, the Combined Company 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 OnKure's cash equivalents in interest-bearing money market accounts.

#### *Interest Expense*

Interest expense consists of interest expense generated from OnKure's convertible notes payable.

## **Results of Operations**

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

The following table summarizes OnKure's results of operations for the periods indicated:

	Three Months Ended June 30,		<u>\$ Change</u>
	<u>2024</u>	<u>2023</u>	
	(in thousands)		
Operating expenses:			
Research and development	\$ 10,752	\$ 7,514	\$ 3,238
General and administrative	3,591	1,120	2,471
Total operating expenses	14,343	8,634	5,709
Loss from operations	(14,343)	(8,634)	(5,709)
Other income (expense), net			
Interest income	230	451	(221)
Interest expense	(26)	—	(26)
Total other income (expense), net	204	451	(247)
Net loss and comprehensive loss	<u>\$(14,139)</u>	<u>\$(8,183)</u>	<u>\$(5,956)</u>

### *Research and Development Expenses*

Research and development expenses were \$10.8 million for the three months ended June 30, 2024 compared to \$7.5 million for the three months ended June 30, 2023, an increase of \$3.2 million. This increase was primarily due to an increase in research and development costs, consisting of a \$0.9 million increase in clinical trial and manufacturing expenses and a \$2.7 million increase in personnel-related costs due to an increase in headcount, severance and share-based compensation charges. These increases were partially offset by a decrease of \$0.5 million in outsourced research.

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### *General and Administrative Expenses*

General and administrative expenses were \$3.6 million for the three months ended June 30, 2024 compared to \$1.1 million for the three months ended June 30, 2023, an increase of \$2.5 million. The increase was primarily due to an increase in personnel-related and consulting costs of \$0.6 million and an increase in legal service costs of \$1.8 million.

### *Other Income (Expense), net*

Other income (expense), net was \$0.2 million for the three months ended June 30, 2024 compared to \$0.5 million for the three months ended June 30, 2023, a decrease of \$0.3 million. The decrease was primarily due to a decrease in cash and cash equivalents available during the quarter ended June 30, 2024.

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

The following table summarizes OnKure's results of operations for the periods indicated:

	Six Months Ended June 30,		\$ Change
	2024	2023	
	(in thousands)		
Operating expenses:			
Research and development	\$ 19,318	\$ 15,037	\$ 4,281
General and administrative	4,857	2,349	2,508
Total operating expenses	24,175	17,386	6,789
Loss from operations	(24,175)	(17,386)	(6,789)
Other income (expense), net			
Interest income	526	524	2
Interest expense	(26)	—	(26)
Total other income (expense), net	500	524	(24)
Net loss and comprehensive loss	<u>\$(23,675)</u>	<u>\$(16,862)</u>	<u>\$ (6,813)</u>

### *Research and Development Expenses*

Research and development expenses were \$19.3 million for the six months ended June 30, 2024 compared to \$15.0 million for the six months ended June 30, 2023, an increase of \$4.3 million. This increase was primarily due to an increase in research and development costs, consisting of a \$1.9 million increase in clinical trial and manufacturing expenses and a \$3.5 million increase in personnel-related costs due to an increase in headcount, severance and share-based compensation charges. These increases were partially offset by a decrease of \$1.2 million in outsourced research.

### *General and Administrative Expenses*

General and administrative expenses were \$4.9 million for the six months ended June 30, 2024 compared to \$2.3 million for the six months ended June 30, 2023, an increase of \$2.5 million. The increase was primarily due to an increase in personnel-related and consulting costs of \$0.6 million and an increase in legal service costs of \$1.8 million.

### *Other Income (Expense), net*

Other income (expense), net was \$0.5 million for each of the six months ended June 30, 2024 and June 30, 2023.

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### *Comparison of the Years Ended December 31, 2024 and 2023*

The following table summarizes OnKure's results of operations for the periods indicated:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
	<b>(in thousands)</b>	
<b>Operating expenses:</b>		
Research and development	\$ 32,115	\$ 25,862
General and administrative	4,819	3,904
Total operating expenses	<u>36,934</u>	<u>29,766</u>
<b>Loss from operations</b>	<b>(36,934)</b>	<b>(29,766)</b>
<b>Other income (expense), net</b>		
Interest income	1,623	254
Total other income (expense), net	<u>1,623</u>	<u>254</u>
<b>Net loss and comprehensive loss</b>	<b><u>\$ (35,311)</u></b>	<b><u>\$ (29,512)</u></b>

#### *Research and Development Expenses*

Research and development expenses were \$32.1 million for the year ended December 31, 2023 compared to \$25.9 million for the year ended December 31, 2022, an increase of \$6.2 million. The increase was primarily due to an increase in manufacturing costs of \$3.4 million, an increase in clinical trial costs of \$2.0 million, as well as an increase in personnel-related costs of \$1.9 million related to an increase in headcount. These increases were partially offset by a decrease in outsourced research costs of \$1.3 million.

#### *General and Administrative Expenses*

General and administrative expenses were \$4.8 million for the year ended December 31, 2023 compared to \$3.9 million for the year ended December 31, 2022, an increase of \$0.9 million. The increase was primarily due to an increase of \$0.6 million in personnel-related costs and an increase of \$0.4 million in legal service costs.

#### *Other Income (Expense), net*

Other income (expense), net was \$1.6 million for the year ended December 31, 2023 compared to \$0.3 million for the year ended December 31, 2022, an increase of \$1.4 million. The increase was primarily due to an increase in cash and cash equivalents available during 2023.

## **Liquidity and Capital Resources**

### ***Sources of Liquidity***

Since inception, OnKure has not generated any revenue from product sales and has incurred significant operating losses and negative cash flows from its operations. OnKure expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances the clinical development of its product candidates. OnKure expects that its research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing its product candidates to support commercialization and providing general and administrative support for its operations, including the costs associated with operating as a public company following the Closing. As a result, OnKure will need additional capital to fund its operations, which OnKure may seek to obtain from equity or debt financings, collaborations, licensing arrangements or other sources.

OnKure has funded its operations primarily through private placements of common stock, convertible preferred stock and convertible debt, for cumulative gross proceeds of approximately \$122 million as of June 30,

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2024. However, OnKure has incurred significant recurring losses, including net losses of \$23.7 million and \$35.3 million for the six months ended June 30, 2024 and the year ended December 31, 2023, respectively. OnKure had an accumulated deficit of \$125.7 million as of June 30, 2024.

### ***Going Concern***

As of June 30, 2024, OnKure had cash and cash equivalents of \$18.6 million. These factors raised substantial doubt about OnKure's ability to continue as a going concern prior to the completion of the Merger and the PIPE Financing in October 2024. OnKure now believes the resulting cash resources will be sufficient to fund its planned operations for at least the next twelve months.

### ***Future Capital Requirements***

OnKure's primary uses of cash to date have been to fund its research and development activities, including with respect to its PI3Ka and other programs, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these activities.

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

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

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



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OnKure's 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 OnKure may pursue;
- the costs, timing and outcome of regulatory review of OnKure's product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution for OnKure's product candidates for which it receives marketing approval;
- the costs of manufacturing commercial-grade products and producing sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sales of OnKure's products, should its product candidates receive marketing approval;
- the cost and timing of attracting, hiring and retaining skilled personnel to support OnKure's operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing OnKure's intellectual property rights and defending intellectual property-related claims;
- OnKure's 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 OnKure acquires 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 OnKure's future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, OnKure's operating plans may change in the future, and OnKure may need additional capital to meet the capital requirements associated with such operating plans.

### **Cash Flows**

The following table summarizes OnKure's cash flows for the periods indicated, in thousands:

	Six Months Ended June 30,		Year Ended December 31,	
	2024	2023	2023	2022
Net cash used in operating activities	\$(17,102)	\$(15,646)	\$(34,546)	\$(26,953)
Net cash used in investing activities	(19)	(71)	(246)	(1,134)
Net cash provided by financing activities	5,878	53,106	53,125	26,465
Net increase (decrease) in cash and cash equivalents	<u>\$(11,243)</u>	<u>\$ 37,389</u>	<u>\$ 18,333</u>	<u>\$ (1,622)</u>

### **Cash Flows from Operating Activities**

Net cash used in operating activities during the six months ended June 30, 2024 was \$17.1 million. This consisted primarily of a net loss of \$23.7 million, and a net decrease in OnKure's operating assets and liabilities of \$4.4 million, partially offset by non-cash charges for share-based compensation and depreciation and amortization.

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Net cash used in operating activities during the six months ended June 30, 2023 was \$15.6 million. This consisted primarily of a net loss of \$16.9 million, partially offset by a net increase in OnKure's operating assets and liabilities of \$0.9 million, primarily due to increases in accounts payable and accrued expenses.

Net cash used in operating activities during the year ended December 31, 2023 was \$34.5 million. This consisted primarily of a net loss of \$35.3 million, partially offset by the non-cash charge for share-based compensation, depreciation and amortization.

Net cash used in operating activities during the year ended December 31, 2022 was \$27.0 million. This consisted primarily of a net loss of \$29.5 million, partially offset by a net increase in OnKure's operating assets and liabilities of \$2.1 million, primarily due to increases in accounts payable and accrued expenses.

### *Cash Flows from Investing Activities*

Net cash used in investing activities for the six months ended June 30, 2024 was \$19 thousand and related to purchase of property and equipment.

Net cash used in investing activities for the three months ended June 30, 2023 was \$71 thousand and related to purchase of property and equipment.

Net cash used in investing activities for the year ended December 31, 2023 was \$0.2 million and related to purchase of property and equipment.

Net cash used in investing activities for the year ended December 31, 2022 was \$1.1 million and related to leasehold improvements and the purchase of property and equipment.

### *Cash Flows from Financing Activities*

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

Net cash provided by financing activities was \$53.1 million during the six months ended June 30, 2023. This consisted primarily of proceeds of \$53.8 million resulting from the sale of shares of OnKure preferred stock, partially offset by \$0.7 million of issuance costs.

Net cash provided by financing activities during the year ended December 31, 2023 was \$53.1 million. This consisted primarily of proceeds of \$53.8 million resulting from the sale of shares of OnKure preferred stock, partially offset by \$0.7 million of issuance costs.

Net cash provided by financing activities during the year ended December 31, 2022 was \$26.5 million. This consisted primarily of proceeds of \$27.5 million resulting from the sale of shares of OnKure preferred stock and \$0.3 million related to proceeds from the sale of shares of OnKure common stock, partially offset by \$1.4 million of issuance costs.

### *Contractual Obligations and Commitments*

OnKure leases certain office space in Boulder, Colorado pursuant to a lease which is scheduled to expire on December 31, 2026.

The following table summarizes OnKure's contractual obligations and commitments as of June 30, 2024 (in thousands):

	Payments Due by Period			
	Total	Remainder of 2024	2025-2026	Thereafter
Operating lease obligation	\$605	\$ 118	\$ 487	\$ —

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OnKure also entered into agreements in the normal course of business with certain vendors for the provision of goods and services, which includes manufacturing services with CMOs and development services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amounts of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not separately presented.

### **Off-Balance Sheet Arrangements**

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

### **Critical Accounting Policies and Significant Judgments and Estimates**

OnKure's financial statements are prepared in accordance with U.S. GAAP. The preparation of OnKure's financial statements and related disclosures requires OnKure to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in its financial statements. OnKure bases its estimates on historical experience, known trends and events and various other factors that OnKure believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. OnKure evaluates its estimates and assumptions on a periodic basis. OnKure's actual results may differ from these estimates.

While OnKure's significant accounting policies are described in more detail in the notes to its annual audited financial statements appearing elsewhere in this prospectus, OnKure believes that the following accounting policies are critical to understanding its historical and future performance, as the policies relate to the more significant areas involving management's judgments and estimates used in the preparation of OnKure's financial statements.

There have been no material changes to OnKure's significant accounting policies during the period ended June 30, 2024.

#### ***Accrued Research and Development Expense***

OnKure 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. OnKure is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants and CROs in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which 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. OnKure reflects research and development expenses in its financial statements by matching those expenses with the period in which services are expended. OnKure accounts for these expenses according to the progress of the preclinical studies or clinical trials, as measured by the timing of various aspects of the study or related activities. OnKure 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, OnKure adjusts its rate of expense recognition if actual results differ from its estimate. 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***

Legacy OnKure maintained equity incentive compensation plans under which incentive stock options and nonqualified stock options to purchase Legacy OnKure common stock, and restricted stock units for OnKure preferred stock, were granted to employees, members of the Legacy OnKure board of directors, and non-employee consultants. Share-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 Legacy OnKure stock options granted to employees was 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 Legacy OnKure common stock, expected term of the option before exercise, expected volatility of Legacy OnKure common stock, the risk-free interest rate and expected dividend. Legacy OnKure stock options granted have a maximum contractual term of 10 years. Legacy OnKure had 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 Legacy OnKure stock option and its weighted-average vesting term. The expected volatility of Legacy OnKure stock options was based on the historical volatility of several publicly traded companies in similar stages of clinical development. 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 applicable Legacy OnKure stock option. Legacy OnKure did not declare or pay any dividends and we do not currently expect to do so in the foreseeable future, and therefore have estimated the dividend yield to be zero.

### ***Legacy OnKure Common Stock Valuation***

There had been no public market for Legacy OnKure common stock prior to completion of the Merger. As such, the estimated fair value of Legacy OnKure common stock has been determined at each grant date by the Legacy OnKure board of directors, with input from management, based on the information known to Legacy OnKure on the grant date and upon a review of any recent events and their potential impact on the estimated per-share fair value of Legacy OnKure common stock. As part of these fair value determinations, the Legacy OnKure board of directors obtained and considered valuation reports prepared by an independent third-party valuation specialist in accordance with the guidance outlined in the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. In order to determine the fair value, management considered, among other things, Legacy OnKure's actual operating and financial performance, Legacy OnKure's current business conditions and projections, the lack of marketability of Legacy OnKure common Stock and the market performance of comparable publicly traded companies.

Each valuation methodology includes estimates and assumptions that require management's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which Legacy OnKure sold shares of Legacy OnKure preferred stock, the superior rights and preferences of the Legacy OnKure preferred stock senior to Legacy OnKure common stock at the time, the progress of Legacy OnKure's research and development programs, including their stages of development, Legacy OnKure's business strategy, trends within the biotechnology industry, Legacy OnKure's financial position, including cash on hand and its historical and forecasted performance and operating results, the lack of an active public market for Legacy OnKure common stock, the market performance of peer companies in the biopharmaceutical industry, and a probability analysis of various liquidity events, such as a public offering or sale of Legacy OnKure, under differing scenarios. Changes to the key assumptions used in the valuations could result in materially different fair values of Legacy OnKure common stock at each valuation date.

Following the closing of the Merger, the Combined Company Board has and will continue to determine the fair value of our Class A Common Stock based on the closing price of our Class A Common Stock as reported on the date of grant on the primary stock exchange on which such common stock is traded.

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See Note 6 to Legacy OnKure's annual audited financial statements appearing elsewhere in this prospectus for further details.

Legacy OnKure recorded share-based compensation expense of \$1.8 million and \$17 thousand for the three months ended June 30, 2024 and 2023, respectively, \$1.9 million and \$32 thousand for the six months ended June 30, 2024 and 2023, respectively, and \$0.2 million and \$48 thousand for the years ended December 31, 2023 and 2022, respectively. Legacy OnKure recorded accelerated share-based compensation expenses related to modifications of RSUs under certain separation agreements of \$1.7 million during the three and six months ended June 30, 2024. As of June 30, 2024, Legacy OnKure had \$0.4 million of unrecognized share-based compensation expense for unvested stock options, which it expects to recognize over an estimated weighted-average period of 2.6 years. As of June 30, 2024, Legacy OnKure had \$0.3 million of unrecognized share-based compensation expense for unvested restricted stock unit awards, which it expects to recognize over an estimated weighted-average period of 2.7 years. We expect to continue to grant stock options and other share-based awards in the future, and to the extent that we do, our share-based compensation expense recognized in future periods will likely increase.

### **Recent Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial condition and results of operations is disclosed in Note 2 of Legacy OnKure's annual audited financial statements and unaudited interim financial statements appearing elsewhere in this prospectus.

### **Quantitative and Qualitative Disclosures About Market Risks**

#### ***Interest Rate Risk***

As of June 30, 2024 and December 31, 2023, OnKure's cash and cash equivalents consisted primarily of U.S. Treasury-backed money market funds. OnKure's primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term maturities of OnKure's investments, OnKure believes a hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would not have had a material impact on its financial results.

As of June 30, 2024, OnKure had convertible notes payable outstanding with fixed interest rates and was therefore not exposed to interest rate risk with respect to debt.

#### ***Foreign Currency Exchange Risk***

OnKure's primary operations are transacted in U.S. dollars. However, OnKure has entered into a limited number of contracts with vendors for research and development services that are denominated in foreign currencies, including the British Pound or Euros. OnKure could be subject to foreign currency transaction gains or losses on OnKure's contracts denominated in foreign currencies. OnKure does not currently engage in any hedging activity to reduce OnKure's potential exposure to currency fluctuations, although it may choose to do so in the future. OnKure believes a hypothetical 100 basis point increase or decrease in foreign exchange rates during any of the periods presented would not have had a material impact on its financial condition or results of operations.

## BUSINESS

### 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, OnKure is committed to improving clinical outcomes for patients by building a robust pipeline of small molecule drugs designed to selectively target specific mutations thought to be key drivers of cancer. By improving selectivity for the oncogenic and mutated form of these cancer-driver proteins, OnKure aims 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. OnKure believes 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. OnKure designed its current product candidates utilizing x-ray crystallography and computational chemistry to inhibit specified mutated versions of phosphoinositide 3 kinase alpha (“PI3K $\alpha$ ”), a key mediator in cancer growth signaling. OnKure’s lead product candidate, OKI-219, is a highly selective inhibitor of PI3K $\alpha$  harboring the H1047R mutation (“PI3K $\alpha$ <sup>H1047R</sup>”) that has a much smaller impact on wild-type PI3K $\alpha$  (“PI3K $\alpha$ <sup>WT</sup>”). OnKure plans to initially focus on the development of OKI-219 in patients with advanced breast cancer of genetic subtypes that are (a) both hormone receptor positive (“HR+”) and human epidermal growth factor receptor 2 negative (“HER2-”); and (b) human epidermal growth factor receptor 2 positive (“HER2+”). OnKure believes it 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 1 monotherapy dose-escalation trial in H1074R-mutated advanced solid tumors including breast cancer. Early clinical data are anticipated in the fourth quarter of 2024.

Genetic analysis of tumors has become standard of care in oncology and has enabled oncologists to characterize tumors much more precisely than simple segmentation based on the tissue of origin. A more precise understanding of the genetic alterations driving the growth of specific tumors has also created an opportunity for the industry to develop drugs that are intended to target mutated or oncogenic forms of proteins that drive cancer growth and survival. In a number of notable cases, this approach has profoundly changed how these tumors are treated and has significantly improved outcomes for patients with cancers that depend on these oncogenes for survival. However, in many cases, it has been challenging to effectively target the mutated oncogenic form of a target protein. In particular, non-selective inhibition of the wild-type protein in normal tissues often leads to toxic effects that can limit effective target inhibition of the intended oncogenic protein in cancers and, therefore, offers suboptimal clinical benefit. One such challenging target is the oncogene PI3K $\alpha$ .

PI3K $\alpha$  is an attractive target for cancer drugs because it is one of the most commonly mutated oncogenes in cancers and is a key mediator of abnormal cell growth. Furthermore, PI3K $\alpha$  kinase mutations are clinically correlated with drug resistance and poor clinical outcomes. Single amino acid mutations such as E542K, E545K, H1047R, H1047L, and H1047Y account for over 70% of PI3K $\alpha$  mutations. Notably, the PI3K $\alpha$ <sup>H1047R</sup> mutation is very common in breast cancer, being identified in approximately 13% of breast cancer cases. The PI3K $\alpha$  inhibitor alpelisib has been approved to treat patients with advanced breast cancers harboring PI3K $\alpha$  mutations. Alpelisib is non-selective for the key mutations, and its inhibition of not only mutant but also wild-type PI3K $\alpha$  leads to significant toxicities in patients, such as hyperglycemia, rash and diarrhea. These toxicities can present significant challenges to optimal dosing and use in this patient population. OnKure is focused on addressing the shortcomings of alpelisib and other first-generation PI3K $\alpha$  inhibitors by developing product candidates that target these genetic alterations selectively while sparing the wild-type PI3K $\alpha$ .

OnKure has shown preclinical data supporting the selectivity of its lead product candidate, OKI-219. OKI-219 targets the H1047R mutated PI3K $\alpha$  with approximately 80-fold selectivity over the wild-type PI3K $\alpha$ . OnKure designed this mutant-specific approach in order to minimize or eliminate potential toxicities and enable potentially higher and more continuous target coverage than has been achievable with drugs that also inhibit

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wild-type PI3K $\alpha$ . OnKure is currently conducting a Phase 1 dose-escalation trial to test the efficacy and tolerability of OKI-219 in patients with solid tumors harboring the H1047R mutation.

OnKure is also developing next-generation product candidates designed to selectively target not just H1047R, but also to inhibit H1047L and H1047K mutations, providing an opportunity to potentially broaden the patient population and address possible resistance mechanisms. Additional programs at OnKure include targeting other highly prevalent PI3K $\alpha$  mutations such as E542K and E545K. Over time, OnKure aims to design and develop product candidates that effectively target all of the key oncogenic mutations in PI3K $\alpha$ .

### *OnKure's Team*

OnKure has assembled a leadership team with extensive experience in drug discovery and development, with particular strengths in the discovery of small molecule protein kinase inhibitors. OnKure believes that the team's shared history at prior successful drug development organizations provides a promising opportunity for driving efficient drug development, especially for this class of drugs.

**Nicholas Saccomano, Ph.D.**, our President and Chief Executive Officer ("CEO"), joined Legacy OnKure as a member of the Legacy OnKure board of directors in 2021 and became CEO in September 2023, and has nearly 35 years of experience leading pharmaceutical research and development across multiple therapeutic areas. Prior to OnKure, he was the Chief Science Officer at Pfizer's Boulder facility, leading a team of 170 research scientists focused on small molecule drug programs. Dr. Saccomano oversaw the discovery and progression of multiple central nervous system ("CNS") drugs, including ziprasidone, marketed by Pfizer as Geodon<sup>®</sup>; donepezil, marketed by Eisai and Pfizer as Aricept<sup>®</sup>; and varenicline, marketed by Pfizer as Chantix<sup>®</sup>.

**Dylan Hartley, Ph.D.** has served as OnKure's Chief Scientific Officer since July 2024. Dr. Hartley has over 20 years of experience in drug research and development, including expertise in pharmacology, toxicology, drug metabolism and pharmacokinetics. Most recently, Dr. Hartley served as Vice President, Head of Research at Pfizer, Inc.'s Boulder facility (previously Array BioPharma, Inc. prior to its acquisition by Pfizer, Inc. in 2019) from September 2021 to July 2024. Dr. Hartley held roles of increasing responsibility at Array BioPharma, Inc. since 2011.

**Samuel Agresta, M.D.** is OnKure's Chief Medical Officer and has over 15 years of experience in global oncology drug development. Dr. Agresta has played key roles in the development of ivosidenib, marketed by Servier as TIBSOVO<sup>®</sup>; endasidenib, marketed by BMS and Servier as IDHIFA<sup>®</sup>; and ado-trastuzumab emtansine, marketed by Genentech as KADCYLA<sup>®</sup>.

**Jason Leverone, C.P.A.** is OnKure's Chief Financial Officer. He brings over 25 years of strategic finance and operational experience across multiple industries, including the last 16 years in life sciences. Prior to joining OnKure, Mr. Leverone served as the Chief Financial Officer and Secretary of miRagen Therapeutics, Inc., a publicly traded biotechnology company which merged with Viridian Therapeutics, Inc. in 2021. During his tenure at miRagen, he held roles of increasing responsibility in operations, corporate finance and strategic planning, including key roles in the company's public offering, strategic license transactions, and mergers and acquisitions. Prior to joining miRagen, Mr. Leverone served as Senior Director of Finance and Controller for Replidyne, Inc., a publicly traded biotechnology company acquired by Cardiovascular Systems in 2008. He also served as Corporate Controller for CreekPath Systems, Inc., a private international software development company. Mr. Leverone began his professional career in public accounting at Ernst and Young LLP and continued with Arthur Andersen LLP. He is a Certified Public Accountant and holds a B.S. in Business Administration from Bryant University.

OnKure is supported by both a scientific advisory board and a board of directors with extensive experience in drug development and building public companies. OnKure's early stage investors include Acorn Bioventures, BlackRock, Cormorant Asset Management, Deep Track Capital, Perceptive Advisors, Samsara BioCapital, Surveyor Capital (a Citadel company) and others.

## OnKure’s Development Pipeline

OnKure is focused on the discovery and development of precision oncology therapies that target biologically validated drivers of cancers underserved by available therapies. OnKure is currently advancing OKI-219 in a Phase 1 clinical trial and has two other programs targeting PI3K $\alpha$  in the early stages of development.

## OnKure’s Clinical Pipeline

Program/Target	Initial Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Current Status	Next Anticipated Milestone
OKI-219 PI3K $\alpha^{H1047R}$ selective inhibitor	Breast cancer	PIKture-01 Trial					Phase 1 enrolling	Early phase 1 data (Q4 2024)

## Strategy

OnKure’s strategic objective is to conceive, develop and commercialize mutation-specific PI3K $\alpha$  inhibitors based on its team’s expertise in x-ray crystallography, computational chemistry and precision kinase inhibitor drug design. To carry out its strategy, OnKure intends to:

- a) *Rapidly advance the clinical development of its highly selective PI3K $\alpha^{H1047R}$  inhibitor, OKI-219.* The Phase 1 dose-escalation and expansion cohort trial, OKI-219-101, known as PIKture-01, is currently enrolling breast cancer patients with advanced solid tumors with a PI3K $\alpha^{H1047R}$  mutation in the monotherapy dose escalation Part A. OnKure also plans to conduct two combination studies: OKI-219 in combination with the selective estrogen receptor degrader (“SERD”) fulvestrant in patients with PI3K $\alpha^{H1047R}$ -mutated, HR+/HER2- advanced breast cancer in Part B, and OKI-219 in combination with trastuzumab in patients with PI3K $\alpha^{H1047R}$ -mutated, HER2+ advanced breast cancer in Part C. If these trial parts show evidence of anti-tumor activity, these data will inform OnKure’s clinical development plans and timelines.
- b) *Select a next-generation PI3K $\alpha^{H1047X}$  inhibitor for clinical development.* OnKure has generated multiple next-generation PI3K $\alpha$  inhibitors that target not just the H1047R mutation, but also additional mutations, including H1047L and H1047Y, that may have the potential to treat a broader patient population and address mechanisms of resistance to PI3K $\alpha^{H1047R}$ -selective inhibitors. OnKure’s research and development team has extensive expertise in discovering early development candidates with favorable drug properties, and OnKure plans to select a product candidate for PI3K $\alpha^{H1047X}$  inhibition in 2024.
- c) *Develop novel PI3K $\alpha$  inhibitors targeting additional mutations.* OnKure’s most advanced pipeline programs target the PI3K $\alpha^{H1047X}$  mutation and it is applying its precision drug design approach and its team’s expertise to develop kinase inhibitors for PI3K $\alpha$  E542K and E545K mutations. These mutants are well-known oncogenic drivers, and highly selective inhibitors targeting these mutations have the potential to further expand OnKure’s addressable patient population. OnKure anticipates announcing a product candidate against one of these targets in 2025.
- d) *Conduct clinical and regulatory programs to support OnKure’s global regulatory and commercialization strategy.* OnKure retains worldwide rights to OKI-219, its next-generation PI3K $\alpha^{H1047R}$  inhibitor program, as well as its discovery stage program targeting PI3K $\alpha$  E542K and E545K mutations. OnKure plans to conduct clinical development and seek regulatory approval for these product candidates in the United States and abroad. OnKure’s long-term goal is to establish a commercial organization in the United States and potentially seek partnerships for commercialization outside the United States.



## Genetic Tumor Profiling is Unlocking Novel Targets for Cancer Therapy

Over the past 20 years, drug developers have translated findings from tumor genetic analysis into greater insight into tumor biology, a development that has led to a major improvement in anti-cancer therapies. Tumors are no longer simply classified based on their tissue of origin; rather, they are segmented based on genetic alterations, which frequently predict the likely pathogenesis of a specific malignancy and/or its sensitivity to treatment with specific targeted therapies. As a key part of this genetic analysis, mutations in critical signaling pathways have been identified, many of which are potential targets for precision medicines. The signaling axis encompassing PI3K/AKT and mammalian target of rapamycin (“mTOR”) is believed to be a key growth driver of tumor cells and is often considered a master regulator of cancer. PI3K activity is upregulated by upstream oncogenes and growth factor receptors, or by activating mutations of PI3K itself, and aberrant PI3K activation is a common hallmark in tumor cell growth in both hematologic malignancies and solid tumors. PI3K activation is believed to contribute to cancer cell survival, angiogenesis, and tumor metastasis.

There are three subtypes of PI3K, known as Type I, Type II and Type III. Type I PI3K is believed to drive the proliferation of tumor cells and has been a key target for drug development. There are four biochemical variants, also known as isoforms or subtypes, of Type I PI3K: PI3K $\alpha$ , PI3K $\beta$ , PI3K $\gamma$  and PI3K $\delta$ . While they are differentiated from each other in sequence and structure, all these variants are based on the same fundamental kinase sequence, structure, and function.

PI3K $\alpha$  is one of the most commonly mutated oncogenes in cancer. PI3K $\alpha$  can be activated by oncogenic point mutations in the PI3K $\alpha$  gene. The three most common mutations of PI3K $\alpha$  are H1047R, E542K and E545K. Mutation of PI3K $\alpha$ <sup>H1047R</sup> in a mouse model has induced breast cancer tumorigenesis and is also associated with drug resistance to HER2-targeting agents in breast cancer. PI3K $\alpha$  is mutated in up to 36% of breast cancer cases. Notably, the PI3K $\alpha$ <sup>H1047R</sup> mutation is also found in approximately 13% of breast cancer cases, making this an attractive target for novel therapeutics in metastatic breast cancer. In addition, targeting mutated PI3K $\alpha$  is a clinically-validated approach following approvals of two drugs for patients with PI3K $\alpha$ -mutated breast cancers: the PI3K $\alpha$  inhibitor alpelisib, marketed by Novartis as PIQRAY<sup>®</sup>, and the AKT inhibitor capivasertib, marketed by AstraZeneca as TRUQAP<sup>®</sup>, both of which are approved in combination with fulvestrant for the treatment of HR+, HER2-, locally advanced or metastatic breast cancer with PI3K $\alpha$  mutations. Both drugs are ATP-competitive kinase inhibitors that do not distinguish between mutant and wild-type PI3K $\alpha$ . Unlike these drugs, OKI-219 is a specific and selective allosteric inhibitor of H1047R-mutated PI3K $\alpha$ . OKI-219 is designed to bind at an allosteric site located adjacent to the 1047R mutation which is distal from the active site. This has been shown in numerous x-ray images of OKI-219 bound to PI3K $\alpha$ <sup>H1047R</sup>.

Drug-related toxicities associated with non-selective PI3K pathway inhibitors such as alpelisib and capivasertib are caused by inhibiting the wild-type PI3K $\alpha$  enzyme in normal tissues and limit the therapeutic dosing of these agents, resulting in sub-optimal dosing and limited efficacy. Adverse events commonly associated with PI3K $\alpha$  inhibitors include hyperglycemia, rash, diarrhea, and stomatitis. Tumor sequencing analysis has led to the identification of specific mutations in the PI3K $\alpha$  genes that offer novel drug targets for precision medicine with the potential to minimize the toxicities of non-selective PI3K $\alpha$  inhibitors.

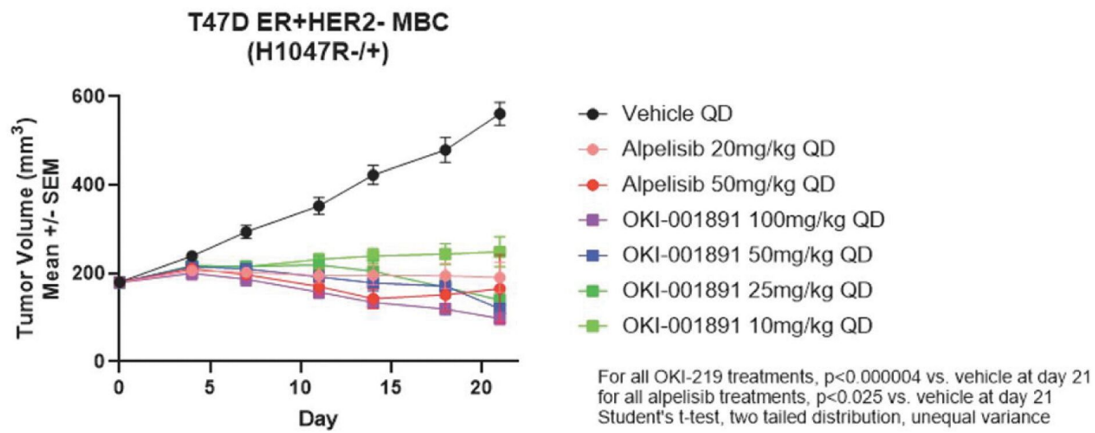
OnKure is utilizing its precision medicine small-molecule drug discovery platform to identify and develop therapeutic candidates that specifically bind to and inhibit PI3K $\alpha$  with H1047R, H1047X, E542K and E545K mutations. OnKure believes that by avoiding the targeting of wild-type PI3K $\alpha$ , its product candidates may have the potential to improve upon the safety, efficacy, or both, of first-generation non-selective PI3K $\alpha$  inhibitors.

### OnKure’s Product Candidates

#### *OKI-219, a Targeted Inhibitor of PI3K $\alpha$ H1047R*

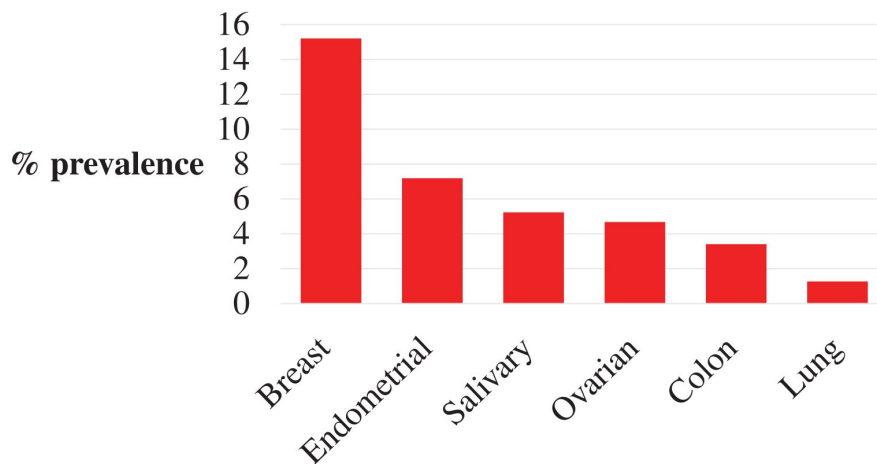
OnKure’s lead product candidate is OKI-219, an orally administered small molecule designed to selectively bind to and inhibit PI3K $\alpha$ <sup>H1047R</sup>, while avoiding wild-type PI3K $\alpha$ . As such, OKI-219 is designed to avoid the

adverse effects of inhibiting wild-type PI3K $\alpha$  in patients. Preclinical *in vivo* studies of OKI-219 in the T47D human tumor xenograft model harboring the PI3K $\alpha$ <sup>H1047R</sup> mutation indicated 10mg/kg/day dosing as minimally effective, and the drug was safely dosed up to 200mg/kg twice daily (commonly referred to as “BID,” and therefore totaling 400mg/kg/day). The ability to dose up to 200mg/kg BID further supports OKI-219’s potential to be well-tolerated in human trials. Alpelisib control at 20mg/kg four times daily (commonly referred to as “QID,” and therefore totaling 80mg/kg/day) in the mouse xenograft model showed similar drug exposure to alpelisib human doses, while dosing at 50 mg/kg was utilized to demonstrate the maximal effect in this mouse xenograft model.



**Figure 1. Preclinical comparison of tumor shrinkage for OKI-219 vs. alpelisib in ER-/HER2- breast cancer model. Source: OnKure data.**

OKI-219 is currently being investigated in a first-in-human Phase 1 trial. This is an open-label, international trial designed to evaluate OKI-219 for safety, tolerability, pharmacokinetics (“PK”), pharmacodynamics (“PD”), and efficacy with planned sites in the United States, European Union, and Asia. OnKure expects to announce early clinical data in the fourth quarter of 2024. OnKure will require additional Phase 2 and Phase 3 clinical trials to demonstrate that OKI-219 is safe and effective before OnKure can seek regulatory approvals for the commercial sale of OKI-219.

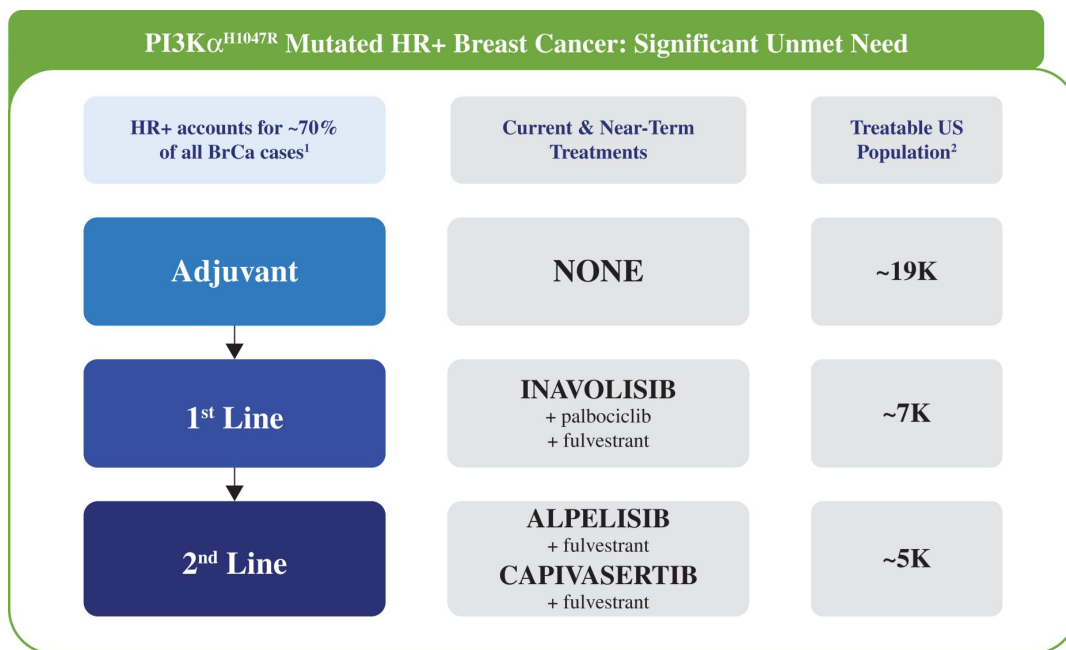


**Figure 2. Prevalence of PI3K $\alpha$ H1047R mutations in key cancer types.**

**Commercial Opportunity in Breast Cancer**

Breast cancer is the most diagnosed cancer and is the leading cause of death in women. In the United States, there were an estimated 300,590 new cases of breast cancer in 2023, resulting in 43,700 deaths. According to the National Cancer Institute, approximately 70% of breast cancer patients are HR+/HER2-, approximately 14% are HER2+ and approximately 11% are classified as triple negative, with the remaining 6% of patients being unclassified. As estimated by Wilcock et. Al. in the *Nature Review*, the total sales of breast cancer drugs in the world’s seven major markets (United States, France, Germany, Italy, Spain, United Kingdom, and Japan) are estimated to exceed \$42 billion in 2024 and grow to \$48 billion in 2029, sales of HER2-targeted therapies are expected to reach \$15 billion and drugs targeting cyclin-dependent kinase (“CDK”) 4/6 are expected to reach \$20 billion. The HER2+ population in breast cancer accounts for approximately 14% of all patients, which is a similar prevalence to PI3K $\alpha$ H1047R (13% to 15%). This suggests that the market for PI3K $\alpha$ H1047R-targeted therapies will be substantial.

OnKure believes that PI3K $\alpha$ H1047R inhibitors have a substantial commercial opportunity in HR+ breast cancer and OnKure estimates that there is a potential addressable U.S. population of approximately 5,000 patients in the second-line setting, approximately 7,000 patients in the first-line setting, and approximately 20,000 patients in the adjuvant setting. OnKure plans to develop OKI-219, as well as its future and next-generation targeted PI3K $\alpha$  inhibitors, in second-line, first-line, and adjuvant breast cancer settings.



**Figure 3. Projected treatable patient populations for PI3K $\alpha$ H1047R inhibitors in breast cancer.**

<sup>1</sup> Source: <https://seer.cancer.gov/statfacts/html/breast-subtypes.html>

<sup>2</sup> Sources: Global Cancer Observatory, COMISC, The Cancer Genome Atlas Program, AMA, Slamon, Dennis J et al. *Ther Adv Med Oncol* 2023 May 29;15:17588359231178125, Howlader et al. *J Natl Cancer Inst.* 2014 Apr 28;106(5):dju055.

The marketed PI3K $\alpha$  inhibitor alpelisib is non-selective and exhibits activity against both the wild-type and mutant forms of PI3K $\alpha$ . OnKure proposes that highly selective inhibition of the mutant oncogenic form of PI3K $\alpha$  may enable effective targeting of the only oncogenic form of the enzyme in cancers, while having little

effect against the wild-type enzyme in normal tissues, thus limiting the toxicities seen with non-selective inhibitors and enabling more effective target inhibition and efficacy. OnKure designed OKI-219 to selectively inhibit the H1047R mutation to minimize the inhibition of wild-type PI3K $\alpha$  in normal cells and thus potentially to improve efficacy and minimize known side-effects such as hyperglycemia, diarrhea, stomatitis, and rash that are commonly associated with wild-type PI3K $\alpha$  inhibitors. Preclinical data for OKI-219 have shown approximately 80-fold selectivity for PI3K $\alpha$ <sup>H1047R</sup> over PI3K $\alpha$ <sup>WT</sup>. OnKure performed studies to investigate the selectivity of OKI-219 using inhibition of phosphorylated protein kinase B (“pAKT”) in two different cell lines: the T47D cancer cell line which has a PI3K $\alpha$ <sup>H1047R</sup> mutation and the SKBR3 cancer cell line which has wild type PI3K $\alpha$ . The T47D and SKBR3 cell lines were treated for six hours with OKI-219 and inhibition of pAKT was measured using an HTRF assay and IC50 values were calculated from the dose response curves. In three separate experiments, OKI-219 inhibited pAKT with an average IC50 of 86.7 nanomolar in T47D cells as compared to 7458 nanomolar in SKBR3 cells. This corresponded to a pAKT cellular selectivity for PI3K $\alpha$ <sup>H1047R</sup> of 92 when comparing T47D and SKBR3 cell data. The values highlighted here have a statistically significant difference by an unpaired t-test (p value = 0.0001). The sample size is sufficient for an alpha of 0.05 with 80% power.

The PI3K $\alpha$ <sup>H1047R</sup> mutation is estimated to be present in approximately 4% of human cancer cases and is the most common single mutation in PI3K. The PI3K $\alpha$ <sup>H1047R</sup> mutation is commonly found in breast, endometrial, salivary, ovarian, colon and lung cancers. In breast cancer, the H1047R mutation is found in approximately 13% of all breast cancer cases and is associated with poorer outcomes in patients with HR+ metastatic breast cancer treated with aromatase inhibitors (“AI”) and CDK 4/6 inhibitors and resistance to widely used HER2+ targeted therapies such as trastuzumab, marketed initially by Roche as Herceptin<sup>®</sup>, and lapatinib, marketed by Novartis as Tykerb<sup>®</sup>.

### **Limitations of Currently Approved PI3K Inhibitors**

Mutations in the PI3K/AKT/mTOR signaling axis occur frequently in many cancer types. There are four subtypes of PI3K kinase: PI3K $\alpha$ , PI3K $\beta$ , PI3K $\gamma$  and PI3K $\delta$ . Aberrant PI3K $\alpha$  activation is believed to be involved in tumor growth and metastasis. PI3K $\alpha$  is composed of two components, a regulatory subunit, p85 $\alpha$ , and catalytic subunit, p110 $\alpha$ . An activating gain-of-function mutation in the catalytic p110 $\alpha$  region of PI3K $\alpha$  is one of the most common drivers of mutations in solid tumors.

The clinical importance of targeting mutated PI3K $\alpha$  has been identified in several clinical trials conducted on compounds discovered and developed by parties other than OnKure. OnKure has not independently conducted any clinical trials to study the prevalence of PI3K $\alpha$  mutations in breast cancers. The first-in-human Phase 1 trial of alpelisib, developed by Novartis, included both PI3K $\alpha$  mutant and PI3K<sup>WT</sup> tumors in the dose expansion component of the trial. PI3K $\alpha$  mutations were detected with commonly used next-generation sequencing assays in 64 of 76 (84.2%) of patients. The clinical benefit rate was observed to be 44% in PI3K $\alpha$  mutants vs. 20% in PI3K<sup>WT</sup> tumors. Phase 1 data for taselisib, a PI3K $\alpha$  inhibitor formerly developed by Roche, also showed a similar effect. Taselisib was tested in patients with tumors specifically selected for the H1047R mutation in PI3K $\alpha$ . Results indicated a response rate of 36% in PI3K $\alpha$ <sup>H1047R</sup> mutant patients vs. 0% in those with the PI3K<sup>WT</sup> tumors.

Inhibition of wild-type PI3K $\alpha$  is associated with multiple toxicities, including hyperglycemia, rash, diarrhea, nausea and stomatitis, which present a challenge to maintenance of patients on therapy. Hyperglycemia is one of the readily monitorable key toxicities in both patients and animal models that limits the efficacy of currently approved PI3K $\alpha$  inhibitors. Hyperglycemia was reported in 65% of patients treated with alpelisib. Specifically, 33% of hyperglycemia cases were classified as Grade 3 and 3.9% as Grade 4, and ketoacidosis was observed in 0.7% of patients. The median time to first occurrence of hyperglycemia was 15 days with a range of five days to 517 days. Of the patients who experienced elevated FPG (fasting plasma glucose) on alpelisib, 96% had their FPG level return to normal after alpelisib discontinuation.

For capivasertib, an AKT inhibitor developed by Astra Zeneca and approved for PI3K $\alpha$ /AKT1/PTEN-mutated breast cancer, Grade 3 or Grade 4 hyperglycemia occurred in 18% of treated patients. This is considered to be a severe degree of hyperglycemia. This is despite the fact that patients with insulin-dependent diabetes were excluded from the pivotal trial of capivasertib. Patients with Grade 3 hyperglycemia required insulin therapy or

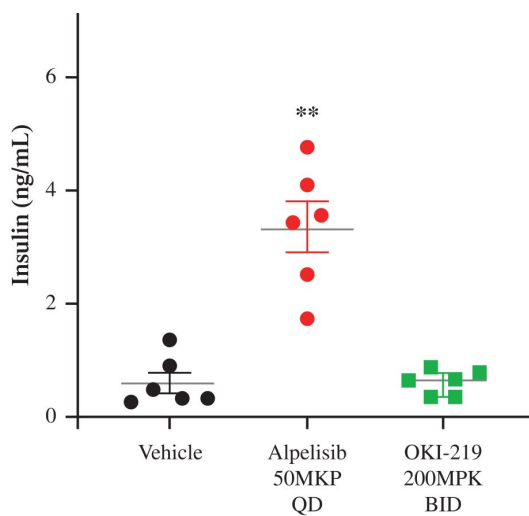
metformin therapy or both, and hospitalization was indicated in those cases. A total of 2.8% of treated patients experienced Grade 4 hyperglycemia, which was deemed life threatening and required urgent intervention. The median time to first occurrence of hyperglycemia was 15 days, with a range from one day to 367 days. Furthermore, 66% of patients who required anti-hyperglycemic medication following capivasertib treatment remained on these medications as of capivasertib treatment discontinuation or last follow-up.

**Figure 4. Side Effects in Patients Treated with First Generation Non-Selective PI3K $\alpha$  Inhibitors.**

	Alpelisib (PI3Ki)		Capivasertib (AKTi)		Inavolisib (PI3Ki)	
Sample Size	284		155		60	
Toxicity	All grades (%)	Grade 3+ (%)	All grades (%)	Grade 3+ (%)	All grades (%)	Grade 3+ (%)
Hyperglycemia	79	39	19	2	62	22
Diarrhea	58	7	77	12	42	0
Nausea	45	3	35	1	32	3
Fatigue	42	5	38	2	13	0
Rash	52	20	56	15	12	0
Stomatitis	30	3	25	2	25	0

Source: Data from product labels for alpelisib and capivasertib and from Juric et al SABCS 2021 for inavolisib.

By minimizing the targeting of PI3K $\alpha$ <sup>WT</sup> (approximately 80-fold selectivity for PI3K $\alpha$ <sup>H1047R</sup> over PI3K $\alpha$ <sup>WT</sup>), OnKure believes OKI-219 will not have a significant impact on insulin homeostasis. Preclinical OKI-219 data in a mouse xenograft model show no significant impact on insulin levels after three weeks at doses estimated to be 15x greater than the minimally efficacious dose. OnKure believes that this is a key differentiator for OKI-219 compared to first-generation non-selective PI3K $\alpha$  inhibitors.



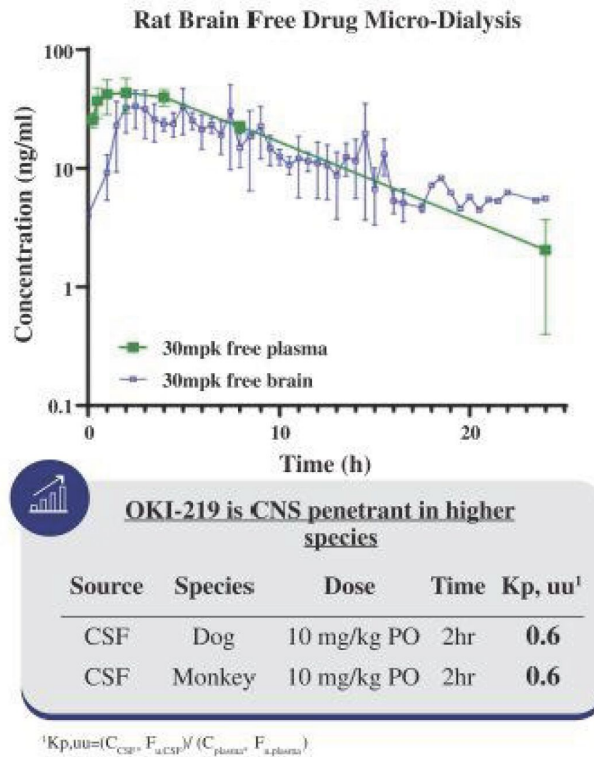
**Figure 5. Changes in measured insulin after 21 days of dosing. OKI-219 does not appear to have significant impact on insulin homeostasis.**

Source: OnKure data.

**Blood-Brain Barrier Penetration**

Brain metastases are estimated to occur in 98,000 to 170,000 cancer patients in the United States each year and in 10% to 26% of patients who die from their cancers. The observed growth in the incidence of brain metastasis over the last decade is believed to be partially attributed to the challenges of chemotherapeutic agents gaining access to the brain. While clinical outcomes for systemic malignancies have improved, the survival prognosis for brain metastasis has remained poor and for many patients remains at less than one year.

The blood-brain barrier (the “BBB”) is a semi-permeable membrane that regulates the transfer of substances from the circulatory system into the brain and provides protection for the brain from potentially harmful substances present in the rest of the body. The BBB is composed of cells that line blood vessels, known as endothelial cells, that are joined to each other with tight junctions and are surrounded by a layer of cells known as pericytes found in the capillary basement membrane. The tight junctions limit the entry of most molecules greater than approximately four hundred Daltons in molecular weight. While it is protective of the brain and contributes to overall health, the BBB nonetheless presents a challenge to physicians seeking to deliver anti-cancer agents to the brain and to treat brain metastasis. Preclinical data for OKI-219 in a rat model suggest that OKI-219 is highly brain penetrant, reaching brain concentrations of the drug similar to those observed in free plasma.



**Figure 6. Comparison of OKI-219 concentration in the brain and free plasma in rat, dog, and monkey. The data suggests that OKI-219 easily permeates the blood brain barrier.** Source: OnKure data.

Good OKI-219 brain penetration has also been confirmed in both dogs and monkeys. OnKure believes that the ability of OKI-219 to penetrate the BBB may enable it to effectively treat patients with brain metastasis in addition to those with systemic malignancies.

## Current Standard of Care in Breast Cancer

Many cancers are treated with combinations of two or more anti-cancer drugs. Specifically, in breast cancer, the choice of therapy is dependent on the type and stage of disease. Breast cancers are segmented diagnostically based on growth drivers, including hormonal receptors such as estrogen and progesterone receptors and the HER2/neu receptor. Approximately 70% of breast cancers over-express an estrogen receptor (“ER”) or progesterone receptor, and are classified as HR+/HER2-. If diagnosed with early-stage disease, patients are usually treated with endocrine therapy, such as aromatase inhibitors or tamoxifen in the adjuvant setting, or they may receive chemotherapy before hormonal inhibitors if they are diagnosed with later-stage, intermediate or high-risk disease. For patients initially diagnosed with metastatic HR+/HER2- disease, and for those who have disease that has progressed to become metastatic HR+/HER2- disease, first-line treatment includes an aromatase inhibitor plus a CDK 4/6 inhibitor, or the SERD fulvestrant with or without a CDK 4/6 inhibitor. In the second-line setting, treatment can vary depending on identified mutations in various genes. Patients with PI3K $\alpha$  mutations are eligible to receive fulvestrant plus a PI3K $\alpha$ - or AKT-targeting agent such as alpelisib or capivasertib. For patients with ESR1 mutations, physicians may prescribe a SERD such as elacestrant, the next-generation SERD marketed by Stemline Therapeutics, a subsidiary of Menarini Group, as Orserdu<sup>®</sup>. For other patients, fulvestrant with or without the mTOR inhibitor everolimus would be indicated.

Approximately 14% of breast cancer patients over-express the HER2/neu receptor and are classified as HER2+. These patients are treated with HER2-targeting agents such as trastuzumab, marketed by Roche as Herceptin<sup>®</sup>; generic biosimilars to trastuzumab; pertuzumab, marketed by Roche as Perjeta<sup>®</sup>; ado-trastuzumab emtansine or T-DM1, marketed by Roche as Kadcyla<sup>®</sup>; fam-trastuzumab deruxtecan-nxki or T-DXd, marketed by Daiichi Sankyo and AstraZeneca as Enhertu<sup>®</sup>; and tucatinib, marketed by Pfizer as Tykysa<sup>®</sup>. Typically, in early-stage or metastatic disease, the standard of care is trastuzumab plus chemotherapy, with or without pertuzumab. Ado-trastuzumab emtansine was the standard of care in second-line metastatic disease until the approval of trastuzumab deruxtecan in 2019. Trastuzumab deruxtecan is frequently prescribed in second-line HER2+ disease, whereas ado-trastuzumab emtansine is now typically used in the third-line setting. In patients with disease that progresses on all these therapy regimens, a triple combination of tucatinib, trastuzumab and capecitabine is often used in the fourth-line or salvage setting.

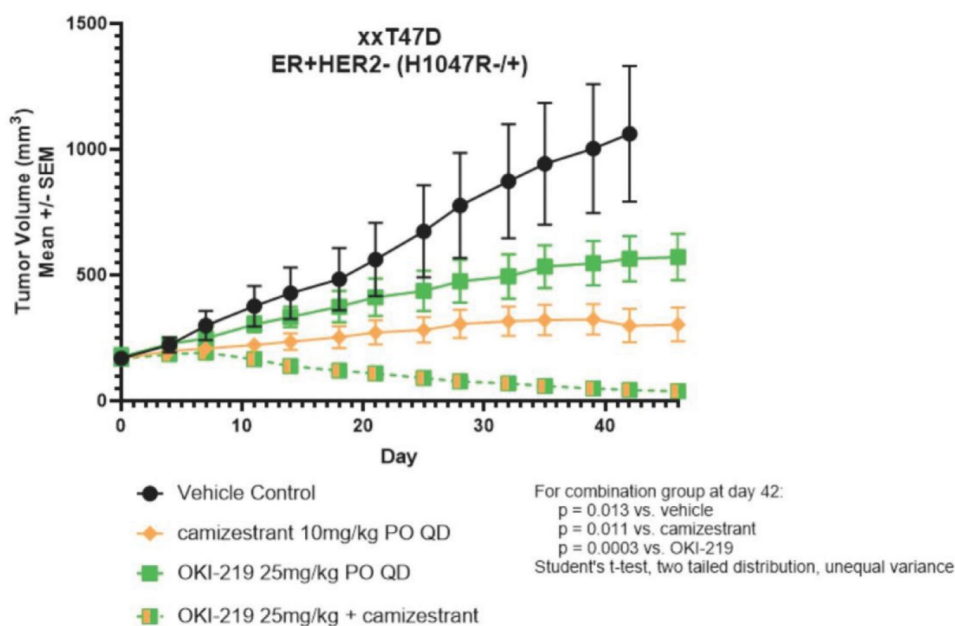
Approximately 10% of breast cancer patients do not over-express HR or HER2 receptors. These tumors are classified as triple negative breast cancer (“TNBC”). Patients with TNBC are treated with chemotherapy, sacituzumab govitecan, marketed by Gilead as Trodelvy<sup>®</sup>, immunotherapy such as pembrolizumab, marketed by Merck as Keytruda<sup>®</sup>, or atezolizumab, marketed by Genentech as Tecentriq<sup>®</sup>.

Beyond HR and HER2 receptors, breast cancer patients are also screened for PD-L1 positivity, which encompasses approximately 40% of patients, as well as for mutations in the germline BRCA1 or BRCA2 genes. The prevalence of a BRCA1 or BRCA2 mutation is only 3%–4% in HR+/HER2- patients but is approximately 15% in patients with TNBC. In PD-L1 positive, triple negative breast cancer, patients are treated with atezolizumab or pembrolizumab, while two Poly ADP Polymerase inhibitors (“PARP inhibitors”) are approved for BRCA 1/2 mutants: Olaparib, marketed by AstraZeneca as Lynparza<sup>®</sup>, and talazoparib, marketed by Pfizer as Talzenna<sup>®</sup>.

The PI3K $\alpha$ -targeting agent alpelisib and the AKT-targeting agent capivasertib are currently approved in combination with fulvestrant in advanced HR+/HER2- breast cancer, providing a proof of concept for targeting mutated PI3K $\alpha$  in this disease. These therapies have significant toxicity, however, which presents a challenge for their use. OnKure believes that the ability to safely combine with fulvestrant or other SERDs is a critical advantage for any new therapy targeting PI3K $\alpha$ -mutated HR+ breast cancer. OKI-219 was tested in combination with a next-generation SERD known as camizestrant in a preclinical breast cancer model utilizing the T47D cell. T47D is an estrogen receptor-positive luminal A subtype breast cancer cell line that harbors the PI3K $\alpha$ <sup>H1047R</sup> mutation and is frequently utilized in research of hormonal signaling in breast cancer. Monotherapy treatment with camizestrant at 10mg/kg QID resulted in slower tumor growth than the control but did not result



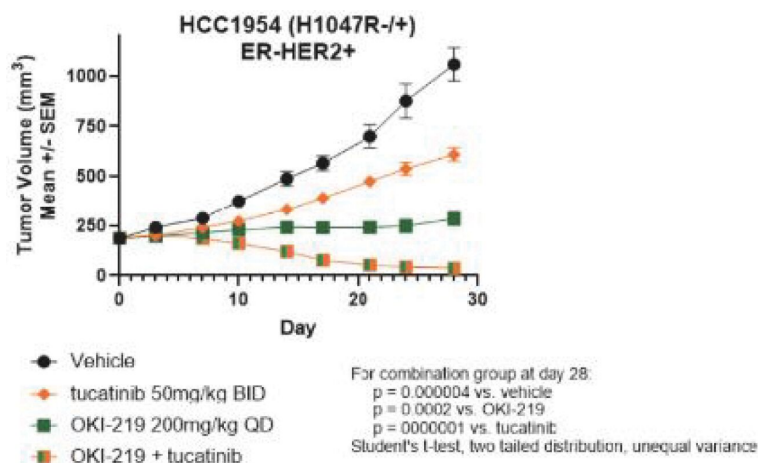
in significant tumor volume reduction from baseline. Similarly, monotherapy dosing with OKI-219 at 25mg/kg QID resulted in delay of tumor growth as well. The combination of OKI-219 and camizestrant resulted in significant and dose-dependent tumor shrinkage, supporting the potential for combination therapy of OKI-219 and SERDs in metastatic breast cancer.



**Figure 7. Efficacy assessment of OKI-219 in combination with camizestrant. The data suggest that the drugs result in greater tumor shrinkage in combination vs. monotherapy.** Source: OnKure data.

OnKure tested the combination of OKI-219 with tucatinib, an anti-HER2 small molecule tyrosine kinase inhibitor, in the HER2+ PI3K $\alpha$ <sup>H1047R</sup> HCC1954 breast cancer cell line. This cell line is resistant to tucatinib treatment, as demonstrated by the continued tumor growth with 50mg/kg BID tucatinib dosing. OKI-219 monotherapy at 200mg/kg QID appears to limit the tumor's ability to grow, but is not effective enough by itself to drive tumor shrinkage. The combination of tucatinib and OKI-291 resulted in tumor shrinkage, suggesting that inhibiting mutant PI3K $\alpha$  in combination with targeting HER2 can overcome poor responses to HER2-targeting agents used alone.





**Figure 8. Efficacy comparison of OKI-219 vs. tucatinib in tucatinib-resistant tumor model. The combination of OKI-219+ tucatinib appears to have efficacy synergy and potentially overcomes tucatinib resistance in this model.** Source: OnKure data.

OnKure believes that breast cancer is an ideal tumor type for the initial development of mutant-selective PI3K $\alpha$  inhibitors due to several factors:

- the fact that PI3K $\alpha$  inhibitors have been approved in PI3K $\alpha$ -mutated HR+ metastatic breast cancer;
- the high prevalence of the PI3K $\alpha$ <sup>H1047R</sup> mutation in breast cancer;
- the poor prognosis of patients with metastatic breast cancer who have PI3K $\alpha$  mutations; and
- the fact that PI3K $\alpha$  mutations appear to be truncal, meaning that they originate early in cancer development and, when mutated, are found in most cancer cells in a patient.

OnKure believes that initially focusing on PI3K $\alpha$ <sup>H1047R</sup> in advanced breast cancer patients may enable the eventual development of OKI-219 in earlier lines of therapy as well as in patients with tumors with different tissues of origin besides breast and expanding the patient population that may benefit from treatment with OKI-219.

### Phase 1 PIKture-01 Trial

OKI-219 is currently being investigated in the PIKture-01 trial, a Phase 1 trial. This is an open-label international trial with planned sites in the United States, European Union, and Asia designed to evaluate the safety, tolerability, PK, PD, and preliminary antitumor activity of OKI-219 as monotherapy as well as in combination with fulvestrant and trastuzumab. OnKure anticipates that it will report early data from the PIKture-01 trial in the fourth quarter of 2024.

The PIKture-01 trial has three parts:

- **Part A** is a dose-ranging basket trial of solid tumors with a target enrollment of 24 subjects testing OKI-219 as a monotherapy. This part of the trial is enrolling patients with solid tumors with the PI3K $\alpha$ <sup>H1047R</sup> mutation for whom there is no effective available therapy. The starting dose is 300mg BID, and this trial uses a Bayesian Optimal Interval (“BOIN”) design. OnKure estimates that it will be dosing 600mg BID in cohort 2 in Part A to potentially reach exposure sufficient for single-agent activity. Once monotherapy safety and dosing are established in Part A, OnKure plans to commence two dose-ranging combination trials.

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- **Part B** will investigate OKI-219 in combination with fulvestrant in HR+/HER2- advanced breast cancer. These patients must have locally advanced, unresectable or metastatic cancer with the PI3K $\alpha$ <sup>H1047R</sup> mutation and have received at least one prior line of hormonal therapy and at least one prior line of CDK 4/6 inhibitor therapy in the advanced or metastatic setting unless contraindicated. Part B is anticipated to commence in the second half of 2024.
- **Part C** will investigate OKI-219 in combination with trastuzumab in HER2+ advanced breast cancer with the PI3K $\alpha$ <sup>H1047R</sup> mutation. These patients must have HER2+, locally advanced unresectable or metastatic breast cancer and also have received prior taxane, trastuzumab, pertuzumab, tucatinib and trastuzumab deruxtecan unless unavailable or contraindicated. Part C is anticipated to commence in the first half of 2025.

Both Part B and Part C would initially enroll approximately nine patients in a single-arm dose escalation trial and then would investigate high (n=20) and low (n=20) doses to comply with FDA's project OPTIMUS dose exploration requirement. The objective of a dose-finding trial is to find the optimum dose instead of utilizing the maximum tolerated dose, which historically has been the dose chosen for pivotal trials of cancer drugs. OnKure anticipates that it will report early data from the PIKture-01 trial in the fourth quarter of 2024.

The primary endpoint of Part A is to assess the safety of OKI-219 and to identify the maximum tolerated dose and pharmacologically active dose(s) ("PAD"). Secondary endpoints include additional measures of safety and tolerability designed to:

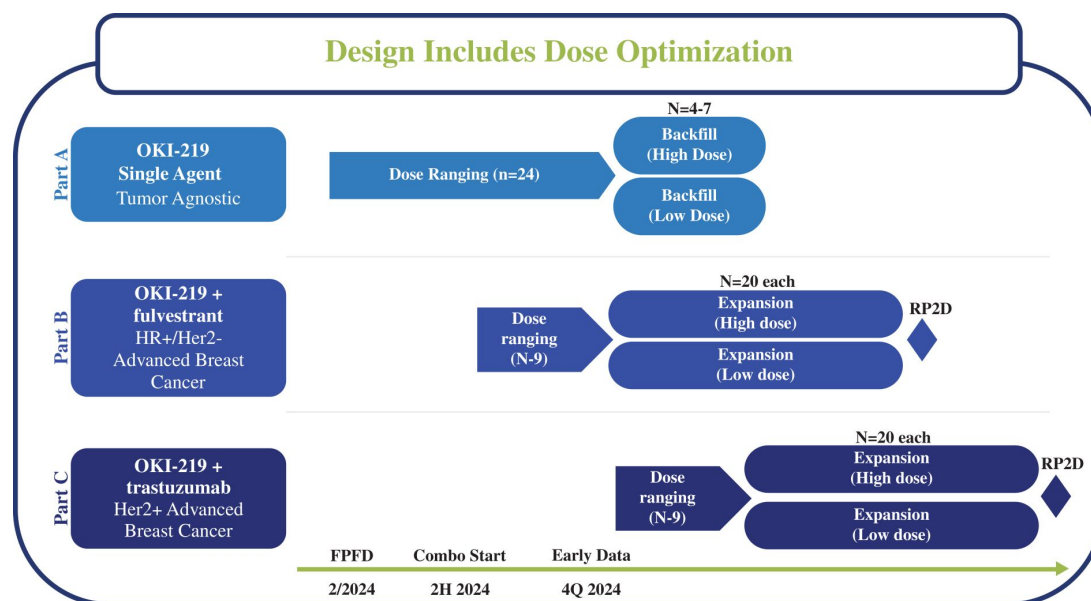
- assess plasma PK of OKI-219;
- assess the effect of food on the PK of OKI-219;
- estimate preliminary antitumor activity;
- assess the dose-response impact of circulating tumor DNA ("ctDNA"); and
- assess the PD activity of OKI-219 and its association with PK, safety, and efficacy.

For Parts B and C, the primary endpoints during dose-ranging are to assess the safety of OKI-219 when taken in combination with fulvestrant and trastuzumab, respectively, and to identify two PAD doses that will be utilized during the dose optimization portion, for which the primary endpoint is to compare two PAD dose levels of OKI-219 plus a fixed dose of fulvestrant or trastuzumab in order to identify the recommended Phase 2 dose ("RP2D"). Secondary endpoints include additional measures of safety and tolerability of OKI-219 when taken in combination with fulvestrant or trastuzumab, and are designed to:

- assess the plasma PK of OKI-219 when in combination with fulvestrant or trastuzumab;
- assess effect of food on the PK of OKI-219 when in combination with fulvestrant or trastuzumab;
- estimate preliminary antitumor activity of OKI-219 when taken in combination with fulvestrant or trastuzumab;
- assess the dose-response impact of ctDNA of OKI-219 when taken in combination with fulvestrant or trastuzumab; and
- assess the PD activity of OKI-219 and, finally, to determine the impact of OKI-219 dosing in combination with fulvestrant or trastuzumab on blood glucose and insulin.

Additionally, exploratory endpoints for all parts include an exploration of predictive biomarkers of response to OKI-219 in blood and tumor tissue as monotherapy and while in combination with fulvestrant and trastuzumab. For dose optimization only, OnKure also seeks to determine the impact of OKI-219 on quality of life.

During dose optimization, 20 participants will be randomized between two PAD levels in parts B and C. A sample size of 20 participants in each arm will provide 79% power to detect an increase in objective response rate from 5% to 20% within each PAD arm using a one-sided exact binomial test at the 10% level of significance. Monotherapy is not powered to assess efficacy.

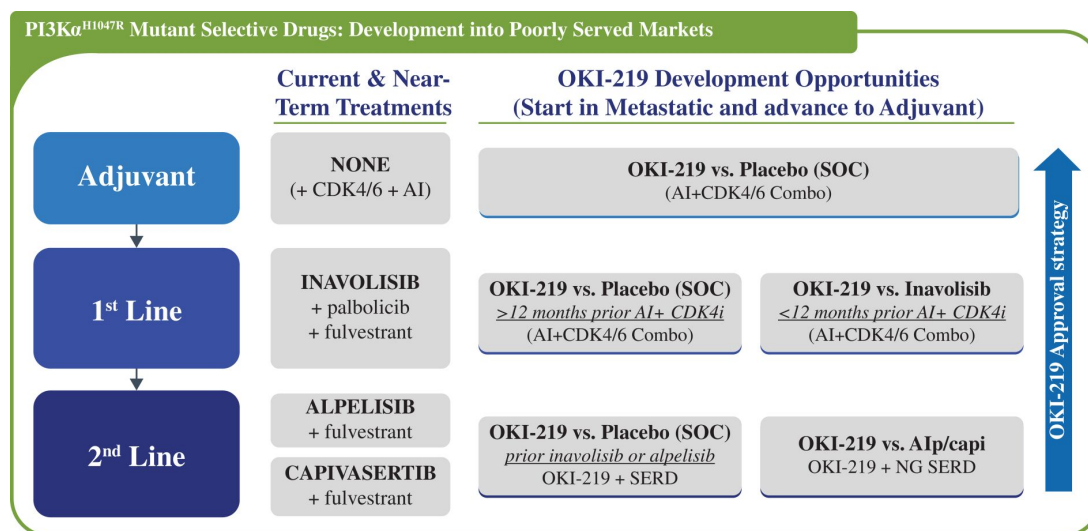


**Figure 9. PIKture-01 trial design and timeline**

**OKI-219 Future Trials**

OKI-219 was designed to target the PI3K $\alpha^{H1047R}$  mutation to maintain or improve upon the efficacy and simultaneously to minimize the toxicities associated with first-generation PI3K $\alpha^{WT}$  inhibitors. OnKure anticipates that this precision targeting of the H1047R mutation and minimal inhibition of wildtype PI3K $\alpha$  should enable OKI-219 to safely combine with other cancer drugs and potentially result in synergistic clinical efficacy. OnKure plans to explore OKI-219 in combination with approved drugs in multiple lines of treatment in breast cancer. Based on initial data from these combination studies, a number of possible development strategies may be considered, including developing OKI-219 in combination with a SERD in second-line breast cancer patients; developing in patients who have disease that has progressed on prior inavolisib or alpelisib treatment; and development in front-line metastatic breast cancer, in combination with CDK 4/6 inhibitors, plus either an

aromatase inhibitor or a SERD. With positive data in the metastatic setting, OnKure also plans to develop OKI-219 in combination with an AI+ CDK 4/6 inhibitor in the adjuvant setting.



**Figure 10. OKI-219 Clinical development approach**

**Next-Generation PI3K Precision Kinase Inhibitor Programs**

OnKure is progressing research programs with the goal of developing novel inhibitors targeting additional PI3K $\alpha$  mutations. One program has designed small-molecule PI3K $\alpha$ <sup>H1047X</sup> inhibitors, which have shown predictable mouse PK/PD with favorable drug properties. These compounds also exhibit activity against H1047L and H1047Y mutants in addition to H1047R. OnKure’s lead next-generation PI3K $\alpha$ <sup>H1047X</sup> inhibitor program is currently in the candidate selection stage, and it plans to nominate a product candidate in 2024 and file an Investigational New Drug Application (an “IND”) in 2025.

OnKure has an additional discovery-stage program with PI3K $\alpha$  inhibitors targeting E542K and E545K mutations, and anticipates that it will select a product candidate in 2025.

**Competition**

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While OnKure believes that its technology, the expertise of its team, and its development experience and scientific knowledge provide it with competitive advantages, OnKure faces increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that OnKure successfully develops and commercializes may compete with existing therapies and new therapies that may become available in the future.

Many of OnKure’s 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 OnKure does. These competitors also compete with OnKure in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in-licensing or acquiring technologies complementary to, or necessary for, OnKure’s programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative

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arrangements with companies. Additional mergers and acquisitions may result in even more resources being concentrated in OnKure's competitors. OnKure's commercial potential could be reduced or eliminated if its competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, and are more convenient or less expensive than products that OnKure may develop. OnKure's competitors also may obtain FDA or other regulatory approval for their products more rapidly than OnKure can, which could result in its competitors establishing a strong market position before OnKure is able to enter the market or could otherwise make the development or commercialization of its products more complicated. The key competitive factors affecting the success of all of OnKure's programs are likely to be efficacy, safety and patient convenience.

There are multiple PI3K $\alpha$ -pathway targeted agents either approved or under clinical development that will potentially compete with OKI-219 and OnKure's PI3K $\alpha$ -targeted portfolio. These include the marketed medicines alpelisib (Piqray<sup>®</sup>, a PI3K $\alpha$ -selective inhibitor marketed by Novartis) and capivasertib (Truquap<sup>™</sup>, an AKT1 inhibitor marketed by Astra Zeneca), both of which are approved for the treatment of PI3K $\alpha$ -mutated breast cancer patients in combination with the SERD fulvestrant. OnKure is also aware of several novel PI3K-targeted therapies that are in clinical development. This includes both multiple non-mutation-selective PI3K inhibitors (inavolisib, developed by Roche Holdings AG; gedatolisib (Celcuity Inc.); MEN1611 (menarini) and TOS-358 (Totus Medicines)) and inhibitors designed to have greater selectivity for mutated PI3K $\alpha$ , including RLY-2608 (Relay Therapeutics), STX-473 (Scorpion Therapeutics) and LOXO-783 (Loxo Oncology). Multiple other companies have disclosed or published research efforts in PI3K inhibitors that are at an early stage, but could potentially advance to the clinic.

Finally, there are numerous other investigational therapies, spanning many modalities that are being evaluated preclinically and in clinical trials for breast cancer.

### **Manufacturing**

OnKure does not own or operate, and currently has no plans to establish, any manufacturing facilities. OnKure relies, and expects to continue to rely, on third parties for the manufacture of its product candidates for preclinical and clinical testing, and expects to rely on third parties for commercial manufacturing should any of its product candidates obtain marketing approval. OnKure believes that this strategy allows it to maintain a more efficient infrastructure by eliminating the need for to invest in its own manufacturing facilities, equipment and personnel while also enabling OnKure to focus its expertise and resources on the discovery and development of its product candidates. In addition, OnKure generally expects to rely on third parties for the manufacture of any companion diagnostics it may develop.

To date, OnKure has obtained the regulatory starting materials and cGMP-compliant active pharmaceutical ingredients from a single-source supplier, PharmaBlock Sciences (Nanjing), Inc., but could contract with other CMOs for these materials as the raw materials OnKure uses are commonly used and are available from multiple sources. OnKure also currently relies on a single-source CMO, STA Pharmaceutical Hong Kong Limited, for the drug product for OKI-219, but may contract with other CMOs for the manufacture of drug product in the future. OnKure is in the process of developing its supply chain for its product candidates and intends to put in place framework agreements under which third-party CMOs will generally provide OnKure with necessary quantities of API and drug product on a project-by-project basis based on its development requirements.

As OnKure advances its product candidates through development, it plans to explore adding backup suppliers for the API and drug product for OKI-219 and future product candidates in order to protect against any potential supply disruptions.

### **Intellectual Property**

OnKure strives to protect and enhance the proprietary technologies, inventions and improvements that are commercially important to its business by, among other methods, pursuing and obtaining patent protection in the

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United States and in jurisdictions outside of the United States directed to these technologies, inventions, improvements and to its drug candidates. OnKure also relies on trade secrets, know-how, trademarks, continuing technological innovation and licensing opportunities to develop and maintain its proprietary and intellectual property position.

As of August 1, 2024, OnKure's owned and licensed patent portfolio included 129 patents and patent applications, including two licensed U.S. issued patents and six owned U.S. issued patents, covering various aspects of its proprietary technology, product candidates, and related inventions and improvements. The patent portfolio also includes 36 licensed patents issued in jurisdictions outside of the United States, and 17 owned patent applications pending in jurisdictions outside of the United States that, in many cases, are counterparts to the foregoing U.S. patents and patent applications. OnKure's licensed patents relate to a patent family that is no longer material to OnKure's business.

### ***PI3K Platform***

OnKure currently owns 11 patent families directed to its PI3K platform technology as summarized below. The patent families are differentiated based on the chemical structures of the PI3K inhibitor compounds. All of the family members are currently at the application stage and exist as either a U.S. provisional ("USP") application or as a Patent Cooperation Treaty ("PCT") application. Several of OnKure's current patent applications relate to and include composition of matter claims for OKI-219. Three of the families which are at the PCT application stage also have a Taiwanese ("TW") application. The US provisional applications secure an early filing date and provide an additional twelve months of patent protection beyond the normal 20 year lifetime of any patent granted thereon. The PCT applications are single application placeholders for filings in a majority of the countries and geographic regions of the world. The types of claims for each application are listed and an expiration year for each family based on the actual or projected PCT filing dates is also provided.

Family 1: PCT and TW applications/product and method of treatment claims/2043 expiration

Family 2: PCT and TW applications/product and method of treatment claims/2043 expiration

Family 3: PCT application/product and method of treatment claims/2043 expiration

Family 4: PCT and TW applications/product and method of treatment claims/2043 expiration

Family 5: 2 USP applications/product and method of treatment claims/2044 expiration

Family 6: USP application/product and method of treatment claims/2045 expiration

Family 7: USP application/product and method of treatment claims/2045 expiration

Family 8: USP application/product and method of treatment claims/2045 expiration

Family 9: USP application/product and method of treatment claims/2045 expiration

Family 10: USP application/product and method of treatment claims/2045 expiration

Family 11: USP application/product and method of treatment claims/2045 expiration

OnKure cannot guarantee that its owned pending patent applications, or any patent applications that it may in the future file or license from third parties, will result in the issuance of patents. OnKure also cannot predict the scope of claims that may be allowed or enforced in its patents. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, OnKure may not obtain or maintain adequate patent protection for any of its programs and product candidates.

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The terms of individual patents depend upon the legal terms of the patents in the countries in which they are obtained. In most countries in which OnKure files, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. Similar provisions are available in Europe and other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when its products receive FDA approval, OnKure expects to apply for patent term extensions on patents covering those products. OnKure also plans to seek patent term extensions on any of its issued patents in any jurisdiction where available, but there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with OnKure's assessment of whether such extensions should be granted, and if granted, the length of such extensions.

In addition to patent protection, OnKure also relies on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain its competitive position. OnKure protects and maintains the confidentiality of proprietary information to protect aspects of its business that are not amenable to, or that it does not consider appropriate for, patent protection. Although OnKure takes steps to protect its proprietary information and trade secrets, including through contractual means with its employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to OnKure's trade secrets or disclose its technology. Therefore, OnKure may not be able to meaningfully protect its trade secrets. It is OnKure's policy to require its employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with it. These agreements provide that all confidential information concerning OnKure's business or financial affairs developed or made known to the individual during the course of the individual's relationship with OnKure is to be kept confidential and not disclosed to third parties except in specific circumstances. OnKure's agreements with employees also provide that all inventions conceived by the employee in the course of employment or from the employee's use of OnKure's confidential information are OnKure's exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and OnKure may not have adequate remedies for any such breach.

The patent positions of biotechnology companies like OnKure are generally uncertain and involve complex legal, scientific and factual questions. OnKure's commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require OnKure to alter its development or commercial strategies, alter its products or processes, obtain licenses or cease certain activities. OnKure's breach of any license agreements or its failure to obtain a license to proprietary rights required to develop or commercialize its future products may have a material adverse impact on OnKure. If third parties prepare and file patent applications in the United States that also claim technology to which OnKure has rights, OnKure may have to participate in derivation proceedings in the USPTO to determine priority of invention. For more information, see the section entitled "*Risk Factors—Risks Related to OnKure—Risks Related to OnKure's Intellectual Property.*"

### **Government Regulation**

OnKure's product candidates and its operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in other countries.

The FDA and other federal, state, local and foreign authorities regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and combination products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.



### ***U.S. Drug Development***

In the United States, the FDA regulates drugs under the Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations. Drug products and substances are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on OnKure.

OnKure’s current product candidates and any future small molecule product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process generally involves the following:

completion of extensive preclinical studies in accordance with applicable regulations, including the FDA’s good laboratory practice (“GLP”) requirements;

- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- approval by an IRB or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related regulations to establish the safety and efficacy of an investigational product for each proposed indication;
- preparation and submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug product will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug identity, strength, quality, and purity;
- potential FDA audit of the preclinical study and/or clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS, and the potential requirement to conduct post-approval studies.

### ***Preclinical and Clinical Studies***

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and OnKure cannot be certain that any approvals for any future product candidates will be granted on a timely basis, or at all. Preclinical tests generally involve laboratory evaluations of drug chemistry, formulation, and stability, as well as studies to evaluate toxicity in animals, including pharmacology, pharmacokinetics, toxicokinetic, and metabolism studies that support subsequent clinical testing in humans. The results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, are submitted to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin.



Long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

The central focus of an IND submission is the general investigation plan and the protocol(s) for human studies. An IND must become effective before clinical trials may begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

For each successive clinical trial conducted with the investigational drug, a separate, new protocol submission to an existing IND must be made, along with any subsequent changes to the investigational plan. Sponsors are also subject to ongoing reporting requirements, including submission of IND safety reports for any serious adverse experiences associated with use of the investigational drug or findings from preclinical studies suggesting a significant risk for human subjects, as well as IND annual reports on the progress of the investigations conducted under the IND.

Clinical studies involve the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND.

Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries, including the website maintained by the U.S. National Institutes of Health, [ClinicalTrials.gov](http://ClinicalTrials.gov).

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA. The FDA will generally accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials in the United States generally are conducted in three phases, known as Phase 1, Phase 2 and Phase 3. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate.
- The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug.
- Phase 2 clinical trials typically involve studies in a limited population of disease-affected patients to determine possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to evaluate the effectiveness of the product for its intended use, its safety in use and to establish the

overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check-points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal safety studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of OnKure's product candidates. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that OnKure's product candidates do not undergo unacceptable deterioration over their labeled shelf life.

### ***NDA Review***

Following completion of clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry and manufacturing information in a request for approval to market the drug for one or more specified indications. The application must include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA must be obtained before a drug may be marketed in the United States.

Under the Prescription Drug User Fee Act, as amended (the "PDUFA"), each NDA must be accompanied by an application user fee. FDA adjusts the PDUFA user fees on an annual basis. The PDUFA also imposes an annual program fee for each marketed human drug. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a qualifying small business.

The FDA reviews all submitted NDAs before it accepts them for filing to determine if they are sufficiently complete to permit a substantive review, and the FDA may request additional information rather than accepting the NDA for filing. In this event, the application must be resubmitted with the additional information and is subject to payment of additional user fees. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. Under the PDUFA, the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, standard review and priority review. According to the PDUFA performance goals, the FDA endeavors to review applications subject to standard review within ten months, whereas the FDA's goal is to review priority review applications within six months. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

The FDA may refer applications for novel drug products or products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions.

Before approving an NDA, the FDA typically will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. The FDA also closely analyzes the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA and conducts inspections of manufacturing facilities, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data, including the potential requirement to conduct additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, or to conduct additional preclinical studies or manufacturing changes. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than OnKure interprets the same data.

#### ***Expedited Development and Review Programs***

The FDA has a fast-track program that is intended to expedite or facilitate the process of reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast-track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast-track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast-track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting with the FDA. Any product submitted to the FDA for marketing, including under a fast-track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, such product must demonstrate

an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”), which endpoint is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. FDA may withdraw drug approval or require changes to the labeled indication of the drug if confirmatory post-market trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product. The Food and Drug Omnibus Reform Act made several changes to the FDA’s authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

Additionally, a drug may be eligible for designation as a breakthrough therapy if (a) the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and (b) preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast-track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast-track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

### ***Post-Approval Requirements***

Following approval of a new product, the product is subject to continuing regulation by the FDA, including, among other things, requirements relating to facility registration and drug listing monitoring and record-keeping adverse event and other periodic reporting, product sampling and distribution, and product promotion and advertising. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication.

After approval, if there are any changes to the approved product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved NDA. In addition, quality control, drug manufacture, packaging, and labeling products must continue to conform to cGMP requirements after approval. OnKure relies, and expects to continue to rely, on third parties for the production of clinical and commercial quantities of its products in accordance with cGMP regulations. Manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, its manufacturer or the NDA holder, including recalls.

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The FDA may also place other conditions on approvals including the requirement for a REMS, to assure the safe use of the product. If the FDA concludes that a REMS is needed, the NDA sponsor must submit a proposed REMS. The FDA will not approve the product without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

The FDA may withdraw approval of a product if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Corrective action could delay drug distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- mandated modifications of promotional materials and labeling and the issuance of corrective information;
- issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

OnKure also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling, known as "off-label use," industry-sponsored scientific and educational activities, and promotional activities involving the internet and social media.

The FDA may also require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

Failure to comply with the applicable regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant or manufacturer to, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

### ***U.S. Patent-Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of OnKure's U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. Application for patent extension must be filed with the USPTO within 60 days of FDA approval of the drug product even if the product cannot be commercially marketed at that time.

The patent term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of the NDA application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, OnKure may apply for restoration of patent term for its currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Such three-year and five-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

### **Other U.S. Regulatory Matters**

OnKure's current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which OnKure researches, as well as, sells, markets, and distributes any products for which it obtains marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect OnKure's ability to operate include, but are not limited to the following:

- The AKS, which makes it illegal for any person, including a prescription drug or medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the ACA provides that the

government may assert that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the FCA.

- The federal false claims, including the civil FCA that can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, and/or impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct.
- HIPAA prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.
- HIPAA also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain health care providers and their respective business associates and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the CMS information regarding certain payments and other transfers of value to 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.
- The FCPA prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring OnKure to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations; and analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and foreign laws that govern the privacy and security of health information in some circumstances (such as Washington's My Health, My Data Act, which, among other things, provides for a private right of action), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical and/or medical device products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical



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and/or medical device products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act of 1970 as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

### ***Coverage and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which OnKure may seek regulatory approval. Sales in the United States will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which OnKure's customers seek reimbursement for its product candidates can be subject to challenge, reduction or denial by third-party payors.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product OnKure develops may not be possible.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, OnKure may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider OnKure's product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable OnKure to maintain price levels sufficient to realize an appropriate return on its investment in drug development.

In most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of OnKure's products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. For more information, see the section entitled "*Risk Factors—Risks Related to OnKure—OnKure 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 its business and results of operations.*"



## ***Healthcare Reform***

In the United States, there has been, and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect the profitable sale of product candidates. Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

The ACA, among other things: (1) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; (2) created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (3) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in certain government healthcare programs; (4) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (5) expanded the eligibility criteria for Medicaid programs; (6) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; (7) created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and (8) established a Center for Medicare Innovation at the CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period in 2021 for purposes of obtaining health insurance coverage through the ACA marketplace.

This executive order also instructs certain governmental agencies to review existing policies and rules that limit access to health insurance coverage through Medicaid or the ACA, among others. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and healthcare measures promulgated by the Biden administration will impact the ACA, OnKure's business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on OnKure's business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032, unless additional congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for OnKure's drugs, if approved, and accordingly, its financial operations.

Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. For example, the American Rescue Plan Act of 2021 eliminated the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on OnKure's business. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax 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, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges and other legislative, executive and administrative actions of the government on OnKure and the pharmaceutical industry as a whole is unclear.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase OnKure's compliance burdens and expose us to greater liability under such state laws once OnKure begins commercialization after obtaining regulatory approval for any of OnKure's products. Further, the FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. OnKure expects 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 OnKure's drug candidates or additional pricing pressures. OnKure is unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. If OnKure or any third parties it may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if OnKure or such third parties are not able to maintain regulatory compliance, OnKure's product candidates may lose regulatory approval that may have been obtained and OnKure may not achieve or sustain profitability.

### ***Foreign Regulation***

In addition to regulations in the United States, OnKure will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of its product candidates to the extent OnKure chooses to develop or sell any product candidates outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

### **Employees and Human Capital Resources**

As of October 17, 2024, OnKure had 47 employees, 35 of whom were engaged in research and development activities. OnKure also engages contractors and consultants. None of its employees are represented by a labor

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union or covered under a collective bargaining agreement. OnKure has not experienced any work stoppages due to employee disputes, and it considers its relationship with its employees to be good.

OnKure's human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating its existing and new employees, advisors and consultants. The principal purposes of its equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of OnKure by motivating such individuals to perform to the best of their abilities and achieve OnKure's objectives.

### **Facilities**

OnKure's corporate headquarters is located in Boulder, Colorado, and consists of office and laboratory space pursuant to a lease that expires in December 2026.

OnKure leases all of its facilities and does not own any real property. OnKure believes that its existing facilities are adequate and suitable for its current needs and that, should it be needed, suitable additional or alternative space will be available as and when needed.

### **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 PIPE 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 PIPE 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 PIPE Financing. Absent new or significantly different allegations, the Company will not necessarily disclose such additional filings.

#### *Other Proceedings*

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

**MANAGEMENT****Executive Officers and Directors**

The following table sets forth the names, ages, and positions of our executive officers and members of our board of directors (the “Board”) as of October 1, 2024:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
<b><i>Executive Officers</i></b>		
Nicholas A. Saccomano, Ph.D.	65	President and Chief Executive Officer
Jason Leverone, C.P.A.	51	Chief Financial Officer
Samuel Agresta, M.D.	51	Chief Medical Officer
Dylan Hartley, Ph.D.	56	Chief Scientific Officer
<b><i>Non-Employee Directors</i></b>		
Isaac Manke, Ph.D.	47	Director
R. Michael Carruthers	67	Director
Andrew Phillips, Ph.D.	53	Chairman of the Board of Directors
Valerie M. Jansen	47	Director
Michael Grey	71	Director
Edward T. Mathers	64	Director

***Executive Officers***

**Nicholas Saccomano, Ph.D.** has served as our Chief Executive Officer and President since the closing of the Merger. He previously served as Legacy OnKure’s Chief Executive Officer since September 2023, as President since May 2024, and as a member of the Legacy OnKure board of directors since March 2021. Dr. Saccomano has over 30 years of experience in pharmaceutical and biotechnology research and development, with expertise in discovery research, clinical development, portfolio strategy, technology and clinical candidate licensing, and scientific partnering. Prior to joining Legacy OnKure, he was the Chief Science Officer at Pfizer Inc.’s Boulder facility from August 2019 to January 2022, the Chief Scientific Officer at Array BioPharma Inc. from May 2014 to August 2019, and the Chief Technology Officer at SomaLogic from July 2009 to May 2014. Dr. Saccomano currently serves on the board of directors of Latigo Biotherapeutics, Inc. and BioLoomics, Inc. Dr. Saccomano holds a B.S. from the State University of New York at Buffalo and a Ph.D. in organic chemistry from Columbia University. OnKure believes Dr. Saccomano is qualified to serve on our Board because of his role as OnKure’s President and Chief Executive Officer and his extensive leadership and operational experience within the pharmaceutical and biotech industries.

**Jason Leverone, C.P.A.** has served as our Chief Financial Officer since the closing of the Merger. He previously served as Legacy OnKure’s Chief Financial Officer since January 2022. Prior to joining Legacy OnKure, Mr. Leverone was the Chief Financial Officer and Secretary of Viridian Therapeutics (NASDAQ: VRDN, which became a publicly-traded company via a reverse merger with miRagen Therapeutics, Inc. in October 2020) from November 2008 to May 2021, and Senior Director of Finance and Controller of Replidyne, Inc., a publicly-traded biotechnology company, from November 2005 to February 2009. He began his professional career in public accounting at Ernst & Young LLP and continued with Arthur Andersen LLP. Mr. Leverone is a Certified Public Accountant and holds a B.S. in business administration from Bryant University.

**Samuel Agresta, M.D.** has served as our Chief Medical Officer since the closing of the Merger. He previously served as Legacy OnKure’s Chief Medical Officer since February 2024. Prior to joining Legacy OnKure, he was Chief Medical Officer at Foghorn Therapeutics Inc. from September 2019 to September 2023, Director and Chief Medical Officer at Infinity Pharmaceuticals, Inc. from August 2018 to August 2019, and Vice President and Head of Clinical Development at Agios Pharmaceuticals Inc. from December 2011 to August

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2018. Dr. Agresta holds a B.S. from Georgetown University, an M.P.H. and T.M. from Tulane School of Public Health and Tropical Medicine, an M.D. from Tulane University Medical School and an M.S. in clinical investigation from the University of South Florida.

**Dylan Hartley, Ph.D.** has served as our Chief Scientific Officer since the closing of the Merger. He previously served as Legacy OnKure's Chief Scientific Officer since July 2024. Dr. Hartley has over 20 years of experience in drug research and development, including expertise in pharmacology, toxicology, drug metabolism and pharmacokinetics. Most recently, Dr. Hartley served as Vice President, Head of Research at Pfizer, Inc.'s Boulder facility (previously Array BioPharma, Inc. prior to its acquisition by Pfizer, Inc. in 2019) from September 2021 to July 2024. Dr. Hartley held a succession of roles of increasing responsibility at Array BioPharma, Inc. since 2011. He holds a B.A. in biological sciences from the University of Northern Colorado and a Ph.D. in pharmaceutical sciences from the University of Colorado Health Sciences Center.

### *Non-Employee Directors*

**Isaac Manke, Ph.D.** has been a member of the Board since the closing of the Merger and on the OnKure board of directors since March 2021. Dr. Manke has more than 15 years of experience in the life science industry as an investor, research analyst, consultant and scientist. Dr. Manke has served as a General Partner at Acorn Bioventures since April 2020, where he focuses on investing in small cap public and private biotechnology companies. Prior to Acorn, Dr. Manke spent 11 years at New Leaf Venture Partners (NLV) through 2019. In addition to private venture investments, during his time at NLV, he also led the firm's public investment activities. Dr. Manke has been a board member for several biotechnology companies, including Q32 Bio Inc. (NASDAQ: QTTB) since October 2020, True North Therapeutics (acquired by Bioverativ) and Karos Pharmaceuticals (acquired by an undisclosed company). Dr. Manke holds a B.A. in biology and a B.A. in chemistry from Minnesota State University (Moorhead), and a Ph.D. in biophysical chemistry and molecular structure from the Massachusetts Institute of Technology. OnKure believes Dr. Manke is qualified to serve on our Board because of his education and his experience in the life sciences industry and in venture capital.

**Andrew Phillips, Ph.D.** has been a member of the Board since the closing of the Merger and on the OnKure board of directors since March 2021. He was appointed as Chairman in connection with the closing of the Merger. Dr. Phillips has served as President and Chief Executive Officer of Aleksia Therapeutics, Inc., a biotechnology company, and Nexo Therapeutics, Inc., a biotechnology company, since August 2022. Previously, Dr. Phillips served as a Managing Director at Cormorant Asset Management, an investment manager, from August 2020 to August 2022. Dr. Phillips has served as on the board of directors of Enliven Therapeutics, Inc. (NASDAQ: ELVN) since December 2020, and MoonLake Immunotherapeutics, Inc. (NASDAQ: MLTX), since April 2021. He has also served as the Chief Financial Officer of Helix Acquisition Corp. from April 2021 to April 2022, and since June 2021, he has served as Chief Executive Officer of Blossom Bioscience Ltd. From January 2016 to March 2020, Dr. Phillips was with C4 Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on therapeutics for the treatment of cancer and other diseases, where he served as Chief Executive Officer from May 2018 to March 2020, President from September 2016 to May 2018 and Chief Scientific Officer from January 2016 to May 2018. From July 2014 to January 2016, he served as Senior Director, Center for Development of Therapeutics at the Broad Institute, a biomedical and genomic research organization. From June 2010 to January 2015, Dr. Phillips was a Professor of Chemistry at Yale University, and from July 2001 to June 2010, he was Assistant Professor, Associate Professor, and Professor of Chemistry and Biochemistry at the University of Colorado. He holds a B.Sc. in biochemistry and a Ph.D. in chemistry from the University of Canterbury in New Zealand. OnKure believes Dr. Phillips is qualified to serve on our Board because of his extensive experience in the biotechnology industry, his education and his leadership experience as a senior executive.

**R. Michael Carruthers** has been a member of the Board since the closing of the Merger and on the OnKure board of directors since March 2021. Mr. Carruthers has served as the Chief Financial Officer of Edgewise Therapeutics, Inc. (NASDAQ: EWTX), a publicly traded biopharmaceutical company, since September 2020.

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Mr. Carruthers consulted as Chief Financial Officer of OnKure between March 2019 and May 2021, and has served on the board of directors of Elevation Oncology, a targeted cancer treatment company, since May 2021. Mr. Carruthers previously served as Chief Financial Officer of Brickell Biotech, Inc., a clinical-stage pharmaceutical company focused on treatment of skin diseases, from December 2017 to October 2020, and ClinOne, Inc., clinical trial management company, from August 2018 to May 2020. He also served as Interim President of Nivalis Therapeutics, Inc., a clinical-stage pharmaceutical company, from January 2017 to August 2017 and Chief Financial Officer and Secretary from February 2015 to August 2017. From December 1998 to February 2015, he served as Chief Financial Officer of Array BioPharma Inc. Prior to Array, he served as Chief Financial Officer of Sievers Instruments, Inc., a water purification technology company, Treasurer and Controller for the Waukesha division of Dover Corporation, a global manufacturing company, and an accountant with Coopers & Lybrand, LLP. Mr. Carruthers studied accounting at Western Colorado University, and received a B.S. in accounting from the University of Colorado Boulder and a M.B.A. from the University of Chicago. OnKure believes Mr. Carruthers is qualified to serve on our Board because of his experience serving as chief financial officer for publicly traded biopharmaceutical companies and his extensive knowledge of corporate finance and strategic planning.

**Valerie M. Jansen, M.D., Ph.D.**, joined the Board in connection with the closing of the Merger. She has served as the Chief Medical Officer of Elevation Oncology, Inc. since October 2021 and as the Vice President of Clinical Development from April 2021 to October 2021. Prior to that, she served as Executive Medical Director of Mersana Therapeutics from January 2020 to April 2021. Prior to Mersana Therapeutics, Dr. Jansen was employed at Eli Lilly and Company, where she served as Senior Medical Advisor from September 2017 to January 2020. Prior to Eli Lilly, Dr. Jansen was employed at the Vanderbilt University Medical Center from July 2010 to July 2018 serving, most recently, as Adjunct Instructor in Medicine. Dr. Jansen received a B.A. in Chemistry from Maryville College, a Ph.D. in Molecular Sciences from the University of Tennessee Health Science Center and an M.D. from the University of Chicago Pritzker School of Medicine. OnKure believes Dr. Jansen is qualified to serve on our Board because of her experience serving as chief medical officer and other clinical development roles for biopharmaceutical companies.

**Michael Grey** served as Executive Chairman of the Reneo board of directors since December 2017 until stepping down from that position in connection with the closing of the Merger. Mr. Grey previously served as Reneo's Chairman and Chief Executive Officer from September 2014 to December 2017. Mr. Grey has served as the Executive Chairman of the board of the following life science companies: Spruce Biosciences, Inc., a public company, since March 2018, Plexium, Inc., a private company, since August 2020, and Theolytics Ltd., a private company, since November 2023. Additionally, Mr. Grey previously served in the below listed capacities for the following life science companies: Executive Chairman and Chief Executive Officer of Mirum Pharmaceuticals, Inc., a public company, from May 2018 to March 2019, Chief Executive Officer of Amplyx Pharmaceuticals, Inc., a private company, from September 2014 to December 2017 and then as Executive Chairman from January 2018 until April 2020, and as Executive Chairman of Curzion Pharmaceuticals, Inc., a private company, from May 2019 to April 2020. Mr. Grey has served on the board of directors of Mirum Pharmaceuticals, Inc., a public pharmaceutical company, since May 2018. Mr. Grey also previously served on the board of directors of the following publicly-traded life science companies: BioMarin Pharmaceuticals from December 2005 until May 2021, Horizon Therapeutics plc from January 2011 until October 2023, and Mirati Therapeutics Inc. from November 2014 to June 2021. Mr. Grey has also served as a venture partner at Pappas Ventures, a venture capital firm since January 2010. Mr. Grey has more than 45 years of experience in the pharmaceutical and biotechnology industries and has held senior positions at a number of companies, including President and Chief Executive Officer of SGX Pharmaceuticals, Inc. (sold to Lilly in 2008), President and Chief Executive Officer of Trega Biosciences, Inc. (sold to LION Bioscience, Inc. in 2001) and President of BioChem Therapeutic Inc. Prior to these, Mr. Grey served in various roles with Glaxo, Inc., and Glaxo Holdings PLC, culminating in his position as Vice President, Corporate Development and director of international licensing. Mr. Grey received a B.S. in chemistry from the University of Nottingham in the United Kingdom. Reneo believes that Mr. Grey's extensive experience managing and leading both early stage and established companies within the pharmaceutical and biotechnology industries qualify him to serve on our Board.

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**Edward T. Mathers** has served as a member of the Reneo board of directors since December 2017. Mr. Mathers is Partner at New Enterprise Associates, Inc. (NEA), a private venture capital firm focusing on technology and healthcare investments. Mr. Mathers serves on the board of directors of the following publicly-traded life science companies: Trevi Therapeutics, Inc. since July 2012, Inozyme Pharma, Inc. since January 2017, Rhythm Pharmaceuticals, Inc. since March 2015, Synlogic, Inc. since October 2012, and Senti Biosciences, Inc. since July 2016. Mr. Mathers previously served on the board of directors of the following publicly-traded companies: ObsEva SA from November 2015 to June 2023, Mirum Pharmaceuticals, Inc. from November 2018 to September 2022, Akouos, Inc. from October 2017 to December 2022, Liquidia Technologies, Inc. from April 2009 to May 2019, Lumos Pharma, Inc. from January 2014 to March 2020, and Ra Pharmaceuticals, Inc. from February 2010 to April 2020. From 2002 to 2008, Mr. Mathers served as Executive Vice President, Corporate Development and Venture at MedImmune, Inc., a biopharmaceutical company, and led its venture capital subsidiary, MedImmune Ventures, Inc. Before joining MedImmune in 2002, Mr. Mathers was Vice President, Marketing and Corporate Licensing and Acquisitions at Inhale Therapeutic Systems, a biotechnology company. Previously, Mr. Mathers spent 15 years at Glaxo Wellcome, Inc. (GlaxoSmithKline), where he held various sales and marketing positions. Mr. Mathers received a B.S. in Chemistry from North Carolina State University. Reneo believes that Mr. Mathers' experience as a venture capitalist, as an executive and in business development and his experience in serving on the board of directors for several public and private pharmaceutical and life sciences companies qualifies him to serve on our Board.

### **Family Relationships**

There are no family relationships among any of our directors or executive officers.

### **Board of Directors**

Our business and affairs are organized under the direction of the Board. The Board currently consists of seven directors divided into three staggered classes, with one class to be elected at each annual meeting to serve for a three-year term. Andrew Philips serves as Chairman of our Board. The primary responsibilities of the Board are to provide oversight, strategic guidance, counseling and direction to our management. The Board will meet on a regular basis and additionally as required.

In accordance with the terms of the Company's Amended Certificate of Incorporation and the Amended Bylaws, the Board is divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. The members of the classes are divided as follows:

- the Class I directors are Nicholas Saccomano and Isaac Manke, and their terms will expire at the annual meeting of stockholders to be held in 2025;
- the Class II directors are R. Michael Carruthers, Valerie M. Jansen and Edward T. Mathers, and their terms will expire at the annual meeting of stockholders to be held in 2026; and
- the Class III directors are Andrew Phillips and Michael Grey, and their terms will expire at the annual meeting of stockholders to be held in 2027.

### **Committees of the Board**

The Board has three standing committees: an audit committee, a compensation committee and a nominating and corporate governance committee. Each committee operates pursuant to a charter, which is available at [www.investors.onkuretherapeutics.com](http://www.investors.onkuretherapeutics.com). The Board may establish other committees from time to time.

#### *Audit Committee*

The audit committee is responsible for the following activities, among other things:

- select, retain, compensate, evaluate, oversee and, where appropriate, terminate the Company's independent registered public accounting firm;



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- review and approve the scope and plans for the audits and the audit fees and approve all non-audit and tax services to be performed by the independent auditor;
- evaluate the independence and qualifications of the Company's independent registered public accounting firm;
- review our financial statements, and discuss with management and the Company's independent registered public accounting firm the results of the annual audit and the quarterly reviews;
- review and discuss with management and the Company's independent registered public accounting firm the quality and adequacy of our internal controls and our disclosure controls and procedures;
- discuss with management our procedures regarding the presentation of our financial information, and review earnings press releases and guidance;
- oversee the design, implementation and performance of our internal audit function, if any;
- set hiring policies with regard to the hiring of employees and former employees of the Company's independent auditor and oversee compliance with such policies;
- review, approve and monitor related party transactions;
- adopt and oversee procedures to address complaints regarding accounting, internal accounting controls and auditing matters, including confidential, anonymous submissions by our employees of concerns regarding questionable accounting or auditing matters;
- review and discuss with management and the Company's independent auditor the adequacy and effectiveness of our legal, regulatory and ethical compliance programs; and
- review and discuss with management and the Company's independent auditor our guidelines and policies to identify, monitor and address enterprise risks, including the oversight of risks from cybersecurity threats.

The members of the audit committee are R. Michael Carruthers, Andrew Phillips and Isaac Manke. R. Michael Carruthers is the chair of the audit committee and is a financial expert under the rules of the SEC. To qualify as independent to serve on the audit committee, listing standards of Nasdaq and the applicable SEC rules require that a director not accept any consulting, advisory or other compensatory fee from the Company, other than for service as a director, or be an affiliated person of the Company. The composition of the audit committee complies with the applicable requirements of the rules and regulations of Nasdaq and the SEC.

### *Compensation Committee*

The compensation committee is responsible for the following activities, among other things:

- review, approve or make recommendations to the board of directors regarding the compensation for our executive officers, including our chief executive officer;
- review, approve and administer our employee benefit and equity incentive plans;
- establish and review the compensation plans and programs of our employees, and ensure that they are consistent with our general compensation strategy;
- determine or make recommendations to the board of directors regarding non-employee director compensation;
- monitor compliance with any stock ownership guidelines; and
- approve or make recommendations to the board of directors regarding the creation or revision of any clawback policy.



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The members of the compensation committee are Andrew Phillips, Isaac Manke, and Edward T. Mathers. Andrew Phillips is the chair of the compensation committee. Each member of our compensation committee is a “non-employee” director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. The composition of the compensation committee complies with the applicable requirements of the rules and regulations of Nasdaq.

### *Nominating and Corporate Governance Committee*

The nominating and corporate governance committee has responsibility for the following activities, among other things:

- review and assess and make recommendations to the Board regarding desired qualifications, expertise and characteristics sought of Board members;
- identify, evaluate, select or make recommendations to the Board regarding nominees for election to the Board;
- develop policies and procedures for considering stockholder nominees for election to the Board;
- review our succession planning process for our chief executive officer and any other members of our executive management team;
- review and make recommendations to the Board regarding the composition, organization and governance of the Board and its committees;
- review and make recommendations to the Board regarding our corporate governance guidelines and corporate governance framework;
- oversee director orientation for new directors and continuing education for the Board;
- oversee the evaluation of the performance of the Board and its committees;
- review and monitor compliance with our code of business conduct and ethics, and review conflicts of interest of the director and officers other than related party transactions reviewed by the audit committee; and
- administer policies and procedures for communications with the non-management members of the Board.

The members of the nominating and corporate governance committee are Isaac Manke and Valerie M. Jansen. Isaac Manke is the chair of the nominating and corporate governance committee. The composition of the nominating and corporate governance committee meets the requirements for independence under, and complies with, any applicable requirements of the rules and regulations of Nasdaq.

### *Compensation Committee Interlocks and Insider Participation*

Each member of the compensation committee is a “non-employee” director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and is independent within the meaning of the independent director guidelines of Nasdaq. None of our executive officers serves as a member of the Board or compensation committee of any entity that has one or more executive officers who serves on our Board or compensation committee.

### **Non-Employee Director Compensation**

We maintain an outside director compensation policy that is designed to provide a total compensation package that enables us to attract and retain, on a long-term basis, high-caliber directors.

## EXECUTIVE COMPENSATION

To achieve our goals, we have designed, and intend to modify as necessary, our compensation and benefits program to attract, retain, incentivize and reward deeply talented and qualified executives who share our philosophy and desire to work towards achieving these goals.

We believe our compensation program should promote the success of the company and align executive incentives with the long-term interests of our stockholders. As our needs evolve, we intend to continue to evaluate our philosophy and compensation programs as circumstances require.

This section provides an overview of our and Legacy OnKure’s executive compensation programs, including a narrative description of the material factors necessary to understand the information disclosed in the summary compensation table below. This section also sets forth information relating to the compensation earned by Reneo’s named executive officers for the fiscal years ended December 31, 2023 and 2022, as well as certain information regarding equity awards granted to Reneo’s named executive officers that remained outstanding as of December 31, 2023. Unless otherwise indicated, as used in this section, “OnKure,” the “Company,” “we,” “us” and “our” refer to Legacy OnKure prior to the closing of the Merger and OnKure Therapeutics, Inc. after the closing of the Merger. Upon the closing of the Merger, the executive officers of Legacy OnKure became our executive officers.

Legacy OnKure’s named executive officers, consisting of its principal executive officer, former principal executive officer, and the two most highly compensated executive officers (other than Legacy OnKure’s principal executive officer), as of December 31, 2023, each of whom has become an executive officer of the Company (with the exception of Dr. Piscopio and Dr. Winkler), were:

- Nicholas A. Saccomano, Ph.D., President and Chief Executive Officer;
- Anthony D. Piscopio, Ph.D., former President, Chief Executive Officer and Head of Research and Development;
- Jason Leverone, Chief Financial Officer; and
- James Winkler, Ph.D., former Chief Scientific Officer.

For the year ended December 31, 2023, Reneo’s named executive officers were:

- Gregory J. Flesher, President and Chief Executive Officer;
- Alejandro Dorenbaum, M.D., Chief Medical Officer; and
- Ashely F. Hall, J.D., Chief Development Officer.

### Summary Compensation Table for Fiscal 2023

The following table sets forth information regarding the compensation awarded to, earned by or paid to Legacy OnKure’s named executive officers for the fiscal year ended December 31, 2023:

Name and Principal Position	Year	Salary (\$)	Bonus (\$) <sup>(1)</sup>	Stock Awards (\$) <sup>(2)</sup>	Option Awards (\$) <sup>(2)</sup>	All Other Compensation (\$) <sup>(3)</sup>	Total (\$)
Nicholas A. Saccomano, Ph.D. <i>President and Chief Executive Officer</i>	2023	67,709 <sup>(4)</sup>	22,000	86,958	132,185	—	308,852
Anthony D. Piscopio, Ph.D. <i>Former President, Chief Executive Officer &amp; Head of Research and Development</i>	2023	446,250	157,080	1,206,211	112,120	13,320	1,934,981
Jason Leverone, C.P.A. <i>Chief Financial Officer</i>	2023	346,500	91,476	311,684	28,972	13,315	791,947
James Winkler, Ph.D. <i>Former Chief Scientific Officer</i>	2023	364,000	88,704	237,238	22,052	13,320	725,313

(1) The amounts reported represent discretionary bonuses paid in 2023 based upon the achievement of company goals for the year ended December 31, 2023, as determined by the OnKure Board.

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- (2) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the stock option awards granted during 2023, computed in accordance with FASB ASC 718, Compensation—Stock Compensation. The assumptions used in calculating the grant date fair value of the awards disclosed in this column are set forth in Note 6 to the OnKure audited financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the OnKure Class A Common Stock underlying such stock options.
- (3) The amounts reported represent matching contributions under Legacy OnKure’s 401(k) plan.
- (4) The amount reported represents a prorated salary following Dr. Saccomano’s appointment as Chief Executive Officer in September 2023.

The following table presents all of the compensation awarded to, earned by, or paid to Reneo’s named executive officers during the fiscal years indicated below.

Name and Principal Position(s)	Year	Salary	Option Awards (1)	Non-Equity Incentive Plan Compensation (2)	All Other Compensation	Total
Gregory J. Flesher	2023	\$563,942	\$ —	\$ —	\$ 5,762 (3)	\$ 569,704
<i>President and Chief Executive Officer</i>	2022	\$545,000	\$393,000	\$ 245,300	\$ 10,152	\$1,193,452
Alejandro Dorenbaum, M.D.	2023	\$460,471	\$ —	\$ —	\$ 5,758 (3)	\$ 466,229
<i>Chief Medical Officer</i>						
Ashley F. Hall, J.D.	2023	\$441,346	\$ —	\$ —	\$ 5,758 (3)	\$ 447,104
<i>Chief Development Officer</i>	2022	\$420,000	\$163,750	\$ 151,200	\$ 90,354	\$ 825,304

- (1) Represents grant date fair value of stock options granted during the fiscal year indicated above, as computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 Compensation-Stock Compensation (ASC Topic 718), not including any estimates of forfeiture. See Notes 4 and 9 of Reneo’s Notes to Consolidated Financial Statements in Reneo’s Annual Report on Form 10-K filed with the SEC on March 28, 2024 for a discussion of assumptions used in determining the grant date fair value of Reneo’s option awards. Note that amounts reported in this column reflect the accounting cost for these stock options and do not correspond to actual economic value that may be received by the named executive officers from the stock options.
- (2) Represents annual performance-based bonuses earned by Reneo’s named executive officers pursuant to Reneo’s Non-Equity Incentive Compensation Plan for performance. No annual performance-based bonuses were earned for 2023.
- (3) All Other Compensation includes (i) matching contributions under Reneo’s 401(k) plan, (ii) premiums paid for group term life insurance and (iii) fringe benefits paid on behalf Reneo’s named executive officers in 2023.

### Narrative Disclosure to Summary Compensation Table for Fiscal 2023

#### Base Salary

For 2023, Dr. Saccomano’s base salary was \$250,000, Dr. Piscopio’s base salary was \$446,250, Mr. Leverone’s base salary was \$346,500 and Dr. Winkler’s base salary was \$364,000.

#### 2023 Annual Cash Bonuses

Each of Legacy OnKure’s named executive officers was eligible to participate in an annual cash incentive compensation program which provides participants with an opportunity to earn variable cash incentive compensation based on individual and company performance. For 2023, Dr. Saccomano’s target bonus was 40%

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of his base salary, Dr. Piscopio's target bonus was 40% of his base salary, Mr. Leverone's target bonus was 30% of his base salary, and Dr. Winkler's target bonus was 30% of his base salary.

The determination of the 2023 bonus amounts was discretionary based on the legacy OnKure board of directors' assessment of company performance against corporate goals.

The actual annual cash bonuses awarded to each named executive officer for 2023 performance are set forth in the "Bonus" column of Legacy OnKure's Summary Compensation Table for Fiscal 2023 above.

### Outstanding Equity Awards at Fiscal 2023 Year-End

The following table sets forth information regarding outstanding equity awards held by Legacy OnKure's named executive officers as of December 31, 2023.

Name	Grant Date	Option Awards <sup>(1)</sup>				Stock Awards <sup>(1)</sup>	
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$) <sup>(2)</sup>	Option Expiration Date	Number of Shares or Units of Stock that have not Vested (#)	Market Value of Shares or Units of Stock that have not Vested (\$) <sup>(3)</sup>
Nicholas A. Saccomano, Ph.D.	10/19/23					31,469 <sup>(10)</sup>	86,958
	1/11/22	66,666	33,334 <sup>(4)</sup>	0.50	1/10/32		
	8/30/23	10,489	52,449 <sup>(5)</sup>	0.33	8/29/33		
	10/15/23	358,089	358,089 <sup>(6)</sup>	0.33	10/14/33		
Anthony D. Piscopio, Ph.D.	10/15/23	107,426	250,663 <sup>(7)</sup>	0.33	10/14/33		
	10/19/23					436,511 <sup>(10)</sup>	1,206,211
	7/7/21	236,111	41,667 <sup>(8)</sup>	0.50	7/6/31		
Jason Leverone	8/30/23	145,503	727,519 <sup>(5)</sup>	0.33	8/29/33		
	10/19/23					112,794 <sup>(10)</sup>	311,684
	1/11/22	117,395	127,605 <sup>(9)</sup>	0.50	1/10/32		
James Winkler, Ph.D.	8/30/23	37,598	187,991 <sup>(5)</sup>	0.33	8/29//33		
	10/19/23					85,853 <sup>(10)</sup>	237,238
	7/7/21	201,666	18,334 <sup>(8)</sup>	0.50	7/6/31		
	10/11/22	15,277	—	0.58	10/10/32		
	8/30/23	28,617	143,089 <sup>(5)</sup>	0.33	8/29/33		

(1) All of the outstanding stock option awards were granted under and subject to the terms of Legacy OnKure's 2021 Stock Incentive Plan and cover shares of Legacy OnKure Class A Common Stock. All of the outstanding restricted stock unit awards were granted under and subject to the terms of Legacy OnKure's 2023 RSU Equity Incentive Plan (the "2023 RSU Plan") and cover shares of Legacy OnKure Series C Preferred Stock.

(2) The stock option awards were granted with a per share exercise price equal to the fair market value of one share of Legacy OnKure Class A Common Stock on the date of grant, as determined in good faith by the Legacy OnKure board of directors based on third party valuations of Legacy OnKure Class A Common Stock.

(3) This amount reflects the fair market value of Legacy OnKure Series C Preferred Stock of \$2.7633 as of October 28, 2023 (based on the determination of the fair market value by the Legacy OnKure board of directors as of the most proximate date) multiplied by the amount shown in the column for the number of shares or units of stock that have not vested.

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- (4) 1/12th of the shares subject to the award shall vest on each of March 31, June 30, September 30 and December 31, starting on March 31, 2022, subject to the optionee continuing to be a service provider to Legacy OnKure through each such date.
- (5) 1/48th of the shares subject to the award shall vest each month after the Grant Date on the same day of the month, subject to the optionee continuing to be a service provider to Legacy OnKure through each such date. The award also is subject to certain acceleration of vesting provisions as described under “Equity-Based Incentive Awards” below.
- (6) 1/6th of the shares subject to the award shall vest each month starting October 26, 2023 on the same day of the month, subject to the optionee continuing to be a service provider to Legacy OnKure through each such date. The award also is subject to certain acceleration of vesting provisions as described under “Equity-Based Incentive Awards” below.
- (7) 107,426 of the shares subject to the award vested upon determination by the Legacy OnKure board of directors that Legacy OnKure has filed an IND application for OKI-219 on or prior to December 31, 2023; 107,425 of the shares subject to the award were scheduled to vest upon the determination by the Legacy OnKure board of directors that Legacy OnKure hired a Chief Medical Officer; 71,617 shares subject to the award were scheduled to vest upon the determination by the Legacy OnKure board of directors that first patient dose for OKI-219 occurred by March 31, 2024; and 71,620 of the shares subject to the award were scheduled to vest upon the determination by the Legacy OnKure board of directors that Legacy OnKure hired a Chief Executive Officer. The award also is subject to certain acceleration of vesting provisions as described under “Equity-Based Incentive Awards” as described below.
- (8) 1/36th of the shares subject to the award shall vest each month, beginning April 1, 2021, on the same day of the month, subject to the optionee continuing to be a service provider to Legacy OnKure through each such date.
- (9) 25% of the shares subject to the award vested on January 1, 2023, and 1/36th of the remaining shares subject to the award shall vest each month thereafter on the same day of the month, subject to the optionee continuing to be a service provider to Legacy OnKure through each such date.
- (10) 1/16th of the shares subject to the award of restricted stock units shall vest each month beginning on June 20, 2023, subject to the optionee continuing to be a service provider to Legacy OnKure through each such date and, if there is a “Liquidity Event” (as defined in the award agreement) (x) that is a Go-Public Transaction (as defined in the award agreement), then through the 181st day following the Liquidity Event (the Mergers would constitute a Go-Public Transaction under this definition), or (y) that is a “Change in Control” (as defined in the 2023 RSU Plan), through such Liquidity Event. The award also is subject to certain acceleration of vesting provisions as described under “Equity-Based Incentive Awards” below.

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The following table sets forth specified information regarding outstanding stock options held by each of our named executive officers as of December 31, 2023.

Name	Grant Date	Option Awards (1)				Stock Awards (2)	
		Number of Securities Underlying Unexercised Options Vested (#)	Number of Securities Underlying Unexercised Options Unvested (#)	Option Exercise Price Per Share (\$)	Option Expiration Date	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$ (3))
Gregory J. Fleisher <i>President and Chief Executive Officer</i>	12/9/22 (4)	75,000	225,000	\$ 1.80	12/8/32	—	\$ —
	12/10/21 (5)	100,000	100,000	\$ 6.69	12/9/31	—	\$ —
	12/10/21 (6)	—	—	\$ —	—	100,000	\$ 160,000
	1/21/21 (7)	811,415	241,232	\$ 4.88	1/20/31	—	\$ —
Alejandro Dorenbaum, M.D. <i>Chief Medical Officer</i>	12/9/22 (4)	31,250	93,750	\$ 1.80	12/8/32	—	\$ —
	12/10/21 (5)	50,000	50,000	\$ 6.69	12/9/31	—	\$ —
	12/10/21 (8)	—	—	\$ —	—	30,000	\$ 48,000
	1/21/21 (9)	75,422	25,141	\$ 4.88	1/20/31	—	\$ —
	6/26/19 (9)	41,119	—	\$ 3.76	6/25/29	—	\$ —
	4/5/18 (7)	15,033	—	\$ 1.97	4/4/28	—	\$ —
Ashley F. Hall, J.D. <i>Chief Development Officer</i>	12/9/22 (4)	15,625	93,750	\$ 1.80	12/8/32	—	\$ —
	11/12/21 (7)	97,500	82,500	\$ 8.85	11/11/31	—	\$ —
	11/12/21 (10)	—	—	\$ —	—	30,000	\$ 48,000

- (1) All of the option awards were granted under Reneo's 2014 Equity Incentive Plan, as amended, or under Reneo's 2021 Equity Incentive Plan.
- (2) All of the stock awards were granted under Reneo's 2021 Equity Incentive Plan
- (3) The market value of the award is calculated using Reneo's closing price of common stock on the last trading day of its 2023 fiscal year (December 29, 2023), which was \$1.60 multiplied by the number of shares subject to the award.
- (4) Vests in equal quarterly installments over four years following the grant date.
- (5) Vests in equal monthly installments over four years following the grant date.
- (6) Restricted stock units (RSUs) will vest upon the date that the closing price of Reneo's common stock has remained above \$20 per share, as adjusted for stock splits, combinations, and the like, for 30 consecutive trading days.
- (7) Vests 25% on first anniversary date of employment commencement date with the remainder vesting monthly over three years thereafter. Mr. Fleisher's employment commenced on November 2, 2020, Dr. Dorenbaum's employment commenced on January 1, 2018, and Ms. Hall's employment commenced on October 11, 2021.
- (8) RSUs vest at 50% upon the first acceptance by the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) of a New Drug Application (NDA) or Marketing Authorization Application (MAA) filed by Reneo, respectively, and 50% upon the first approval by the FDA or EMA of an NDA or MAA, respectively.
- (9) Vests 25% on first anniversary date of the vesting commencement date with the remainder vesting monthly over three years thereafter.
- (10) RSUs vest at 100% upon the first acceptance by the FDA or EMA of an NDA or MAA filed by Reneo, respectively.

## **Employment Arrangements with OnKure’s Named Executive Officers**

The Legacy OnKure board of directors and the Reneo board of directors approved and we entered into a New Employment Agreement with each of Dr. Saccomano and Mr. Leverone, relating to their continued employment with OnKure and as executive officers following the closing of the Merger.

Each New Employment Agreement provides for continued employment as an executive officer of the Combined Company on an at-will basis and include terms for base salary, benefits, target annual bonus opportunities and eligibility to participate the benefit plans. Dr. Saccomano’s New Employment Agreement provides for a base salary of \$600,000 and a target annual bonus opportunity of 55% of his base salary (\$330,000) and Mr. Leverone’s New Employment Agreement provides for a base salary to \$444,000 and a target annual bonus opportunity of 40% of his base salary (\$177,600). Additionally, each New Employment Agreement provides for certain change in control and severance benefits described below.

Each of our named executive officers has executed our standard form of confidential information, invention assignment and arbitration agreement.

## **Equity-Based Incentive Awards**

In connection with Dr. Saccomano’s transition from interim chief executive officer to full-time chief executive officer, the performance stock option granted to Dr. Saccomano on October 15, 2023 and described in footnote 7 of the *Outstanding Equity Awards at Fiscal 2023 Year-End* table above, was amended such that applicable service requirements conditioned on Dr. Saccomano’s service as interim chief executive officer would be satisfied by service as full-time chief executive officer after the effective date of such transition.

Certain equity grants held by our named executive officers are subject to acceleration of vesting provisions:

Dr. Saccomano was granted a stock option in January 2022 covering 100,000 shares of Legacy OnKure Class A Common Stock which will accelerate vesting in full immediately prior to the occurrence of a Corporate Transaction (as defined in Legacy OnKure’s 2021 Stock Incentive Plan and which the Merger constituted).

Each stock option to purchase shares of Legacy OnKure Class A Common Stock granted to our named executive officers in August 2023 and to Dr. Saccomano in October 2023, and each award of restricted stock units covering shares of Legacy OnKure’s Series C Preferred Stock granted to our named executive officers in October 2023 provides that, if during the period beginning three months prior to through (and inclusive of) the date 12 months following a “change in control” (as defined in the 2023 RSU Plan for the restricted stock units, and in the award agreement for the options; the Merger did not constitute a change in control for purposes of these awards), the named executive officer’s service provider status is terminated by Legacy OnKure or its successor without “cause” (as defined in the applicable award agreement) (and excluding by reason of the named executive officer’s death or disability (as defined in the applicable equity plan), or by the named executive officer for “good reason” (as defined in the applicable award agreement), 100% of the then-unvested options or restricted stock units under the award will immediately vest. In addition, in the event there is a “corporate transaction” (as defined in Legacy OnKure’s 2021 Stock Incentive Plan), if the successor does not assume or substitute for these options, they will vest in full. Similarly, as described below in more detail, in the event there is a merger or change in control, if a successor does not assume or substitute for these restricted stock units, they will vest in full.

For the purpose of the above stock options granted to our named executive officers in August 2023 and Dr. Saccomano’s October 2023 stock options and the October 2023 restricted stock units granted to our named executive officers, “cause” generally means any one or more of the following: (i) the named executive officer’s gross negligence or willful misconduct; (ii) the named executive officer’s conviction of, or plea of *nolo contendere* to, a felony or any crime involving fraud, embezzlement or any other act of moral turpitude, or of any

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crime that causes or is reasonably likely to cause significant harm, including (but not limited to) significant reputational, economic or operational harm, to OnKure or any or successor or, for the stock options, affiliate of Legacy OnKure and for the restricted stock units, parent or subsidiary of Legacy OnKure or its successor (“Harm”); (iii) an act of dishonesty made by the named executive officer in connection with such named executive officer’s responsibilities as a service provider that causes or is reasonably likely to cause Harm, or an act of fraud, embezzlement or misappropriation with respect to Legacy OnKure or employing successor or employing or, for the stock options, affiliate of Legacy OnKure and for the restricted stock units, parent or subsidiary of Legacy OnKure or its successor, (iv) the named executive officer’s unauthorized use or disclosure of any proprietary information or trade secrets of Legacy OnKure or any other party to whom such named executive officer owes an obligation of nondisclosure as a result of such named executive officer’s relationship with Legacy OnKure or employing successor or employing for the stock options, affiliate of Legacy OnKure and for the restricted stock units, parent or subsidiary of Legacy OnKure or its successor, which use or disclosure causes or is reasonably likely to cause Harm; (v) the named executive officer’s willful breach of any obligations under any material written agreement or covenant with Legacy OnKure or any or for the stock options, affiliate of Legacy OnKure and for the restricted stock units, parent or subsidiary of Legacy OnKure or its successor; (vi) a material failure or material violation by the named executive officer to comply with any of Legacy OnKure’s or an employing successor or for the stock options, affiliate of Legacy OnKure and for the restricted stock units, parent or subsidiary of Legacy OnKure or its successor’s material written policies or rules that have been provided to named executive officer; (vii) the named executive officer’s continued failure to perform such named executive officer’s employment duties (other than due to disability) after such named executive officer has received a written demand of performance from Legacy OnKure which specifically sets forth the factual basis for Legacy OnKure’s belief that the named executive officer has not substantially performed such named executive officer’s duties and after the named executive officer has failed to cure such non-performance to Legacy OnKure’s reasonable satisfaction within 10 business days after receiving such notice; provided, however, that in any given 12 month period, the named executive officer will have no more than one opportunity to cure a failure to perform under this clause (vii); or (viii) the named executive officer’s failure to cooperate in good faith with a governmental or internal investigation of Legacy OnKure or its directors, officers or employees, if Legacy OnKure has requested such named executive officer’s cooperation.

For the purpose of the above stock options and restricted stock units, “good reason” generally means the termination of the named executive officer’s status as a service provider by such named executive officer in accordance with the next sentence after the occurrence of one or more of the following events without named executive officer’s express written consent: (i) a material reduction of the named executive officer’s base salary, unless such reduction is part of a generalized salary reduction affecting similarly situated employees (provided that a reduction of ten percent (10)% or less in any one calendar year will not be deemed material); (ii) a material reduction of the named executive officer’s authority, duties or responsibilities as an employee relative to such authority, duties or responsibilities in effect immediately prior to such reduction (provided that such named executive officer’s authority, duties and responsibilities will not be deemed to be materially reduced if the named executive officer has reasonably comparable authority, duties and responsibilities as an employee with respect to OnKure’s business following a change in control, regardless of any change in title or whether such named executive officer subsequently provides services to a subsidiary, affiliate, business unit, division or otherwise); or (iii) a material change in the principal geographic location at which the named executive officer must perform services for OnKure (provided that such named executive officer’s relocation to a facility or a location that would not increase the named executive officer’s one-way commute distance by more than 35 miles from such named executive officer’s then-principal residence will not be considered a material change in geographic location). In order for the termination of the named executive officer’s status as a service provider to be for “good reason,” the named executive officer must not terminate status as a service provider without first providing written notice to OnKure of the acts or omissions constituting the grounds for “good reason” within 90 days of the initial existence of the grounds for “good reason” and a cure period of 30 days following the date of written notice (the “Cure Period”), the grounds must not have been cured during that time, and named executive officer must terminate status as a service provider within 30 days following the Cure Period.



### **Recent Grants**

On October 4, 2024, in connection with the closing of the Merger, each of Dr. Saccomano, Dr. Agresta, Mr. Leverone and Dr. Hartley was granted an option to purchase a number of shares of Class A Common Stock as follows: 542,232 shares for Dr. Saccomano; 131,395 shares for Dr. Agresta; 130,611 shares for Mr. Leverone; and 137,602 shares for Dr. Hartley. The option awards granted to Dr. Saccomano, Dr. Agresta, and Mr. Leverone are scheduled to vest as to 1/36th of the shares subject to the award on a monthly basis following the award's grant date, in each case subject to continued services through the applicable vesting date. The option award granted to Dr. Hartley is scheduled to vest as to 1/4th of the shares subject to the award on June 9, 2025, and 1/48th of the shares subject to the award on a monthly basis thereafter, in each case subject to continued services through the applicable vesting date. Each such option award was granted under the 2024 Plan and is subject to the terms and conditions of such plan and an option award agreement thereunder.

### **Potential Payments upon Termination or Change of Control**

As described above, we entered into New Employment Agreements with certain eligible employees, including Dr. Saccomano and Mr. Leverone, related to their continued employment with the Combined Company and as executive officers of the Combined Company, which are expected to provide for certain change-in-control and severance benefits.

The New Employment Agreements entered into with each of Dr. Saccomano and Mr. Leverone provide that if, other than during the CIC Period, Dr. Saccomano's or Mr. Leverone's employment, as applicable, with us is terminated either (x) by us without "cause" (as defined in the New Employment Agreement, and excluding by reason of his death or "disability" (as defined in the New Employment Agreement)) or (y) by Dr. Saccomano or Mr. Leverone, as applicable, for "good reason" (as defined in the New Employment Agreement), then he will receive the following severance payments and benefits if he timely executes and does not revoke a separation agreement and release of claims in our favor:

- A lump sum cash payment equal to 100% of his base salary as in effect immediately before such termination; and
- OnKure Group payment of the premiums required for continued coverage pursuant to COBRA under the OnKure Group's group health, dental and vision care plans for the named executive officer and his eligible dependents for up to 12 months.

If, during the CIC Period, Dr. Saccomano's or Mr. Leverone's employment, as applicable, with us is terminated either (x) by us without cause or (y) by Dr. Saccomano or Mr. Leverone, as applicable, for good reason, he will receive the following severance payments and benefits if he timely executes and does not revoke a separation agreement and release of claims in our favor:

- A lump sum cash payment equal to 100% for Mr. Leverone or 150% for Dr. Saccomano of his base salary as in effect immediately before such termination, or if greater, the base salary in effect immediately before the change in control;
- A lump sum cash payment equal to 100% for Mr. Leverone or 150% for Dr. Saccomano of his target bonus opportunity as in effect immediately before such termination or if greater, the target bonus opportunity in effect immediately before the change in control;
- Our payment of the premiums required for continued coverage pursuant to COBRA under the our group health, dental and vision care plans for the named executive officer and his eligible dependents for up to 12 months for Mr. Leverone or 18 months for Dr. Saccomano; and
- 100% accelerated vesting and exercisability of the outstanding and unvested equity awards (other than equity awards subject to performance-based vesting criteria).

Each New Employment Agreement provides that, if any of the amounts provided for under a New Employment Agreement or otherwise payable to Dr. Saccomano or Mr. Leverone, as applicable, would

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constitute “parachute payments” within the meaning of Section 280G of the Code and could be subject to the related excise tax, Dr. Saccomano or Mr. Leverone, as applicable, would receive (to the extent he entitled to such receipt) either the full payment of benefits under his New Employment Agreement or such lesser amount that would result in no portion of the payments and benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to the named executive officer. The New Employment Agreements do not provide for any tax gross-ups in connection with a change in control.

### **Employee Benefits and Stock Plans**

We believe that performance and equity-based compensation can be an important component of the total executive compensation package for supporting stockholder value creation while, at the same time, attracting, motivating, and retaining high-quality executives. Our 2024 Equity Incentive Plan is an important element of our compensation arrangements for both executive officers and directors.

#### *2011 Stock Incentive Plan*

Legacy OnKure’s 2011 Stock Incentive Plan was adopted by the Legacy OnKure board of directors on October 11, 2011 and approved by Legacy OnKure stockholders on October 11, 2011. The 2011 Stock Incentive Plan provided for the grant of stock options and restricted stock to employees, officers or directors of Legacy OnKure or any affiliate of Legacy OnKure and any consultant or adviser (who is a natural person) providing services to Legacy OnKure or any affiliate of Legacy OnKure, provided that incentive stock options within the meaning of Section 422 of the Code could only be granted to employees of Legacy OnKure or any subsidiary of Legacy OnKure.

At the closing, the Combined Company assumed all outstanding and unexercised stock options granted under the 2011 Stock Incentive Plan. The 2011 Stock Incentive Plan has terminated and we will not grant any additional awards under the plan following its termination. However, the 2011 Stock Incentive Plan continues to govern the terms and conditions of the outstanding awards previously granted under the 2011 Stock Incentive Plan. The material terms of the 2011 Stock Incentive Plan are summarized below.

As of October 4, 2024, stock options covering 221 shares of Class A Common Stock were outstanding under the 2011 Stock Incentive Plan and there were no outstanding awards of restricted stock under the plan.

*Plan Administration.* The 2011 Stock Incentive Plan is administered by our Board. The Board has such powers and authorities related to the administration of the 2011 Stock Incentive Plan as are consistent with our Certificate of Incorporation and Bylaws and applicable law. Our Board has full power and authority to take all actions and to make all determinations required or provided for under the 2011 Stock Incentive Plan or any award agreement, and has full power and authority to take all other actions and make all such other determinations not inconsistent deemed to be necessary or appropriate to the administration of the 2011 Stock Incentive Plan or any award agreement. The interpretation and construction by our Board of any provision of the 2011 Stock Incentive Plan, any award or any award agreement shall be final, binding and conclusive.

Specifically, subject to the terms of the 2011 Stock Incentive Plan, without limitation, our Board has the power to determine who will be granted awards and the type and amount of any such awards, to establish the terms and conditions of each awards, adopt forms of award agreements and amend, modify or supplement outstanding awards, provided that no amendment, modification or supplement will impair a grantee’s right without consent. Additionally our Board may permit or require the deferral of any award into a deferred compensation arrangement, subject to such rules and procedures it may establish.

Our Board may delegate administrative powers and authorities to a committee of directors. Unless otherwise expressly determined by our Board, any action or determination by such a committee (for which our Board has delegated authority) is final, binding and conclusive. Our Board and any such designated committee is referred to as the “administrator” for purposes of this plan description.

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We may have retained the right to clawback gain realized by a grantee on account of violations or breaches or an applicable employment agreement or certain restrictive covenants. Additionally, we may cancel any award if a grantee's employment is terminated for cause.

*Stock Options.* The 2011 Stock Incentive Plan permitted the grant of stock options. Incentive stock options could be granted only to our employees. Each stock option was designated in an option agreement as either an incentive stock option or a nonstatutory stock option.

The term of each stock option is the term stated in the applicable option agreement; provided that no term is more than 10 years from the date of grant. In the case of an incentive stock option granted to a person who at the time of such grant owned more than 10% of the voting power of all classes of outstanding capital stock, the term of the stock option is no more than five years from the date of grant.

The per share exercise price of options granted under the 2011 Stock Incentive Plan was set at price determined by the administrator that is set forth in the applicable option agreement, but is not less than the fair market value of an underlying share on the date of grant. In the case of incentive stock options granted to an employee who at the time of grant, owned more than 10% of the voting power of all classes of outstanding our capital stock, the exercise price must have equaled at least 110% of the fair market value of an underlying share on the date of grant.

The material terms of an option granted under the 2011 Stock Incentive Plan are stated in the applicable award agreement, including the terms of vesting and exercisability, method of exercise, acceptable forms of consideration for payment of applicable exercise prices and tax withholding and treatment of options following a grantee's termination of service. Options must be exercised as to the lesser of 100 shares or the lesser number of shares set forth in an option agreement. The form of option agreement under the 2011 Stock Incentive Plan generally provides that options will remain outstanding for 12 months following termination of a grantee's service by reason of death or disability or otherwise 90 days following termination of a grantee's service, provided that options will immediately terminate on a grantee's termination of service for cause (as defined in the 2011 Stock Incentive Plan).

Unless otherwise provided in an award agreement, option holders do not have shareholder rights (including the right to receive distributions or dividends or voting rights) until the underlying shares are fully paid and issued. No adjustments will be made for dividends, distribution or other rights for which the record date is prior to the date of such issuance.

*Non-Transferability of Awards.* Except in the limited case of certain family transfers described in the 2011 Stock Incentive Plan, during the lifetime of a grantee, only the grantee (or, in the event of legal incapacity or incompetency, the grantee's guardian or legal representative) may exercise an option and no option is assignable or transferable by the grantee other than by will or the laws of descent and distribution. Restricted stock could not be sold, transferred, assigned, pledged or otherwise encumbered or disposed of during the restricted period or prior to the satisfaction of any other restrictions prescribed by the administrator.

*Certain Adjustments.* In the event of any recapitalization, reclassification, stock split, reverse split, combination of shares, exchange of shares, stock dividend or other distribution payable in capital stock, or other increase or decrease in such shares effected without receipt of consideration by the Company, the number and kinds of shares subject to outstanding awards and the exercise price of outstanding awards will be adjusted proportionately. In the event of any distribution to our stockholders of securities of any other entity or other assets (including an extraordinary dividend but excluding a non-extraordinary dividend) without receipt of consideration by the Company, we will appropriately adjust the number and kind of shares subject to outstanding awards and the exercise price of outstanding options.

*Corporate Transaction.* In the event of (i) the dissolution or liquidation of the Company or a merger, consolidation, or reorganization of the Company with one or more other entities in which the Company is not the

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surviving entity, (ii) a sale of substantially all of the assets of the Company to another person or entity, or (iii) any transaction which results in any person or entity owning 50% or more of the combined voting power of all classes of our capital stock (a “Corporate Transaction”), the administrator may determine (x) that options become immediately exercisable for a period of 15 days prior to the consummation of the Corporate Transaction, and/or (y) awards will be cancelled in exchange for cash or securities with a value equal to the per share consideration paid to our stockholders in the transaction, multiplied by the shares subject to such award, less any applicable exercise price. Any unexercised options will terminate upon the consummation of a Corporate Transaction.

*Amendment and Termination.* The Board may amend the 2011 Stock Incentive Plan as to any shares as to which grants have not been made. An amendment to the 2011 Stock Incentive Plan will only be contingent on approval of our stockholders to the extent required by applicable law, regulations or rules. No amendment, suspension, or termination of the 2011 Stock Incentive Plan will materially alter or impair rights or obligations under any grant without the consent of the applicable grantee. As noted above, the 2011 Stock Incentive Plan has terminated, and we will not grant any additional awards under the plan. However, the 2011 Stock Incentive Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2011 Stock Incentive Plan.

### *2021 Stock Incentive Plan*

Legacy OnKure’s 2021 Stock Incentive Plan was adopted by the Legacy OnKure Board on February 26, 2021 and approved by Legacy OnKure stockholders on March 1, 2021. The 2021 Stock Incentive Plan provides for the grant of stock options and restricted stock to employees, officers or directors of Legacy OnKure or any affiliate of Legacy OnKure and any consultant or adviser (who is a natural person) currently providing services to Legacy OnKure or any affiliate of Legacy OnKure, provided that incentive stock options within the meaning of Section 422 of the Code may only be granted to employees of Legacy OnKure or any subsidiary of OnKure.

Upon the closing of the Merger, the Combined Company assumed all outstanding and unexercised stock options granted under the 2021 Stock Incentive Plan.

In connection with the Closing, the 2021 Stock Incentive Plan was terminated subject to and effective immediately prior to the 2024 Equity Incentive Plan becoming effective, and we will not grant any additional awards under the plan following its termination. However, the 2021 Stock Incentive Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2021 Stock Incentive Plan. The material terms of the 2021 Stock Incentive Plan are summarized below.

As of October 4, 2024, stock options covering 194,694 shares of our Class A Common Stock were outstanding under the 2021 Stock Incentive Plan and there were no outstanding awards of restricted stock under the plan.

*Authorized Shares.* Subject to the adjustment provisions in the 2021 Stock Incentive Plan, the maximum aggregate number of shares that may be issued under the 2021 Stock Incentive Plan is 983,849 shares of Class A Common Stock.

If shares covered by an award are not purchased or are forfeited, or if an award otherwise terminates without delivery of any shares or expires by its terms or is settled in cash, then the number of shares available under the 2021 Stock Incentive Plan with respect to such award will, to the extent of any such forfeiture, termination, expiration or settlement in cash, again be available for grant. If the exercise price of any option granted under the 2021 Stock Incentive Plan is satisfied by tendering shares to the Company, only the net number of shares delivered will count against the share reserve.

*Plan Administration.* The 2021 Stock Incentive Plan is administered by our Board. The Board has such powers and authorities related to the administration of the 2021 Stock Incentive Plan as are consistent with our

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Certificate of Incorporation and Bylaws and applicable law. The Board has full power and authority to take all actions and to make all determinations required or provided for under the 2021 Stock Incentive Plan or any award agreement, and has full power and authority to take all other actions and make all such other determinations not inconsistent deemed to be necessary or appropriate to the administration of the 2021 Stock Incentive Plan or any award agreement. The interpretation and construction by the Board of any provision of the 2021 Stock Incentive Plan, any award or any award agreement is final, binding and conclusive.

Specifically, subject to the terms of the 2021 Stock Incentive Plan, without limitation, the Board has the power to determine who will be granted awards and the type and amount of any such awards, to establish the terms and conditions of each awards, adopt forms of award agreements and amend, modify or supplement outstanding awards, provided that no amendment, modification or supplement will impair a grantee's right without consent. Additionally the Board may permit or require the deferral of any award into a deferred compensation arrangement, subject to such rules and procedures it may establish.

The Board may delegate administrative powers and authorities to a committee of directors. Unless otherwise expressly determined by the Board, any action or determination by such a committee (for which the Board has delegated authority) is final, binding and conclusive. The Board and any such designated committee is referred to as the "administrator" for purposes of this plan description.

We may have retained the right to clawback gain realized by a grantee on account of violations or breaches or an applicable employment agreement or certain restrictive covenants. Additionally, we may cancel any award if a grantee's employment is terminated for cause.

The administrator has the power to modify, extend or renew outstanding options, or cancel options in return for the grant of new options for the same or a different number of shares and at the same or difference exercise price, or in return for a different type of award.

*Stock Options.* The 2021 Stock Incentive Plan permits the grant of stock options. Incentive stock options may be granted only to our employees. Each stock option is designated in an option agreement as either an incentive stock option or a non-statutory stock option.

The term of each stock option is the term stated in the applicable option agreement; provided that the term will be no more than 10 years from the date of grant. In the case of an incentive stock option granted to a person who at the time of such grant owns more than ten percent of the voting power of all classes of outstanding our capital stock, the term of the stock option will be no more than five years from the date of grant.

The per-share exercise price of options granted under the 2021 Stock Incentive Plan is a price determined by the administrator that is set forth in the applicable option agreement, is not less than the fair market value of an underlying share on the date of grant. In the case of incentive stock options granted to an employee who at the time of grant, owns more than 10% of the voting power of all classes of outstanding our capital stock, the exercise price must equal at least 110% of the fair market value of an underlying share on the date of grant.

The material terms of an option granted under the 2021 Stock Incentive Plan are stated in the applicable award agreement, including the terms of vesting and exercisability, method of exercise, acceptable forms of consideration for payment of applicable exercise prices and tax withholding and treatment of options following a grantee's termination of service. The form of option agreement under the 2021 Stock Incentive Plan generally provides that options will remain outstanding for 12 months following termination of a grantee's service by reason of death or disability or otherwise 90 days following termination of a grantee's service, provided that options will immediately terminate on a grantee's termination of service for cause (as defined in the 2021 Stock Incentive Plan).

Unless otherwise provided in an award agreement, optionholders will not have shareholder rights (including the right to receive distributions or dividends or voting rights) until the underlying shares are fully paid and

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issued. No adjustments will be made for dividends, distribution or other rights for which the record date is prior to the date of such issuance.

*Restricted Stock.* The 2021 Stock Incentive Plan permits the grant of restricted stock. Awards of restricted stock may be made for consideration or no consideration (other than par value deemed paid by services rendered). The material terms of an award of restricted stock will be set forth in the applicable award agreement, including any applicable period restriction and the expiration of such period of restriction (which may be based on satisfaction of corporate or individual performance objectives). Unless otherwise provided in an award agreement, holders of restricted stock have the right to vote and receive dividends and distributions in respect of restricted shares, subject to any additional terms determined by the administrator. Upon a grantee's termination of service, restricted stock that has not vested will be deemed immediately forfeited.

*Non-Transferability of Awards.* Except in the limited case of certain family transfers described in the 2021 Stock Incentive Plan, during the lifetime of a grantee, only the grantee (or, in the event of legal incapacity or incompetency, the grantee's guardian or legal representative) may exercise an option and no option is assignable or transferable by the grantee other than by will or the laws of descent and distribution. Restricted stock may not be sold, transferred, assigned, pledged or otherwise encumbered or disposed of during the restricted period or prior to the satisfaction of any other restrictions prescribed by the administrator.

*Certain Adjustments.* If the number of outstanding shares for which awards may be made under the 2021 Stock Incentive Plan is increased or decreased or the shares underlying award are changed into or exchanged for a different number or kind of shares or other securities on account of any recapitalization, reclassification, stock split, reverse split, combination of shares, exchange of shares, stock dividend or other distribution payable in capital stock, or other increase or decrease in such shares effected without receipt of consideration by the Company, the number and kinds of shares subject to the share reserve and subject to outstanding awards and the exercise price of outstanding awards will be adjusted proportionately. In the event of any distribution to our stockholders of securities of any other entity or other assets (including an extraordinary dividend but excluding a non-extraordinary dividend) without receipt of consideration by the Company, we will appropriately adjust the number and kind of shares subject to outstanding awards and the exercise price of outstanding options.

*Corporate Transaction.* In the event of (i) the dissolution or liquidation of the Company or a merger, consolidation, or reorganization of the Company with one or more other entities in which the Company is not the surviving entity, (ii) a sale of substantially all of the assets of the Company to another person or entity, or (iii) any transaction which results in any person or entity owning 50% or more of the combined voting power of all classes of our capital stock (a "Company Transaction"), outstanding awards will be treated as the administrator determines without consent. We have no obligation to treat all awards, all awards held by a grantee, or all awards of the same type, similarly.

Subject to applicable laws, the administrator may provide, without limitation, for one or more of the following: (i) the continuation of the outstanding awards by the Company, if the Company is a surviving corporation; (ii) the assumption, in whole or in part, of the outstanding awards by the surviving corporation or a successor entity or its parent; (iii) the substitution, in whole or in part, by the surviving corporation or a successor entity or its parent of its own awards for such outstanding awards; (iv) exercisability and settlement, in whole or in part, of outstanding awards to the extent vested and exercisable (if applicable) under the terms of the award agreement followed by the cancellation of such awards (whether or not then vested or exercisable) upon or immediately prior to the effectiveness of the transaction; or (v) settlement of the intrinsic value of the outstanding awards to the extent vested and exercisable (if applicable) under the terms of the award agreement, with payment made in cash or cash equivalents or property followed by the cancellation of such awards.

The administrator also has discretion to suspend the right of grantees to exercise outstanding awards during a limited period of time preceding the closing of a Corporate Transaction if such suspension is administratively necessary to facilitate the closing of the transaction, and may terminate optionholders' right to early exercise options, such that following closing of a Corporate Transaction an option may only be exercised to the extent vested.

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*Amendment and Termination.* The Board may amend, suspend or terminate 2021 Stock Incentive Plan as to any shares as to which grants have not been made. An amendment to the 2021 Stock Incentive Plan will only be contingent on approval of our stockholders to the extent required by applicable law, regulations or rules. No amendment, suspension, or termination of the 2021 Stock Incentive Plan will materially alter or impair rights or obligations under any grant without the consent of the applicable grantee. As noted above, the 2021 Stock Incentive Plan was terminated subject to and effective immediately prior to the 2024 Equity Incentive Plan becoming effective, and we will not grant any additional awards under the plan following its termination. However, the 2021 Stock Incentive Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2021 Stock Incentive Plan.

### *2023 RSU Equity Incentive Plan*

Legacy OnKure's 2023 RSU Plan was adopted by the Legacy OnKure Board on September 26, 2023, and approved by Legacy OnKure's stockholders on October 17, 2023. The 2023 RSU Plan provides for the grant of restricted stock units to members of the Board and employees and consultants of the Company and any parent or subsidiary corporation of the Company.

At the closing of the Merger, the Combined Company assumed all outstanding awards of restricted stock units granted under the 2023 RSU Plan.

In connection with the closing of the Merger, the 2023 RSU Plan was terminated subject to and effective immediately prior to the 2024 Equity Incentive Plan becoming effective, and we will not grant any additional awards under the plan following its termination. However, the 2023 RSU Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2023 RSU Plan. The material terms of the 2023 RSU Plan are summarized below.

As of October 4, 2024, restricted stock units covering 213,254 shares of our Class A Common Stock were outstanding under the 2023 RSU Plan.

*Authorized Shares.* Subject to the adjustment provisions contained in the 2023 RSU Plan, the maximum aggregate number of shares that may be subject to awards and sold under the 2023 RSU Plan is 289,588. Shares granted under the 2023 RSU Plan may be authorized but unissued, or reacquired shares.

If an award expires or is surrendered pursuant to an exchange program described in the following paragraph, or is forfeited to or repurchased by the Company due to failure to vest, the forfeited shares will become available for future grant or sale under the 2023 RSU Plan (unless the 2023 RSU Plan has terminated). Shares used to pay the purchase price of an award or satisfy the tax withholdings related to an award will not become available for future grant or sale under the 2023 RSU Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in a reduction in the number of shares available for issuance under the 2023 RSU Plan.

*Plan Administration.* The Board or one or more committees appointed by the Board administers the 2023 RSU Plan. Different committees may administer the 2023 RSU Plan with respect to different service providers. Subject to the provisions of the 2023 RSU Plan, the administrator has the power to administer the 2023 RSU Plan and make all determinations deemed necessary or advisable for administering the 2023 RSU Plan, including the power to determine the fair market value of applicable shares, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2023 RSU Plan, determine the terms and conditions of awards (such as the purchase price, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating to the award), construe and interpret the terms of the 2023 RSU Plan and awards granted under it, prescribe, amend and rescind rules relating to the 2023 RSU Plan (including relating to sub-plans), modify, or amend each award, and allow a participant to defer the receipt of payment of cash or the delivery of shares that



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would otherwise be due to such participant under an award. The administrator also has the authority to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type (which may have a higher or lower exercise or purchase price and/or different terms), awards of a different type, and/or cash, by which participants would have the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, or by which the purchase price of an outstanding award is increased or reduced. The administrator's decisions, interpretations, and other actions are final and binding on all participants and is given maximum deference permitted under by applicable law.

*Restricted Stock Units.* Restricted stock units may be granted under the 2023 RSU Plan. Each restricted stock unit is a bookkeeping entry representing an amount equal to the fair market value of one share. Subject to the provisions of the 2023 RSU Plan, the administrator determines the terms and conditions of restricted stock units, including any vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit, or individual goals (including continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned restricted stock units in the form of cash, shares, or a combination of both. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

*Non-Transferability of Awards.* Unless the administrator provides otherwise, the 2023 RSU Plan generally does not allow for the transfer of awards (other than by will or the laws of descent or distribution), and only the recipient of an award may exercise an award during his or her lifetime.

*Certain Adjustments.* In the event of certain changes in our capitalization, including any dividend (other than an ordinary dividend) or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of shares or other securities, or other change in the corporate structure of the Company affecting the shares, to prevent diminution or enlargement of the benefits or potential benefits available under the 2023 RSU Plan, the administrator will adjust the number and class of shares that may be delivered under the 2023 RSU Plan and/or the number, class, and price of shares covered by each outstanding award.

*Dissolution or Liquidation.* In the event of the Company's proposed liquidation or dissolution, the administrator will notify participants before the effective date of such transaction, and to the extent shares issuable under an award have a purchase price and such purchase price has not previously been paid, such awards will terminate immediately before the consummation of such proposed transaction.

*Merger or Change in Control of OnKure.* The 2023 RSU Plan provides that in the event of a merger or change in control of the Company, as described under the 2023 RSU Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator may provide that awards granted under the 2023 RSU Plan will be assumed or substituted by substantially equivalent awards, be terminated immediately before the merger or change in control, become vested or payable and be terminated in connection with the merger or change in control, be terminated in exchange for cash or other property, be continued by OnKure if it is the surviving company, or any combination of the above. The administrator is not required to treat all awards, all awards held by a participant, or all awards of the same type similarly.

If a successor corporation does not assume or substitute for any outstanding award, then all restrictions on restricted stock units will lapse, and for awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met, unless specifically provided otherwise under the applicable award agreement or other written agreement authorized by the administrator.

*Forfeiture and Clawback.* Awards are subject to any clawback policy that we are required to adopt under applicable laws. The administrator also may specify in an award agreement that the participant's rights, payments



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and benefits with respect to an award will be subject to reduction, cancellation, forfeiture, recoupment, reimbursement, or reacquisition upon the occurrence of certain specified events. The administrator may require a participant to forfeit or return to the Company or reimburse the Company for all or a portion of the award and any amounts paid under the award in order to comply with any clawback policy of the Company as described in the first sentence of this paragraph or with applicable laws.

*Amendment; Termination.* The administrator has the authority to amend, suspend, or terminate the 2023 RSU Plan at any time and for any reason, but such action generally may not materially impair the rights of any participant without his or her written consent. As noted above, the 2023 RSU Plan terminated subject to and effective immediately prior to the 2024 Equity Incentive Plan becoming effective, and we will not grant any additional awards under the plan following its termination. However, the 2023 RSU Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2023 RSU Plan.

### *2024 Equity Incentive Plan*

#### *Purposes of the 2024 Equity Incentive Plan*

The purposes of the 2024 Equity Incentive Plan is to attract and retain the best available personnel for positions of substantial responsibility with the Company or any parent or subsidiary of the Company; to provide additional incentive to eligible employees, directors, and consultants; and to promote the success of the Company's business. These incentives will be provided through the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, and performance awards as the administrator of the 2024 Equity Incentive Plan may determine.

#### *Eligibility*

The 2024 Equity Incentive Plan permits the grant of incentive stock options, within the meaning of Section 422 of the Code, to the Company's employees and any of its parent and subsidiary corporations' employees, and the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights and performance awards to employees, directors and consultants of the Company and employees and consultants of any of its parents or subsidiaries. The Company's non-employee directors are eligible for grants under the 2024 Equity Incentive Plan. The basis for participation in the 2024 Equity Incentive Plan is being eligible and being selected by the plan administrator, in its discretion, to receive a grant thereunder.

#### *Authorized Shares; Adjustments*

Subject to the adjustment provisions contained in the 2024 Equity Incentive Plan and the evergreen provision described below, a total of 2,480,000 shares of our Class A Common Stock was initially reserved for issuance pursuant to the 2024 Equity Incentive Plan. In addition, the shares reserved for issuance under the 2024 Equity Incentive Plan will include (a) any shares of our Class A Common Stock subject to equity awards granted under the Reneo 2021 Plan that, as of immediately prior to the later of the Effective Time or the termination of Reneo 2021 Plan, are cancelled or forfeited, expire or otherwise terminate without having been exercised in full, are tendered to or withheld by the Company for payment of an exercise price or for tax withholding obligations related to awards granted under the Reneo 2021 Plan, are forfeited to or repurchased by the Company due to failure to vest, or otherwise would, but for the termination of the 2024 Equity Incentive Plan, have been added back to the share reserve of the Reneo 2021 Plan in accordance with its terms, plus (b) any shares of our Class A Common Stock subject to the equity awards that are assumed in the Merger and that on or after the Effective Time are cancelled or forfeited, expire or otherwise terminated without being exercised in full, are tendered to or withheld by the Company to satisfy exercise price or tax withholding obligations, or are forfeited to or repurchased by the Company due to failure to vest (provided that the maximum number of shares that may be added to the 2024 Equity Incentive Plan pursuant to the foregoing clause (a) and (b) is 935,841 shares). The number of shares available for issuance under the 2024 Equity Incentive Plan also will include an annual

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increase, or the evergreen feature, on the first day of each fiscal year, beginning with the Company's 2025 fiscal year, equal to the least of:

- 2,407,100 shares of our Class A Common Stock;
- a number of shares of our Class A Common Stock equal to 5% of the outstanding shares of all classes of our Common Stock as of the last day of the immediately preceding fiscal year;
- or such number of shares of our Class A Common Stock as our Board or its designated committee may determine no later than the last day of our immediately preceding fiscal year.

Shares issuable under the 2024 Equity Incentive Plan may be authorized, but unissued, or reacquired shares of our Class A Common Stock. If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program (as described below), or, with respect to restricted stock, restricted stock units, or performance awards, is forfeited to or repurchased due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2024 Equity Incentive Plan. With respect to stock appreciation rights, only the net shares actually issued will cease to be available under the 2024 Equity Incentive Plan and all remaining shares under stock appreciation rights will remain available for future grant or sale under the 2024 Equity Incentive Plan. Shares that actually have been issued under the 2024 Equity Incentive Plan under any award will not be returned to the 2024 Equity Incentive Plan; except if shares issued pursuant to awards of restricted stock, restricted stock units, or performance awards are repurchased or forfeited due to failure to vest, such shares will become available for future grant under the 2024 Equity Incentive Plan. Shares otherwise issuable under an award that are used to pay the exercise price of an award or satisfy the tax liabilities or withholding obligations related to an award (which withholdings may be in amounts greater than the minimum statutory amount required to be withheld as determined by the administrator of the 2024 Equity Incentive Plan) will become available for future grant or sale under the 2024 Equity Incentive Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in a reduction in the number of shares available for issuance under the 2024 Equity Incentive Plan.

If any dividend or other distribution (whether in cash, shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, reclassification, repurchase, or exchange of shares of our Class A Common Stock or other securities, or other change in the corporate structure of the Company affecting the shares of our Class A Common Stock, occurs (other than any ordinary dividends or other ordinary distributions), the administrator of the 2024 Equity Incentive Plan, to prevent diminution or enlargement of the benefits or potential benefits intended to be provided under the 2024 Equity Incentive Plan, will adjust the number and class of shares that may be delivered under the 2024 Equity Incentive Plan; the number, class, and price of shares covered by each outstanding award; and the numerical share limits contained in the 2024 Equity Incentive Plan.

The administrator will not be obligated to treat all awards, all awards held by a participant, all awards of the same type, or all portions of awards, similarly (including with respect to the number of shares covered by such award, the price applicable to such award, or the vesting, forfeiture or other terms and conditions applicable to such award).

### *Plan Administration*

Our Board or one or more committees appointed by the Board has authority to administer the 2024 Equity Incentive Plan. The compensation committee of our Board initially will administer the 2024 Equity Incentive Plan.

In addition, to the extent it is desirable to qualify transactions under the 2024 Equity Incentive Plan as exempt under Rule 16b-3 of the Exchange Act, such transactions will be structured to satisfy the requirements for

exemption under Rule 16b-3. Except to the extent prohibited by applicable laws, the administrator may delegate to one or more individuals the day-to-day administration of the 2024 Equity Incentive Plan and any of the functions assigned to it in the 2024 Equity Incentive Plan, which delegation may be revoked at any time. Subject to the provisions of the 2024 Equity Incentive Plan, the administrator has the power to administer the 2024 Equity Incentive Plan and make all determinations deemed necessary or advisable for administering the 2024 Equity Incentive Plan, including but not limited to, the power to determine the fair market value of our Class A Common Stock, select the service providers to whom awards may be granted, determine the number of shares or dollar amounts covered by each award, approve forms of award agreements for use under the 2024 Equity Incentive Plan, determine the terms and conditions of awards (including, but not limited to, the exercise price, the time or times at which awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of the 2024 Equity Incentive Plan and awards granted under it, prescribe, amend and rescind rules and regulations relating to the 2024 Equity Incentive Plan, including creating sub-plans, modify or amend each award, allow a participant to defer the receipt of payment of cash or the delivery of shares that otherwise would be due to such participant under an award, and to determine whether awards will be settled in share, cash or in any combination thereof. The administrator also has the authority to allow participants the opportunity under an exchange program to transfer outstanding awards granted under the 2024 Equity Incentive Plan to a financial institution or other person or entity selected by the administrator, and to institute an exchange program by which outstanding awards granted under the 2024 Equity Incentive Plan may be surrendered or cancelled in exchange for awards of the same type, which may have a higher or lower exercise price and/or different terms, awards of a different type and/or cash, or by which the exercise price of an outstanding award granted under the 2024 Equity Incentive Plan is increased or reduced. The administrator's decisions, interpretations and other actions are final and binding on all participants and will be given the maximum deference permitted by applicable law.

#### *Types of Awards*

The 2024 Equity Incentive Plan provides for the grant of stock options (including incentive stock options and nonqualified stock options), stock appreciation rights, restricted stock, restricted stock units and performance awards. A brief description of each award type follows.

*Stock Options.* Stock options may be granted under the 2024 Equity Incentive Plan. The per-share exercise price of options granted under the 2024 Equity Incentive Plan generally must be equal to at least 100% of the fair market value of a share of our Class A Common Stock on the date of grant. The term of an option may not exceed 10 years. With respect to any participant who owns more than 10% of the voting power of all classes of Common Stock (or any of its parent's or subsidiary's) outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the per-share exercise price must equal at least 110% of the fair market value of a share of our Class A Common Stock on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, check, promissory note (to the extent permitted by applicable law), certain shares of our Class A Common Stock, cashless exercise, net exercise, as well as other types of consideration permitted by applicable law. After the cessation of service of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. In the absence of a specified time in an award agreement, if such cessation is due to death or disability, the option will remain exercisable for six months. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for three months following the cessation of service. An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of the 2024 Equity Incentive Plan, the administrator determines the terms of options. Until shares are issued under an option, the participant will not have any right to vote or receive dividends or have any other rights as a stockholder with respect to such shares, and no adjustment will be made for a dividend or other right for which the record date is before the date such shares are issued, except as provided in the 2024 Equity Incentive Plan, as summarized further above.

*Stock Appreciation Rights.* Stock appreciation rights may be granted under the 2024 Equity Incentive Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our Class A

Common Stock between the exercise date and the date of grant. The term of a stock appreciation right may not exceed 10 years. After the cessation of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her stock appreciation rights agreement. In the absence of a specified time in an award agreement, if such cessation is due to death or disability, the stock appreciation rights will remain exercisable for six months following the cessation of service. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for three months following the cessation of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of the 2024 Equity Incentive Plan, the administrator determines the terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our Class A Common Stock, or a combination of both, except that the per-share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant. Until shares are issued under a stock appreciation right, the participant will not have any right to vote or receive dividends or have any other rights as a stockholder with respect to such shares, and no adjustment will be made for a dividend or other right for which the record date is before the date such shares are issued, except as provided in the 2024 Equity Incentive Plan, as summarized further above.

*Restricted Stock.* Restricted stock may be granted under the 2024 Equity Incentive Plan. Restricted stock awards are grants of shares of our Class A Common Stock that may have vesting requirements or other terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of the 2024 Equity Incentive Plan, will determine the terms and conditions of such awards. The administrator may impose whatever restrictions on transferability, forfeiture provisions or other restrictions or vesting conditions (if any) it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us). The administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. The administrator may determine that an award of restricted stock will not be subject to any period of restriction and consideration for such award is paid for by past services rendered as a service provider. Recipients of restricted stock awards generally will have voting rights and rights to dividends and other distributions with respect to such shares upon grant, unless the administrator provides otherwise. If such dividends or distributions are paid in shares, the shares will be subject to the same restrictions on transferability and forfeitability as the share of restricted stock with respect to which they were paid. Shares of restricted stock that do not vest are subject to the right of repurchase or forfeiture.

*Restricted Stock Units.* Restricted stock units (“RSUs”) may be granted under the 2024 Equity Incentive Plan. Each RSU is a bookkeeping entry representing an amount equal to the fair market value of one share of our Class A Common Stock. Subject to the provisions of the 2024 Equity Incentive Plan, the administrator determines the terms and conditions of RSUs, including any vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit, or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may settle earned restricted stock units in the form of cash, shares, or a combination of both. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. All RSUs that are unearned or unvested as of the date set forth in the applicable award agreement will be forfeited.

*Performance Awards.* Performance awards may be granted under the 2024 Equity Incentive Plan. Performance awards are awards that may be earned in whole or in part on the attainment of performance goals or other vesting criteria that the administrator may determine, and that may be denominated in cash or stock. Each performance award will have an initial value that is determined by the administrator. Subject to the terms and conditions of the 2024 Equity Incentive Plan, the administrator determines the terms and conditions of performance awards, including any vesting criteria and form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit, or individual goals

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(including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned performance awards in the form of cash, shares, or a combination of both. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. All performance awards that are unearned or unvested as of the date set forth in the applicable award agreement will be forfeited.

### *Non-Employee Directors Limitations*

All outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under the 2024 Equity Incentive Plan. The 2024 Equity Incentive Plan provides that in any given fiscal year, no outside director may be granted any equity awards (including equity awards under the 2024 Equity Incentive Plan) (the value of which will be based on their grant date fair value) and be provided any cash retainers or fees that in the aggregate exceed \$750,000, provided that in the fiscal year of the individual's initial service as a non-employee director, such amount is increased to \$1,000,000. For the purposes of this maximum limit provision, the grant date fair values of awards granted under the 2024 Equity Incentive Plan will be determined according to GAAP. Any awards or other compensation provided to an individual for his or her services as an employee or a consultant (other than an outside director), or before the Closing of the Mergers, will not count toward this limit. For purposes of determining when cash retainers or fees are provided, any deferral elections to delay payout timing will be disregarded. This maximum limit provision does not reflect the intended size of any potential grants or a commitment to make grants to the outside directors under the 2024 Equity Incentive Plan in the future.

### *Non-Transferability of Awards*

Unless the administrator provides otherwise, the 2024 Equity Incentive Plan generally will not allow for the transfer of awards other than by will or the laws of descent and distribution, and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferable, such award will contain such additional terms and conditions as the administrator deems appropriate.

### *Dissolution or Liquidation*

If there is a proposed liquidation or dissolution of the Company, the administrator will notify participants at such time before the effective date of such event as the administrator determines. Unless provided otherwise by the administrator, all awards, to the extent that they have not been previously exercised, vested or settled will terminate immediately before the consummation of such event.

### *Merger or Change in Control*

The 2024 Equity Incentive Plan provides that in the event of the Company's merger with or into another corporation or a change in control, as defined in the 2024 Equity Incentive Plan, each outstanding award will be treated as the administrator determines (subject to the provisions of the following paragraph), without a participant's consent. The administrator may, without limitation, provide that outstanding awards granted under the 2024 Equity Incentive Plan may be (i) assumed, or substantially equivalent awards substituted, by the acquiring or succeeding entity (or an affiliate thereof), (ii) continued, subject to adjustment pursuant to the terms of the 2024 Equity Incentive Plan, (iii) upon written notice to the participant, terminated upon or immediately prior to the merger or change in control, (iv) made vested and exercisable or payable and, to the extent the administrator determines, terminated upon or immediately prior to the merger or change in control, (v) terminated in exchange for cash, other property or other consideration, or any combination of the above (provided, for the avoidance of doubt, that if as of the date of the occurrence of the transaction the administrator determines in good faith that no amount would have been attained upon the exercise of such award or realization of the participant's rights, then such award may be terminated without payment), or replaced with such other

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rights or property selected by the administrator in its sole discretion, or (vi) treated in any combination of the foregoing. The administrator is not required to treat all awards, all awards held by a participant, all portions of awards, or all awards of the same type, similarly.

If a successor (or an affiliate thereof) does not assume, substitute for or continue an award (or portion thereof), then such award (or its applicable portion) will fully vest, all restrictions on such award (or its applicable portion) will lapse, all performance goals or other vesting criteria applicable to such award (or its applicable portion) will be deemed achieved at 100% of target levels and such award (or its applicable portion) will become fully exercisable, if applicable, for a specified period before the transaction, unless specifically provided otherwise under the applicable award agreement or other written agreement with the participant authorized by the administrator. In addition, unless specifically provided otherwise under the applicable award agreement or other written agreement with the participant authorized by the administrator, if an option or stock appreciation right (or a portion of such award) is not assumed, substituted or continued, the administrator will notify the participant that such option or stock appreciation right (or its applicable portion) will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right (or its applicable portion) will terminate upon the expiration of such period.

If awards granted to a non-employee director while such individual was a non-employee director are assumed or substituted for in the merger or change in control and the service of such non-employee director is terminated (other than upon his or her voluntary resignation that does not include a resignation at the request of the acquirer) on or following the merger or change in control, all such awards will fully vest, all restrictions on such awards will lapse, all performance goals or other vesting criteria applicable to such awards will be deemed achieved at 100% of target levels and such awards will become fully exercisable, if applicable, unless specifically provided otherwise under the applicable award agreement or other written agreement with the non-employee director authorized by the administrator.

### *Forfeiture and Clawback*

Awards will be subject to any clawback policy which is in effect at grant and any other clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which our securities are listed or as is otherwise required by applicable laws. The administrator also may specify in an award agreement that the participant's rights, payments and benefits with respect to an award will be subject to reduction, cancellation, forfeiture, recoupment, reimbursement, or reacquisition upon the occurrence of certain specified events. The administrator may require a participant to forfeit or return to the Company or reimburse the Company for all or a portion of the award and any amounts paid under the award in order to comply with any clawback policy of the Company as described in the first sentence of this paragraph or with applicable laws.

### *Amendment or Termination*

The 2024 Equity Incentive Plan became effective upon the closing of the Merger, and will continue in effect for a period of ten years from its effectiveness, unless terminated earlier by the administrator. However, no incentive stock options may be granted after the 10-year anniversary of the earlier of the adoption of the 2024 Equity Incentive Plan by the Reneo board of directors or the approval of the 2024 Equity Incentive Plan by Reneo stockholders. In addition, the administrator has the authority to amend, suspend, or terminate the 2024 Equity Incentive Plan or any part of the 2024 Equity Incentive Plan, at any time and for any reason, but such action generally may not materially impair the rights of any participant without his or her written consent, provided that the conversion of incentive stock options into nonstatutory stock options as a result of actions taken by the administrator will neither constitute nor contribute toward an impairment of a participant's rights under an outstanding award.

*Summary of U.S. Federal Income Tax Consequences*

The following summary is intended only as a general guide to the U.S. federal income tax consequences of participation in the 2024 Equity Incentive Plan. The summary is based on existing U.S. laws and regulations, and there can be no assurance that those laws and regulations will not change in the future. The summary does not purport to be complete and does not discuss the tax consequences upon a participant's death, or the provisions of the income tax laws of any municipality, state or non-U.S. jurisdiction in which the participant may reside. As a result, tax consequences for any particular participant may vary based on individual circumstances.

*Incentive Stock Options.* A participant generally recognizes no taxable income for ordinary income tax purposes as a result of the grant or exercise of an option that qualifies as an incentive stock option under Section 422 of the Code. If a participant exercises the option and then later sells or otherwise disposes of the shares acquired through the exercise of the option after both the two-year anniversary of the date the option was granted and the one-year anniversary of the date of exercise of the option, the participant will recognize a capital gain or loss equal to the difference between the sale price of the shares and the exercise price.

However, if the participant disposes of such shares either on or before the two-year anniversary of the date of grant or on or before the one-year anniversary of the date of exercise of the option (a "disqualifying disposition"), any gain up to the excess of the fair market value of the shares on the date of exercise over the exercise price generally will be taxed as ordinary income, unless the shares are disposed of in a transaction in which the participant would not recognize a gain (such as a gift). Any gain in excess of that amount will be a capital gain. If a loss is recognized with respect to the share disposition, there will be no ordinary income, and such loss will be a capital loss.

For purposes of the alternative minimum tax, the difference between the option exercise price and the fair market value of the shares on the date of exercise of the option is treated as an adjustment item in computing the participant's alternative minimum taxable income in the year of exercise (unless the shares are disposed of in the same year as the option exercise). In addition, special alternative minimum tax rules may apply to certain subsequent disqualifying dispositions of the shares or provide certain basis adjustments or tax credits.

*Nonstatutory Stock Options.* A participant generally recognizes no taxable income for ordinary income tax purposes as a result of the grant of such an option. However, upon exercising the option, the participant generally recognizes ordinary income equal to the amount that the fair market value of the shares on such date exceeds the exercise price. If the participant is an employee, such ordinary income generally is subject to withholding of income and employment taxes. Upon the sale or other disposition of the shares acquired by the exercise of a nonstatutory stock option, any gain or loss (based on the difference between the sale price and the fair market value on the exercise date) will be taxed as capital gain or loss.

*Stock Appreciation Rights.* In general, no taxable income for ordinary income tax purposes is reportable when a stock appreciation right is granted to a participant. Upon exercise, the participant generally will recognize ordinary income in an amount equal to the fair market value of any shares or cash received. If the participant is an employee, such ordinary income generally is subject to withholding of income and employment taxes. Any additional gain or loss recognized upon any later disposition of any shares received would be capital gain or loss.

*Restricted Stock Awards.* A participant acquiring shares of restricted stock generally will recognize ordinary income equal to the fair market value of the shares on the vesting date. If the participant is an employee, such ordinary income generally is subject to withholding of income and employment taxes. The participant, pursuant to Section 83(b) of the Code, may elect to accelerate the ordinary income tax event to the date of acquisition of the shares by filing an election with the IRS generally no later than 30 days after the date the shares are acquired. Upon the sale of shares acquired pursuant to a restricted stock award, any gain or loss, based on the difference between the sale price and the fair market value on the date the ordinary income tax event occurs, will be taxed as capital gain or loss.



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*Restricted Stock Units and Performance Awards.* There generally are no immediate tax consequences of receiving an award of restricted stock units or a performance award. A participant who is granted restricted stock units or performance awards generally will be required to recognize ordinary income in an amount equal to the fair market value of shares or cash issued to such participant at the time of settlement of the award upon vesting. If the participant is an employee, such ordinary income generally is subject to withholding of income and employment taxes. Any additional gain or loss recognized upon any later disposition of any shares received would be capital gain or loss.

*Section 409A.* Section 409A of the Code (“Section 409A”) provides certain requirements for non-qualified deferred compensation arrangements with respect to an individual’s deferral and distribution elections and permissible distribution events. Awards with a deferral feature granted under the 2024 Equity Incentive Plan to a participant subject to U.S. income tax will be subject to the requirements of Section 409A. If an award is subject to and fails to satisfy the requirements of Section 409A, the recipient of that award may recognize ordinary income on the amounts deferred under the award, to the extent vested, which may be prior to when the compensation is actually or constructively received. Also, if an award that is subject to Section 409A fails to comply with Section 409A’s provisions, Section 409A imposes an additional 20% federal income tax on compensation recognized as ordinary income, as well as interest on such deferred compensation.

*Tax Effect for the Company.* The Company generally will be entitled to a tax deduction in connection with an award under the 2024 Equity Incentive Plan in an amount equal to the ordinary income realized by a participant and at the time the participant recognizes such income (for example, the exercise of a nonstatutory stock option) except to the extent such deduction is limited by applicable provisions of the Code. Special rules limit the deductibility of compensation paid to the Company’s chief executive officer and certain “covered employees” as determined under Section 162(m) of the Code and applicable guidance. Under Section 162(m) of the Code, the annual compensation paid to any of these specified individuals will be deductible only to the extent that it does not exceed \$1,000,000.

THE FOREGOING IS ONLY A SUMMARY OF THE EFFECT OF U.S. FEDERAL INCOME TAXATION UPON PARTICIPANTS AND THE COMPANY WITH RESPECT TO AWARDS UNDER THE EQUITY INCENTIVE PLAN. IT DOES NOT PURPORT TO BE COMPLETE AND DOES NOT DISCUSS THE IMPACT OF EMPLOYMENT OR OTHER TAX REQUIREMENTS, THE TAX CONSEQUENCES OF A PARTICIPANT’S DEATH, OR THE PROVISIONS OF THE INCOME TAX LAWS OF ANY MUNICIPALITY, STATE, OR NON-U.S. JURISDICTION IN WHICH THE PARTICIPANT MAY RESIDE.

### *Plan Benefits*

The number of awards that an employee, director, or consultant may receive under the 2024 Equity Incentive Plan is in the discretion of the administrator and therefore cannot be determined in advance. Individuals who will be executive officers and non-employee directors have an interest in this proposal because they are eligible to receive awards under the 2024 Equity Incentive Plan.

### *2024 Employee Stock Purchase Plan*

#### *Purpose*

The purpose of the 2024 Employee Stock Purchase Plan (“2024 ESPP”) is to provide eligible employees with an opportunity to purchase shares of our Class A Common Stock through accumulated contributions, which generally will be made through payroll deductions. The 2024 ESPP will permit the administrator of the 2024 ESPP to grant purchase options that qualify for preferential tax treatment under Section 423 of the Code. In addition, the 2024 ESPP will authorize the grant of purchase options that do not qualify under Code Section 423 pursuant to rules, procedures or sub-plans adopted by the administrator that are designed to achieve desired tax or other objectives.



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### *Shares Available for Issuance; Adjustments*

Subject to adjustment upon certain changes in our capitalization as described in the 2024 ESPP, the maximum number of shares of our Class A Common Stock that will be available for issuance under the 2024 ESPP will be 137,500 shares, plus any annual increase as described in the following sentence. The number of shares of our Class A Common Stock available for issuance under the 2024 ESPP will be increased on the first day of the fiscal year beginning with our 2025 fiscal year in an amount equal to the least of (a) 481,500 shares, (b) a number of shares of our Class A Common Stock equal to 1% of the outstanding shares of all classes of our Common Stock outstanding on the last day of the immediately preceding fiscal year, or (c) a number of shares of our Class A Common Stock determined by the administrator no later than the last day of our immediately preceding fiscal year. Shares issuable under the 2024 ESPP may be authorized, but unissued, or reacquired shares of our Class A Common Stock.

We currently are unable to determine how long this share reserve may last because the number of shares that will be issued in any year or offering period depends on a variety of factors that cannot be predicted with certainty, including, for example, the number of employees who elect to participate in the 2024 ESPP, the level of contributions made by participants and the future price of shares of our Class A Common Stock.

The 2024 ESPP provides that in the event that any dividend or other distribution (whether in the form of cash, shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, reclassification, repurchase or exchange of our Class A Common Stock or other securities or other change in our corporate structure affecting our Class A Common Stock occurs (other than any ordinary dividends or other ordinary distributions), to prevent diminution or enlargement of the benefits or potential benefits intended to be provided under the 2024 ESPP, the administrator will make adjustments to the number and class of shares that may be delivered under the 2024 ESPP and/or the purchase price per share and number and class of shares covered by each option granted under the 2024 ESPP that has not yet been exercised, and the numerical share limits under the 2024 ESPP.

### *Administration*

Our Board or a committee appointed by the Board has authority to administer the 2024 ESPP. Unless and until determined otherwise by the Board, the compensation committee of the Board will administer the 2024 ESPP. The administrator will have full and exclusive discretionary authority to construe, interpret and apply the terms of the 2024 ESPP, delegate ministerial duties to any of our employees, designate separate offerings under the 2024 ESPP, designate any subsidiaries of the Company as participating in the 2024 ESPP, determine eligibility, adjudicate all disputed claims filed under the 2024 ESPP and establish procedures that it deems necessary or advisable for the administration of the 2024 ESPP, including, but not limited to, adopting such procedures, sub-plans and appendices to the subscription agreement as are necessary or appropriate to permit participation in the 2024 ESPP by employees who are non-U.S. nationals or employed outside the United States. The administrator's findings, decisions and determinations will be final and binding on all participants to the maximum extent permitted by law.

### *Eligibility*

Generally, any of our employees will be eligible to participate in our 2024 ESPP if they are customarily employed by the Company or any of its participating subsidiaries for at least 20 hours per week and more than five months in any calendar year (or any lesser number of hours per week and/or number of months in any calendar year established by the administrator or if otherwise required by applicable law). The administrator, in its discretion, before an enrollment date for all options granted on such enrollment date in an offering, may determine (for each offering under the 423 Component, as defined below, on a uniform and nondiscriminatory basis or as otherwise permitted by applicable Treasury Regulations) that the definition of eligible employee will or will not include an individual if he or she: (a) has not completed at least two years of service (or a lesser period of time determined by the administrator) since the employee's last hire date, (b) customarily works not

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more than 20 hours per week (or a lesser period of time determined by the administrator), (c) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator), (d) is a highly compensated employee within the meaning of Code Section 414(q) or (e) is a highly compensated employee within the meaning of Code Section 414(q) with compensation above a certain level or who is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act. In addition, an employee may not be granted an option to purchase stock under our 2024 ESPP if the employee (a) immediately after the grant, would own stock and/or hold outstanding options to purchase such stock possessing 5% or more of the total combined voting power or value of all classes of capital stock of the Company or any parent or subsidiary of the Company; or (b) holds rights to purchase stock under all of our employee stock purchase plans that accrue at a rate that exceeds \$25,000 worth of stock for each calendar year during which his or her right to purchase shares is outstanding at any time.

Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of our Class A Common Stock. Participation ends automatically upon termination of employment with the Company (or its participating subsidiaries).

### *Offering Periods and Purchase Periods*

The 2024 ESPP will include a component (the “423 Component”) that is intended to qualify as an “employee stock purchase plan” under Code Section 423, and a component that does not comply with Code Section 423 (the “Non-423 Component”). The Non-423 Component will provide for substantially the same benefits as the 423 Component, except that the Non-423 Component may include features necessary to comply with applicable non-U.S. laws pursuant to rules, procedures or sub-plans adopted by the administrator. For purposes of this summary, a reference to the 2024 ESPP generally will mean the terms and operations of the 423 Component.

The 2024 ESPP will provide for offering periods with a duration and start and end dates as determined by the administrator, provided that no offering period will have a duration exceeding 27 months. Unless determined otherwise by the administrator, each offering period will have one purchase period with the same duration as the offering period. The administrator is authorized to change the duration of future offering periods and purchase periods under the 2024 ESPP, including the starting and ending dates of offering periods and purchase periods and the number of purchase periods in any offering period. Unless determined otherwise by the administrator and to the extent an offering period provides for more than one exercise date in such offering period, if the fair market value of a share of our Class A Common Stock on an exercise date is less than the fair market value of a share of our Class A Common Stock on the first trading day of the offering period, participants in that offering period will be withdrawn from that offering period following their purchase of shares on such exercise date and automatically will be enrolled in a new offering period.

### *Contributions*

The 2024 ESPP will permit participants to purchase shares of our Class A Common Stock through payroll deductions of up to 15% of their eligible compensation, which includes a participant’s base straight time gross earnings but excludes payments for overtime, shift premium, commissions, incentive compensation, equity compensation, bonuses, and other similar compensation. The administrator may change the compensation eligible for contribution under the 2024 ESPP on a uniform and nondiscriminatory basis for future offering periods.

### *Exercise of Purchase Option*

Amounts deducted and accumulated by a participant under the 2024 ESPP are used to purchase shares of our Class A Common Stock at the end of each purchase period. The purchase price of the shares will be 85% of the lower of (a) the fair market value of a share of our Class A Common Stock on the first trading day of the

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offering period or (b) the fair market value of a share of our Class A Common Stock on the exercise date. A participant will be permitted to purchase a maximum of 1,400 shares during each offering period, provided that the administrator may increase or decrease such maximum number of shares for each purchase period or offering period. Until shares of our Class A Common Stock are issued (as evidenced by the appropriate entry on our books or the books of a duly authorized transfer agent of ours) to a participant, the participant will have only rights of an unsecured creditor with respect to such shares, and no right to vote or receive dividends or any other rights as a stockholder with respect to such shares.

### *Termination of Participation*

Participation in the 2024 ESPP generally will terminate when a participating employee's employment with the Company or a participating subsidiary ceases for any reason, the employee withdraws from the 2024 ESPP or we terminate or amends the 2024 ESPP such that the employee no longer is eligible to participate. An employee may withdraw his or her participation in the 2024 ESPP at any time in accordance with procedures, and prior to any applicable deadline, specified by the administrator. Upon withdrawal from the 2024 ESPP, generally the employee will receive all amounts credited to his or her account without interest (unless otherwise required under applicable law) and his or her payroll withholdings or contributions under the 2024 ESPP will cease.

### *Non-Transferability*

A participant will not be permitted to transfer the contributions credited to his or her 2024 ESPP account or rights granted under the 2024 ESPP, other than by will or the laws of descent and distribution.

### *Dissolution or Liquidation*

In the event of the Company's proposed dissolution or liquidation, any offering period in progress will be shortened by setting a new exercise date and will terminate immediately before the completion of such proposed transaction, unless determined otherwise by the administrator.

### *Merger or Change in Control*

In the event of a merger or change in control of the Company, as defined in the 2024 ESPP, a successor corporation may assume or substitute for each outstanding option. If the successor corporation does not assume or substitute for the options, the offering period then in progress under the 2024 ESPP will be shortened, and a new exercise date will be set to occur before the date of the proposed merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

### *Summary of U.S. Federal Income Tax Consequences*

The following summary is intended only as a general guide to the U.S. federal income tax consequences of participation in the 2024 ESPP. The summary is based on existing U.S. laws and regulations, and there can be no assurance that those laws and regulations will not change in the future. The summary does not purport to be complete and does not discuss the tax consequences upon a participant's death, or the provisions of the income tax laws of any municipality, state or non-U.S. jurisdiction to which the participant may be subject. As a result, tax consequences for any particular participant may vary based on individual circumstances. Further, tax consequences for employees participating in the Non-Section 423 Component of the 2024 ESPP are not discussed. This summary is not intended as tax advice to participants, who should consult their own tax advisors.

The Section 423 Component of the 2024 ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Code. Under an employee stock purchase plan that so qualifies, no

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taxable income will be recognized by a participant, and no deductions will be allowable to the Company, upon either the grant or the exercise of purchase options. Taxable income will not be recognized until there is a sale or other disposition of the shares of our Class A Common Stock acquired under the 2024 ESPP or in the event of the participant's death while still owning the purchased shares of our Class A Common Stock.

If the participant sells or otherwise disposes of the purchased shares of our Class A Common Stock within two years after the start date of the offering period in which the shares of our Class A Common Stock were acquired or within one year after the date of purchase of those shares of our Class A Common Stock, then the participant generally will recognize ordinary income in the year of sale or disposition equal to the amount by which the fair market value of the shares of our Class A Common Stock on the exercise date exceeded the purchase price paid for those shares of our Class A Common Stock, and the Company will be entitled to an income tax deduction equal in amount to such excess, for the taxable year in which such disposition occurs. The amount of this ordinary income will be added to the participant's basis in the shares of our Class A Common Stock, and any resulting gain or loss recognized upon the sale or disposition will be a capital gain or loss. If the shares of our Class A Common Stock have been held for more than one year since the date of purchase, the gain or loss will be long-term capital gain or loss.

If the participant sells or disposes of the purchased shares of our Class A Common Stock more than two years after the start date of the offering period in which the shares of our Class A Common Stock were acquired and more than one year after the date of purchase of those shares of our Class A Common Stock, then the participant generally will recognize ordinary income in the year of sale or disposition equal to the lesser of (a) the amount by which the fair market value of the shares of our Class A Common Stock on the sale or disposition date exceeded the purchase price paid for those shares of our Class A Common Stock, or (b) 15% of the fair market value of the shares of our Class A Common Stock on the start date of that offering period. Any additional gain upon the disposition will be taxed as a long-term capital gain. Alternatively, if the fair market value of the shares of our Class A Common Stock on the date of the sale or disposition is less than the purchase price, there will be no ordinary income and any loss recognized will be a long-term capital loss. The Company will not be entitled to an income tax deduction with respect to such disposition.

### *New Plan Benefits*

Participation in the 2024 ESPP is voluntary and the number of shares of our Class A Common Stock that would be purchased in any year or offering period under the 2024 ESPP is dependent on various factors such as each eligible employee's election to participate, the amount of his or her eligible compensation, and his or her determination as to the portion of his or her eligible compensation to contribute to the 2024 ESPP. Further, such number of shares of our Class A Common Stock that may be purchased under the 2024 ESPP is determined, in part, by the price of the shares of our Class A Common Stock on the first day of each offering period and applicable exercise date of each purchase period. Accordingly, the actual number of shares of our Class A Common Stock that would be purchased by any individual under the 2024 ESPP in the future is not determinable. Although we have previously sponsored an employee stock purchase plan, no offering period has been conducted under such plan, and, therefore, the number of shares which would have been received by or allocated to named executive officers, all current executive officers as a group, and all other current employees who may participate in the 2024 ESPP as a group are not determinable. Non-employee directors are not eligible to participate in the 2024 ESPP.

### *Registration with the SEC*

We intend to file a Registration Statement on Form S-8 relating to the issuance of our Class A Common Stock under the 2024 ESPP with the SEC pursuant to the Securities Act as soon as practicable after we become eligible to use such form.

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### *Effective Date; Amendment; Termination*

The 2024 ESPP became effective upon the closing of the Merger. The administrator will have the authority to modify, amend, suspend or terminate the 2024 ESPP at any time. If the 2024 ESPP is terminated, the administrator may elect to terminate all outstanding offering periods either immediately or upon the next exercise date, or may elect to permit offering periods to expire in accordance with their terms. If the offering periods are terminated prior to expiration, all amounts then credited to participants' accounts that have not been used to purchase shares will be returned to the participants.

### *Executive Incentive Compensation Plan*

Prior to the completion of the Merger, the Reneo board of directors and the Legacy OnKure board of directors approved the Incentive Compensation Plan to provide periodic incentive bonus opportunities to the employees of the Company (or its subsidiaries), which became effective upon closing of the Merger. It is expected that from time to time OnKure's named executive officers will be eligible and selected, subject to their continued employment, to participate in the Incentive Compensation Plan.

### *401(k) Plan*

We do not separately maintain a 401(k) retirement savings plan. Employees are eligible to participate in a tax qualified defined contribution plan under Section 401(k) of the Code sponsored by Insperity, a professional employer organization, on the terms applicable to such plan. Under the Insperity 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code, on a pre-tax (traditional) or post-tax (Roth) basis, through contributions to the Insperity 401(k) plan. As a tax-qualified retirement plan, pre-tax contributions to the Insperity 401(k) plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the Insperity 401(k) plan, and earnings on Roth contributions are not taxable when distributed from the Insperity 401(k) plan.

### **Director Compensation**

Legacy OnKure's policy was to provide each director who is neither a member of management nor affiliated with funds invested in Legacy OnKure preferred stock with an annual retainer of \$40,000, which generally was paid in quarterly installments, subject to the director's continued service to Legacy OnKure. Dr. Saccomano ceased to be eligible to receive this retainer when he assumed a position as Legacy OnKure's interim chief executive officer in September 2023. Legacy OnKure also reimbursed its directors for expenses associated with attending meetings of the Legacy OnKure board of directors and its committees.

On January 11, 2022, Legacy OnKure granted Dr. Saccomano an option grant covering 100,000 shares which accelerated vesting in full immediately prior to the closing of the Merger.

Dr. Saccomano is Legacy OnKure's only director who was an employee director during 2023. See the section entitled "*Executive Compensation*" beginning on page 128 of this prospectus for information about Dr. Saccomano's compensation that he received for serving as Legacy OnKure's Chief Executive Officer during 2023. Dr. Saccomano received additional compensation for serving on the Legacy OnKure's board of directors during 2023 prior to his appointment as Chief Executive Officer as set forth below.

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The following table presents the total compensation that each of Legacy OnKure's then non-employee directors received during the fiscal year ended December 31, 2023.

Name	Fees Earned or Paid in Cash Compensation (\$)	Stock Awards (\$) <sup>(1)</sup>	Option Awards (\$) <sup>(1)</sup>	Total (\$)
Issac Manke, Ph.D. (2)	—	—	—	—
R. Michael Carruthers	40,000	77,580	7,211	124,791
Andrew Phillips, Ph.D. (3)	—	—	—	—
Nicholas A. Saccomano, Ph.D.	29,457	—	8,083	37,540

- (1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the equity awards granted during 2023, computed in accordance with FASB ASC Topic 718, Compensation-Stock Compensation. The assumptions used in calculating the grant date fair value of the awards disclosed in this column are set forth in Note 10 to OnKure's audited financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by the non-employee director upon vesting, settlement or exercise of equity awards or the sale of the common stock underlying such equity awards.
- (2) Dr. Manke was previously an affiliate of Acorn Bioventures, L.P., an investor in Legacy OnKure's capital stock; therefore, Dr. Manke was not entitled to a retainer for fiscal 2023.
- (3) Dr. Phillips was previously an affiliate of Cormorant, an investor in Legacy's OnKure's capital stock; therefore, Dr. Phillips was not entitled to a retainer for fiscal 2023.

The following table lists all outstanding stock and option awards held by non-employee Legacy OnKure directors as of December 31, 2023.

Name	Number of Shares Underlying Outstanding RSU Awards	Number of Shares Underlying Outstanding Options
Issac Manke, Ph.D.	—	—
R. Michael Carruthers	28,075	130,750
Andrew Phillips, Ph.D.	—	—

### **Director Compensation Policy**

In 2024, the compensation committee of the Legacy OnKure board of directors retained Pearl Meyer, a third-party compensation consultant, to provide the Legacy OnKure board of directors and its compensation committee with an analysis of publicly available market data regarding practices and compensation levels at comparable companies and assistance in determining compensation to be provided to our non-employee directors. Based on the discussions with and assistance from the compensation consultant with Legacy OnKure's compensation committee, in connection with the Merger, the Legacy OnKure board of directors and the Reneo board of directors approved an Outside Director Compensation Policy that provides for certain compensation to non-employee directors of the Combined Company, with the Outside Director Compensation Policy to become effective as of immediately prior to the Effective Time.

### **Cash Compensation**

The Outside Director Compensation Policy provides for the following cash compensation program for non-employee directors following the closing of the Merger:

- \$40,000 per year for service as a non-employee director;

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- \$30,000 per year for service as non-employee chair;
- \$15,000 per year for service as chair of the audit committee;
- \$7,500 per year for service as a member of the audit committee;
- \$10,000 per year for service as chair of the compensation committee;
- \$5,000 per year for service as a member of the compensation committee;
- \$8,000 per year for service as chair of the nominating and governance committee; and
- \$4,000 per year for service as a member of the nominating and governance committee.

### *RSU Award in Lieu of Cash Retainers*

Under the Outside Director Compensation Policy, a non-employee director may elect to convert 100% of his or her retainer fees with respect to services to be performed in a future fiscal year (or portion of a fiscal year with respect to certain initial elections) into an award of RSUs (a “Retainer Award”), in accordance with the election procedures under the Outside Director Compensation Policy, and in addition, (i) individuals who are non-employee directors as of immediately following the closing of the Merger may make such election with respect to retainer fees payable for services provided as a non-employee director in fiscal year 2024 (an “Initial Election”), and (ii) individuals who become non-employee directors following the closing of the Merger may make such election with respect to retainer fees payable for services provided as a non-employee director for their initial year of service as a non-employee director. Retainer Awards will be granted automatically on the last day of the fiscal quarter to which such election relates (or on December 31, 2024, with respect to a Retainer Award granted pursuant to an Initial Election), subject to continued service through such date. The number of shares subject to a Retainer Award will be determined by dividing (x) the aggregate annual amount of cash fees described above applicable to the non-employee director as of the last day of the applicable fiscal quarter for which the non-employee director receives the Retainer Award, by (y) the fair market value of a share of our Class A Common Stock on the date of grant of the Retainer Award (which, under the 2024 Equity Incentive Plan generally is the closing sales price of a share of our Class A Common Stock on the date of the grant of the Retainer Award (or, if no closing sales price was reported on that date, on the last trading day such closing sales price was reported)). Each Retainer Award will be fully vested as of the date of grant.

### *Equity Compensation*

*Closing Award.* Pursuant to the Outside Director Compensation Policy, each person who is a non-employee director as of immediately following the closing of the Merger will receive, on the closing date of the Merger, an award of stock options to purchase 15,300 shares of our Class A Common Stock (a “Closing Award”), provided that if an individual was an employee director, becoming a non-employee director at any time after August 1, 2024, due to termination of the individual’s status as an employee will not entitle such individual to a Closing Award and that in no event will such stock options be exercisable prior to the time that a Registration Statement on Form S-8 relating to the issuance of our Class A Common Stock under the 2024 Equity Incentive Plan (or other applicable plan) becomes effective. Each Closing Award will be scheduled to vest as to 1/36th of the shares subject to the Closing Award each month following the Closing Award’s grant date on the same day of the month as such grant date (or on the last day of the month if there is no corresponding day in such month), in each case subject to continued services through the applicable vesting date.

*Initial Award.* Each individual who first becomes a non-employee director following the closing of the Merger will receive, on the first trading day on or after the date on which such individual first becomes a non-employee director, an award of stock options to purchase 15,300 shares of our Class A Common Stock (an “Initial Award”), provided that if an individual was an employee director, becoming a non-employee director due to termination of the individual’s status as an employee will not entitle such individual to an Initial Award and that in no event will such stock options be exercisable prior to the time that a Registration Statement on Form S-8

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relating to the issuance of our Class A Common Stock under the 2024 Equity Incentive Plan (or other applicable plan) becomes effective. Each Initial Award will be scheduled to vest as to 1/36th of the shares subject to the Initial Award each month following the Initial Award's grant date on the same day of the month as such grant date (or on the last day of the month, if there is no corresponding day in such month), in each case subject to continued services through the applicable vesting dates.

*Annual Award.* On the first trading day immediately following each Annual Meeting of our stockholders (an "Annual Meeting") that occurs after the closing of the Merger, each non-employee director will receive an award of stock options to purchase 7,650 shares of our Class A Common Stock (the "Annual Award"). If an individual commenced service as a non-employee director after the date of the Annual Meeting that occurred immediately prior to such Annual Meeting (or if there is no such prior Annual Meeting, then after the closing of the Merger), then such Annual Award will be prorated based on the number of whole months that the individual served as a non-employee director prior to the Annual Award's grant date during the 12-month period immediately preceding such Annual Meeting (with any resulting fractional share rounded down to the nearest whole share). The Annual Award will be scheduled to vest in full on the earlier of the one-year anniversary of the Annual Award's grant date or the day immediately prior to the date of the next Annual Meeting that occurs after the Annual Award's grant date, subject to continued services through the applicable vesting dates.

*Change in Control.* In the event of a change in control (as defined in the 2024 Equity Incentive Plan), each non-employee director's then-outstanding equity awards that were granted to him or her while a non-employee director will accelerate vesting in full, provided that he or she remains a non-employee director through immediately prior to such change in control.

*Other Award Terms.* Each Retainer Award, Closing Award, Initial Award and Annual Award will be granted under the 2024 Equity Incentive Plan (or its successor plan, as applicable) and applicable forms of award agreement under such plan. Other than Retainer Awards, awards will have a maximum term to expiration of ten years from their grant and a per-share exercise price equal to 100% of the fair market value of a share of our Class A Common Stock on the award's grant date.

*Director Compensation Limits.* The Outside Director Compensation Policy will provide that in any fiscal year, a non-employee director may be granted equity awards (with the value of equity awards based on its grant date fair value determined in accordance with U.S. GAAP for purposes of this limit) and be provided any cash retainers or fees with an aggregate value of no more than \$750,000, provided that such amount is increased to \$1,000,000 in the fiscal year of initial service as a non-employee director. Equity awards granted or other compensation provided to a non-employee director for services provided as an employee or consultant (other than a non-employee director), or provided before the closing of the Merger, will not count toward this annual limit. For purposes of determining when cash retainers or fees are provided, any deferral elections to delay payout timing will be disregarded.



**CERTAIN RELATIONSHIPS, RELATED PARTY AND OTHER TRANSACTIONS**

Described below are any transactions occurring since January 1, 2022 and any currently proposed transactions to which we, Legacy OnKure or Reneo was a party and in which:

- the amounts involved exceeded or will exceed the lesser of \$120,000 and 1% of the average of our, OnKure's or Reneo's total assets at year-end for the last two completed fiscal years, as applicable; and
- any of our, OnKure's or Reneo's directors, executive officers or holders of more than 5% of our, OnKure's or Reneo's capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

**PIPE Financing**

On May 10, 2024, in connection with the execution of the Merger Agreement, Reneo entered into the Subscription Agreement with certain existing OnKure stockholders and new investors relating to the PIPE Financing. Pursuant to the Subscription Agreement, the PIPE Investors purchased shares of our Class A Common Stock at a purchase price of approximately \$22.895 per share, for an aggregate purchase price of \$65.0 million. The closing of the PIPE Financing occurred on October 4, 2024 in connection with the closing of the Merger. The table below sets forth the number of shares of our Class A Common Stock purchased by related party holders in the PIPE Financing:

<b>Participant</b>	<b>Shares of Class A Common Stock</b>	<b>Total Purchase Price (\$)</b>
Acorn Bioventures, L.P. <sup>(1)</sup>	199,189	\$ 4,560,475.97
Entities Affiliated with Citadel <sup>(2)</sup>	360,792	\$ 8,260,412.19
Entities Affiliated with Cormorant <sup>(3)</sup>	379,018	\$ 8,677,700.47
Deep Track Biotechnology Master Fund, Ltd. <sup>(4)</sup>	136,147	\$ 3,117,115.51
Perceptive Life Sciences Master Fund, Ltd. <sup>(5)</sup>	207,157	\$ 4,742,905.08
Samsara BioCapital, L.P. <sup>(6)</sup>	169,975	\$ 3,891,615.01

- (1) Isaac Manke, a member of the Legacy OnKure board of directors and a member of our Board, is a partner at Acorn Capital Advisors, GP, LLC, the general partner of Acorn Bioventures, L.P. Entities affiliated with Acorn held more than five percent of outstanding Legacy OnKure's capital stock and hold more than five percent of our outstanding capital stock.
- (2) Citadel Multi-Strategy Equities Master Fund Ltd. held more than five percent of outstanding Legacy OnKure's capital stock and holds more than five percent of our outstanding capital stock. Citadel CEMF Investments Ltd., an affiliate of Citadel Multi-Strategy Equities Master Fund Ltd., purchased 360,792 shares of Class A Common Stock in the PIPE for a total purchase price of \$8,260,412.19.
- (3) Entities affiliated with Cormorant collectively held more than five percent of outstanding Legacy OnKure's capital stock and hold more than five percent of our outstanding capital stock.
- (4) Deep Track Biotechnology Master Fund, Ltd. held more than five percent of outstanding Legacy OnKure's capital stock and holds more than five percent of our outstanding capital stock.
- (5) Perceptive Life Sciences Master Fund, Ltd. held more than five percent of outstanding Legacy OnKure's capital stock and holds more than five percent of our outstanding capital stock.
- (6) Samsara BioCapital, L.P. held more than five percent of outstanding Legacy OnKure's capital stock and holds more than five percent of our outstanding capital stock.

At the closing of the PIPE Financing, in connection with the Subscription Agreement, we entered into a registration rights agreement with the PIPE Investors, pursuant to which we agreed to prepare and file a resale registration statement with the SEC within 45 calendar days following the closing of the PIPE Financing for purposes of registering the resale of the shares issued in the PIPE Financing. We also agreed, among other things, that we will indemnify the PIPE Investors, their officers, directors, members, employees and agents, successors and assigns under the Subscription Agreement from certain liabilities and pay all fees and expenses (excluding any legal fees of the selling holder(s), and any underwriting discounts and selling commissions) incident to our obligations under the registration rights agreement.

### ***Support Agreements Under the Merger Agreement***

Concurrently and in connection with the execution of the Merger Agreement, (i) certain stockholders of Legacy OnKure, owning approximately 98.3% of the outstanding shares of Legacy OnKure's preferred stock and approximately 77.3% of the outstanding shares of Legacy OnKure's capital stock, entered into support agreements with Reneo and Legacy OnKure to vote all of their shares of Legacy OnKure's capital stock in favor of the adoption of the Merger Agreement and the related transactions contemplated thereby and (ii) certain stockholders of Reneo holding approximately 34.7% of the outstanding shares of Reneo's common stock, including Reneo's common stock issuable within 60 days upon (A) exercise of options held by such holders or (B) settlement of RSUs held by such holders, entered into support agreements with Reneo and Legacy OnKure to vote all of their shares of Reneo's capital stock in favor of the Merger Agreement and the related contemplated transactions and against any alternative acquisition proposals.

### ***Lock-Up Agreements***

Concurrently and in connection with the execution of the Merger Agreement, certain executive officers and the directors of Legacy OnKure, certain stockholders of Legacy OnKure and the directors of Reneo that remained on our Board following the closing of the Merger, entered into lock-up agreements pursuant to which, and subject to specified exceptions, they have agreed not to transfer their shares of our Common Stock for the 180-day period following the closing of the Merger.

### ***Legacy OnKure and Reneo Indemnification Agreements***

Legacy OnKure and Reneo each entered into separate indemnification agreements with each of its directors and officers, respectively, in addition to the indemnification provided for in their respective certificate of incorporation and bylaws. The indemnification agreements, certificates of incorporation and bylaws generally require both Legacy OnKure and Reneo to indemnify its directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law.

### ***Policies for Approval of Related Party Transactions***

We maintain a written policy that our executive officers, directors, beneficial owners of more than 5% of any class of our Common Stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our Board or the audit committee. Any request for us to enter into a transaction with an executive officer, director, beneficial owner of more than 5% of any class of our Common Stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds \$120,000 (or, if less, 1% of the average of our total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to our Board or the audit committee for review, consideration and approval. In approving or rejecting any such proposal, our Board or the audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

### ***Legacy OnKure Transactions***

#### **Private Placements of Securities**

##### ***Series B Preferred Stock Financing***

In March 2021, Legacy OnKure issued and sold an aggregate of 20,649,758 shares of its Series B Preferred Stock at a purchase price of \$2.7633 per share for an aggregate purchase price of approximately \$55 million, including \$1.6 million pursuant to the conversion of convertible notes at a discounted purchase price of \$2.21064 per share.

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Purchasers of Legacy OnKure's Series B Preferred Stock included certain of its directors and holders of more than 5% of its capital stock at the time of the financing (or subsequent closings of such financings). The following table presents the number of shares and the total purchase price paid by these entities:

<b>Investor</b>	<b>Shares of Series B Preferred Stock</b>	<b>Total Purchase Price</b>
Alpha Global Investment LP <sup>(1)</sup>	467,478	\$1,033,425.57

- (1) Guobao Zhao, a member of the Legacy OnKure board of directors at the time of the Series B Preferred Stock Financing, is an affiliate of Alpha Global Investment.

### *Series C Preferred Stock Financing*

In March 2023, Legacy OnKure issued and sold an aggregate of 19,463,456 shares of its Series C Preferred Stock at a purchase price of \$2.7633 per share for an aggregate purchase price of approximately \$53.8 million. As part of this transaction, also in March 2023, Legacy OnKure issued an aggregate of 27,780,350 shares of its Series C Preferred Stock in exchange for the conversion of any shares of preferred stock of Legacy OnKure then held by such purchaser.

Purchasers of Legacy OnKure's Series C Preferred Stock included funds related to certain of its directors and holders of more than 5% of its capital stock at the time of the financing (or subsequent closings of such financings). The following table presents the number of shares (including shares that the purchaser received upon conversion of other series of preferred stock of Legacy OnKure then held by such purchaser) and the total purchase price paid by these entities:

<b>Investor</b>	<b>Shares of Series C Preferred Stock</b>	<b>Total Purchase Price</b>
Acorn Bioventures, L.P. <sup>(1)</sup>	8,567,245	\$ 7,007,201
Citadel Multi-Strategy Equities Master Fund Ltd. <sup>(2)</sup>	9,589,983	\$ 9,999,999
Entities Affiliated with Cormorant <sup>(3)</sup>	10,074,472	\$ 9,999,999
Deep Track Biotechnology Master Fund, Ltd. <sup>(4)</sup>	3,618,861	\$ 9,999,999
Perceptive Life Sciences Master Fund, Ltd. <sup>(5)</sup>	5,506,321	\$ 5,465,617
Samsara BioCapital, L.P. <sup>(6)</sup>	4,518,007	\$ 4,484,609

- (1) Isaac Manke, a member of the Legacy OnKure board of directors and a member of our Board, is a partner at Acorn Capital Advisors, GP, LLC, the general partner of Acorn Bioventures, L.P. Entities affiliated with Acorn held more than five percent of outstanding Legacy OnKure's capital stock and hold more than five percent of our outstanding capital stock.
- (2) Citadel Multi-Strategy Equities Master Fund Ltd. held more than five percent of outstanding Legacy OnKure's capital stock and holds more than five percent of our outstanding capital stock.
- (3) Entities affiliated with Cormorant collectively held more than five percent of outstanding Legacy OnKure's capital stock and hold more than five percent of our outstanding capital stock.
- (4) Deep Track Biotechnology Master Fund, Ltd. held more than five percent of outstanding Legacy OnKure's capital stock and holds more than five percent of our outstanding capital stock.
- (5) Perceptive Life Sciences Master Fund, Ltd. held more than five percent of outstanding Legacy OnKure's capital stock and holds more than five percent of our outstanding capital stock.
- (6) Samsara BioCapital, L.P. held more than five percent of outstanding Legacy OnKure's capital stock and holds more than five percent of our outstanding capital stock.

### **Investors' Rights Agreement**

Legacy OnKure was a party to an amended and restated investors' rights agreement with certain holders of its capital stock, including Acorn Bioventures, L.P., entities affiliated with Cormorant, Citadel Multi-Strategy Equities Master Fund Ltd., Deep Track Biotechnology Master Fund, Ltd., Perceptive Life Sciences Master Fund,

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Ltd. and Samsara BioCapital, L.P. (the “OnKure IRA”). Under the OnKure IRA, certain holders of its capital stock had the right to demand that Legacy OnKure file a registration statement or request that their shares of OnKure capital stock be covered by a registration statement that Legacy OnKure was otherwise filing. The OnKure IRA was terminated in connection with the closing of the Merger.

### **Voting Agreement**

Legacy OnKure was a party to an amended and restated voting agreement, as amended, with certain holders of its capital stock, including, among others, Anthony Piscopio, its former President and Chief Executive Officer, Keith Olivia, its former General Counsel, Senior Vice President of Corporate Affairs and Secretary, and Jim Winkler, its former Chief Scientific Officer, Acorn Bioventures, L.P., entities affiliated with Cormorant, Citadel Multi-Strategy Equities Master Fund Ltd., Deep Track Biotechnology Master Fund, Ltd., Perceptive Life Sciences Master Fund, Ltd. and Samsara BioCapital, L.P. Upon the closing of the Merger, the obligations of the parties to the voting agreement to vote their shares terminated and none of the OnKure stockholders have any special rights regarding the nomination, election or designation of members of our Board pursuant to such agreement.

### **Indemnification Agreements and Insurance**

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and officers, in addition to the indemnification provided for in our certificate of incorporation and bylaws. The indemnification agreements and our certificate of incorporation and bylaws generally require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law.

### **Policies for Approval of Related Party Transactions**

Our Board has adopted a written Related Person Transactions Policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of “related person transactions.” For purposes of our policy only, a “related person transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we or any of our subsidiaries are participants involving an amount that exceeds \$120,000, in which any “related person” has a material interest.

Transactions involving compensation for services provided to us as an employee, consultant or director will not be considered related person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than 5% of any class of our voting securities (including our Common Stock), including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, the related person in question or, in the case of transactions with a holder of more than 5% of any class of our voting securities, an officer with knowledge of a proposed transaction, must present information regarding the proposed related person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. To identify related person transactions in advance, we will rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related person transactions, our audit committee will take into account the relevant available facts and circumstances, which may include, but are not limited to:

- the risks, costs, and benefits to us;
- the impact on a director’s independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

Our audit committee will approve only those transactions that it determines are fair to us and in our best interests. All of the transactions described above were entered into prior to the adoption of such policy.

**PRINCIPAL SECURITYHOLDERS**

The following table sets forth information regarding the beneficial ownership of Class A Common Stock as of October 4, 2024, after giving effect to the Merger and the PIPE Financing by:

- each person known by us to be the beneficial owner of more than 5% of our outstanding Class A Common Stock;
- each of our executive officers and directors; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if such person possesses sole or shared voting or investment power over that security. Under those rules, beneficial ownership includes securities that such person has the right to acquire, such as through the exercise of stock options, within 60 days of the closing date of the Merger. Shares subject to warrants and options that are currently exercisable or exercisable within 60 days of the closing date are considered outstanding and beneficially owned by the person holding such warrant and/or options for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Except as noted by footnote, and subject to community property laws where applicable, based on the information provided to us, we believe that the individuals and entities named in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them. Unless otherwise noted, the business address of each of the directors and executive officers of the Company is 6707 Winchester Circle, Suite 400, Boulder, CO 80301. The percentage of beneficial ownership of the Combined Company is calculated based on 12,652,811 shares of Class A Common Stock and 686,527 shares of non-voting Class B Common Stock outstanding immediately after giving effect to the Merger and the PIPE Financing.

Name of Beneficial Owner	Number of Shares of Class A Common Stock Beneficially Owned	Percentage of Shares of Class A Common Stock Outstanding Beneficially Owned
<i>Greater than 5% Stockholders:</i>		
Acorn Bioventures, L.P. <sup>(1)</sup>	1,439,674	11.4%
Entities affiliated with Citadel Advisors <sup>(2)</sup>	1,062,836	8.4%
Entities affiliated with Cormorant Asset Management LP <sup>(3)</sup>	1,837,739	14.5%
Perceptive Life Sciences Master Fund, Ltd. <sup>(4)</sup>	1,004,439	7.9%
Samsara BioCapital, L.P. <sup>(5)</sup>	824,155	6.5%
<i>Named Executive Officers and Directors:</i>		
Nicholas A. Saccomano, Ph.D. <sup>(6)</sup>	15,062	*
Jason Leverone, CPA <sup>(7)</sup>	3,628	*
Isaac Manke, Ph.D. <sup>(8)</sup>	4,250	*
R. Michael Carruthers <sup>(9)</sup>	5,124	*
Andrew Phillips, Ph.D. <sup>(10)</sup>	4,250	*
Michael Grey <sup>(11)</sup>	92,071	*
Edward T. Mathers <sup>(12)</sup>	9,150	*
Valerie M. Jansen <sup>(13)</sup>	4,250	*
All directors and executive officers as a group (eight persons)	137,785	1.1%

\* Represents beneficial ownership of less than 1%.

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- (1) Consists of (i) 1,240,485 shares of Class A Common Stock received in the Merger, and (ii) 199,189 shares of Class A Common Stock purchased in the PIPE Financing. Acorn Capital Advisors, GP, LLC (“**Acorn GP**” is the general partner of Acorn Bioventures L.P. Acorn GP has discretionary authority to vote and dispose of the shares held by Acorn Bioventures L.P. and, accordingly, Acorn GP may be deemed to have beneficial ownership of such shares. Anders Hove is the manager of Acorn GP and, in his capacity as such, may be deemed to beneficially own the shares held by Acorn Bioventures L.P. Dr. Isaac Manke, a member of the Board, is a partner at Acorn GP. Each of Acorn GP, Dr. Hove and Dr. Manke disclaim beneficial ownership of the shares held by Acorn Bioventures L.P., except to the extent of their respective pecuniary interests therein. The business address for these persons is 420 Lexington Avenue, Suite 2626, New York, NY 10170.
- (2) Consists of (i) 702,044 shares of Class A Common Stock received in the Merger and held by Citadel Multi-Strategy Equities Master Fund Ltd. (“**CM**”) and (ii) 360,792 shares of Class A Common Stock purchased by Citadel CEMF Investments Ltd. (“**CEMF Investments**”) in the PIPE Financing. Does not include 686,527 shares of Class A Common Stock otherwise issuable to CM in the Merger that were issued instead as Class B Common Stock. The Class B Common Stock is non-voting and is convertible into the Class A Common Stock subject to a customary 9.9% beneficial ownership blocker. As a result, including the portion of the shares of Class B Common Stock that would be convertible into Class A Common Stock immediately following the Transactions would increase the beneficial ownership of CM and its affiliates to 9.9% of the shares of Class A Common Stock outstanding. Citadel Advisors LLC (“**Citadel Advisors**”) is the portfolio manager of CM and CEMF Investments. Citadel Advisors Holdings LP (“**CAH**”) is the sole member of Citadel Advisors. Citadel GP LLC (“**CGP**”) is the general partner of CAH. Kenneth Griffin owns a controlling interest in CGP. Mr. Griffin, as the owner of a controlling interest in CGP, may be deemed to have shared power to vote or direct the vote of, and/or shared power to dispose or to direct the disposition of, the shares held by CEMF. This response is not and shall not be construed as an admission that Mr. Griffin or any of the Citadel related entities listed above is the beneficial owner of any securities of the Combined Company other than the securities actually owned by such person (if any). The address for each of these persons is c/o Citadel Enterprise Americas, Southeast Financial Center, 200 S. Biscayne Blvd., Suite 3300, Miami, FL 33131.
- (3) Consists of (i) 105,845 shares of Class A Common Stock received in the Merger and held by Cormorant Global Healthcare Master Fund, LP (“**Master Fund**”) and 329,089 shares of Class A Common Stock Purchased in the PIPE Financing; (ii) 1,109,451 shares of Class A Common Stock received in the Merger and held by Cormorant Private Healthcare Fund III, LP (“**Fund III**”); (iii) 235,480 shares of Class A Common Stock received in the Merger and held by Cormorant Private Healthcare Fund IV, LP (“**Fund IV**”); (iv) 7,945 shares of Class A Common Stock received in the Merger and held by CRMA SPV, LP (“**CRMA**”); (v) 49,929 shares of Class A Common Stock purchased by Cormorant Private Healthcare Fund V, LP (“**Fund V**”) in the PIPE Financing. Cormorant Global Healthcare GP, LLC serves as the general partner of Master Fund, Cormorant Private Healthcare GP III, LLC serves as the general partner of Fund III, Cormorant Private Healthcare GP IV, LLC serves as the general partner of Fund IV, Cormorant Private Healthcare GP V, LLC serves as the general partner of Fund V, and Cormorant Asset Management, LP (“**Cormorant**”) serves as the investment manager to Master Fund, Fund III, Fund IV, Fund V and CRMA. Bihua Chen serves as the managing member of Cormorant Global Healthcare GP, LLC, Cormorant Private Healthcare GP III, LLC, Cormorant Private Healthcare GP IV, LLC and Cormorant Private Healthcare GP V, LLC, and the general partner of Cormorant and therefore may be deemed to share voting and investment power over such shares. Each of the reporting persons disclaims beneficial ownership of the shares except to the extent of its pecuniary interest therein. The address for each of reporting person is 200 Clarendon Street 52nd Floor, Boston, Massachusetts 02116.
- (4) Consists of (i) 797,282 shares of Class A Common Stock received in the Merger, and (ii) 207,157 shares of Class A Common Stock purchased by in the PIPE Financing. Perceptive Advisors LLC (the “**Advisor**”) serves as the investment manager to Perceptive Life Sciences Master Fund, Ltd. (the “**Master Fund**”). Joseph Edelman is the managing member of the Advisor. Each of Mr. Edelman and the Advisor disclaims, for purposes of Section 16 of the Securities Exchange Act of 1934, beneficial ownership of the shares held by the Master Fund, except to the extent of his/its indirect pecuniary interest therein, and this report shall not

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be deemed an admission that either Mr. Edelman or the Advisor is the beneficial owner of such securities. The address for Perceptive Life Sciences Master Fund, Ltd. and Perceptive Advisors LLC is 51 Astor Place, 10th Floor, New York, NY 10003.

- (5) Consists of (i) 654,180 shares of Class A Common Stock received in the Merger, and (ii) 169,975 shares of Class A Common Stock purchased in the PIPE Financing. Samsara BioCapital GP, LLC ("*Samsara LLC*") is the general partner of by Samsara BioCapital, L.P. ("*Samsara LP*") and therefore may be deemed to beneficially own the shares held by Samsara LP. Dr. Srinivas Akkaraju, MD, Ph.D. has voting and investment power over the shares held by Samsara LLC and, accordingly, may be deemed to beneficially own the shares held by Samsara LP. Samsara LLC disclaims beneficial ownership in these shares except to the extent of its respective pecuniary interest therein. The address for Samsara LP is 628 Middlefield Road, Palo Alto, CA 94301.
- (6) Consists of shares of Class A Common Stock subject to options held by Dr. Saccomano exercisable within 60 days of the Closing Date.
- (7) Consists of shares of Class A Common Stock subject to options held by Mr. Leverone exercisable within 60 days of the Closing Date.
- (8) Consists of shares of Class A Common Stock subject to options held by Dr. Manke exercisable within 60 days of the Closing Date.
- (9) Consists of shares of Class A Common Stock subject to options held by Mr. Carruthers exercisable within 60 days of the Closing Date.
- (10) Consists of shares of Class A Common Stock subject to options held by Dr. Phillips exercisable within 60 days of the Closing Date.
- (11) Consists of (i) 49,476 shares of Class A Common Stock held by The Grey Family Trust dated November 12, 1999 (the Grey 1999 Trust), (ii) 13,408 shares of Class A Common Stock held by Michael Grey and Rondi Rauch Grey, Co-Trustees of The Grey 2014 Irrevocable Children's Trust u/a/d 12/17/14 (the Grey 2014 Trust), and (iii) 29,187 shares of Class A Common Stock subject to options held by Mr. Grey exercisable within 60 days of the Closing Date. Mr. Grey, Reneo's former Executive Chairman and a member of the Board of the Combined Company, is trustee of each of the Grey 1999 Trust and Grey 2014 Trust, and in such capacity has the power to vote and dispose of such shares held by the Grey 1999 Trust and Grey 2014 Trust.
- (12) Consists of shares of Class A Common Stock subject to options held by Mr. Mathers exercisable within 60 days of the Closing Date.
- (13) Consists of shares of Class A Common Stock subject to options held by Ms. Jansen exercisable within 60 days of the Closing Date.

## SELLING SECURITYHOLDERS

This prospectus relates to the resale by the selling securityholders from time to time of up to an aggregate of 2,839,005 shares of Class A Common Stock that were issued to certain investors in the PIPE Financing. The selling securityholders may from time to time offer and sell any or all of the shares of Class A Common Stock set forth below pursuant to this prospectus and any accompanying prospectus supplement. When we refer to the “selling securityholders” in this prospectus, we mean the persons listed in the table below and their permitted transferees who later come to hold any of the selling securityholders’ interest in the Class A Common Stock in accordance with the terms of the applicable agreements governing their respective registration rights, other than through a public sale.

The following table sets forth, as of October 4, 2024 (after giving effect to the Merger), the names of the selling securityholders, the aggregate number of shares of Class A Common Stock beneficially owned by the selling securityholders, the aggregate number of shares of Class A Common Stock that the selling securityholders may offer pursuant to this prospectus and the number of shares of Class A Common Stock that would be beneficially owned by the selling securityholders after the sale of the shares of Class A Common Stock offered hereby assuming that the selling securityholders sell all of the shares of Class A Common Stock covered by this prospectus. The percentage of beneficial ownership after the offered shares of Class A Common Stock are sold is calculated based on 12,652,811 shares of Class A Common Stock and 686,527 shares of non-voting Class B Common Stock outstanding immediately after giving effect to the Merger and the PIPE Financing.

We have determined beneficial ownership in accordance with the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Unless otherwise indicated below, to our knowledge, the persons and entities named in the tables have sole voting and sole investment power with respect to the shares of Class A Common Stock set forth below, subject to community property laws where applicable.

We cannot advise you as to whether the selling securityholders will in fact sell any or all of such Class A Common Stock. In addition, the selling securityholders may sell, transfer or otherwise dispose of, at any time and from time to time, the Class A Common Stock in transactions exempt from the registration requirements of the Securities Act after the date of this prospectus. For purposes of this table, we have assumed that the selling securityholders will have sold all of the shares of Class A Common Stock covered by this prospectus upon the completion of the offering.



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Selling securityholder information for each additional selling securityholder, if any, will be set forth by a prospectus supplement to the extent required prior to the time of any offer or sale of such selling securityholder's shares pursuant to this prospectus. Any prospectus supplement may add, update, substitute, or change the information contained in this prospectus, including the identity of each selling securityholder and the number of shares registered on its behalf. A selling securityholder may sell or otherwise transfer all, some or none of such shares in this offering. See "Plan of Distribution."

Name of Selling Securityholder	Common Stock Beneficially Owned Prior to Offering	Number of Shares of Common Stock Being Offered	Common Stock Beneficially Owned After the Offered Shares of Common Stock are Sold	
			Number	Percent
Acorn Bioventures, L.P. <sup>(1)</sup>	1,439,674	199,189	1,240,485	9.8
Cormorant Global Healthcare Master Fund, LP <sup>(2)</sup>	434,934	329,089	105,845	*
Cormorant Private Healthcare Fund V, LP <sup>(2)</sup>	49,929	49,929	0	—
Citadel CEMF Investments Ltd. <sup>(3)</sup>	360,792	360,792	0	—
Perceptive Life Sciences Master Fund, Ltd. <sup>(4)</sup>	1,004,439	207,157	797,282	6.3
Deep Track Biotechnology Master Fund, Ltd. <sup>(5)</sup>	660,136	136,147	523,989	4.1
Samsara BioCapital, L.P. <sup>(6)</sup>	824,155	169,975	654,180	5.2
BlackRock, Inc. <sup>(7)</sup>	463,586	95,610	367,976	2.9
StepStone Master G, L.P. <sup>(8)</sup>	491,938	199,189	292,749	2.3
Affinity Healthcare Fund, LP <sup>(9)</sup>	174,708	174,708	0	—
Altium Growth Fund, LP <sup>(10)</sup>	218,386	218,386	0	—
Boulder Ventures VIII, L.P. <sup>(11)</sup>	43,677	43,677	0	—
Entities affiliated with Monashee Investment Management, LLC <sup>(12)</sup>	131,031	131,031	0	—
Sphera Biotech Master Fund LP <sup>(13)</sup>	87,354	87,354	0	—
Entities Affiliated with Vestal Point Capital, LP <sup>(14)</sup>	516,710	436,772	79,938	*
Total Shares	6,901,449	2,839,005	4,062,444	32.1

\* Less than 1%

- (1) Acorn Capital Advisors, GP, LLC ("**Acorn GP**") is the general partner of Acorn Bioventures L.P. Acorn GP has discretionary authority to vote and dispose of the shares held by Acorn Bioventures L.P. and, accordingly, Acorn GP may be deemed to have beneficial ownership of such shares. Anders Hove is the manager of Acorn GP and, in his capacity as such, may be deemed to beneficially own the shares held by Acorn Bioventures L.P. Dr. Isaac Manke, a member of the Board, is a partner at Acorn GP. Each of Acorn GP, Dr. Hove and Dr. Manke disclaim beneficial ownership of the shares held by Acorn Bioventures L.P., except to the extent of their respective pecuniary interests therein. The business address for these persons is 420 Lexington Avenue, Suite 2626, New York, NY 10170.
- (2) Cormorant Global Healthcare GP, LLC serves as the general partner of Master Fund, Cormorant Private Healthcare GP III, LLC serves as the general partner of Fund III, Cormorant Private Healthcare GP IV, LLC serves as the general partner of Fund IV, Cormorant Private Healthcare GP V, LLC serves as the general partner of Fund V, and Cormorant Asset Management, LP ("**Cormorant**") serves as the investment manager to Master Fund, Fund III, Fund IV, Fund V and CRMA. Bihua Chen serves as the managing member of Cormorant Global Healthcare GP, LLC, Cormorant Private Healthcare GP III, LLC, Cormorant Private Healthcare GP IV, LLC and Cormorant Private Healthcare GP V, LLC, and the general partner of Cormorant and therefore may be deemed to share voting and investment power over such shares. Each of the reporting persons disclaims beneficial ownership of the shares except to the extent of its pecuniary interest therein. The address for each of reporting person is 200 Clarendon Street 52nd Floor, Boston, Massachusetts 02116.

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- (3) Citadel Advisors LLC (“**Citadel Advisors**”) is the portfolio manager of Citadel CEMF Investments Ltd. Citadel Advisors Holdings LP (“**CAH**”) is the sole member of Citadel Advisors. Citadel GP LLC (“**CGP**”) is the general partner of CAH. Kenneth Griffin owns a controlling interest in CGP. Mr. Griffin, as the owner of a controlling interest in CGP, may be deemed to have shared power to vote or direct the vote of, and/or shared power to dispose or to direct the disposition of, the shares held by CEMF. This disclosure is not and shall not be construed as an admission that Mr. Griffin or any of the Citadel related entities listed above is the beneficial owner of any securities of the Combined Company other than the securities actually owned by such person (if any). The address for each of these persons is c/o Citadel Enterprise Americas, Southeast Financial Center, 200 S. Biscayne Blvd., Suite 3300, Miami, FL 33131.
- (4) Perceptive Advisors LLC (the “**Advisor**”) serves as the investment manager to Perceptive Life Sciences Master Fund, Ltd. (the “**Master Fund**”). Joseph Edelman is the managing member of the Advisor. Each of Mr. Edelman and the Advisor disclaims, for purposes of Section 16 of the Securities Exchange Act of 1934, beneficial ownership of the shares held by the Master Fund, except to the extent of his/its indirect pecuniary interest therein, and this report shall not be deemed an admission that either Mr. Edelman or the Advisor is the beneficial owner of such securities. The address for Perceptive Life Sciences Master Fund, Ltd. And Perceptive Advisors LLC is 51 Astor Place, 10th Floor, New York, NY 10003.
- (5) Mr. David Kroin is the managing member of Deep Track Capital GP, LLC, the general partner of Deep Track Capital, L.P., and by virtue of such status may be deemed to be the beneficial owner of the shares owned by Deep Track Master Fund. Deep Track Capital, L.P. and Mr. Kroin disclaim beneficial ownership over the shares held by Deep Track Biotechnology Master Fund, Ltd., except to the extent of their respective pecuniary interests. The address for Deep Track Biotechnology Master Fund, Ltd. and Deep Track Capital, L.P. is 200 Greenwich Avenue, 3rd Floor, Greenwich, CT 06830.
- (6) Samsara BioCapital GP, LLC (“**Samsara LLC**”) is the general partner of Samsara BioCapital, L.P. (“**Samsara LP**”) and therefore may be deemed to beneficially own the shares held by Samsara LP. Dr. Srinivas Akkaraju, MD, Ph.D. has voting and investment power over the shares held by Samsara LLC and, accordingly, may be deemed to beneficially own the shares held by Samsara LP. Samsara LLC disclaims beneficial ownership in these shares except to the extent of its respective pecuniary interest therein. The address for Samsara LP is 628 Middlefield Road, Palo Alto, CA 94301.
- (7) The registered holders of the referenced shares to be registered are the following funds and accounts under management by subsidiaries of BlackRock, Inc.: BlackRock Health Sciences Term Trust. BlackRock, Inc. is the ultimate parent holding company of such subsidiaries. On behalf of such subsidiaries, the applicable portfolio managers, as managing directors (or in other capacities) of such entities, and/or the applicable investment committee members of such funds and accounts, have voting and investment power over the shares held by the funds and accounts which are the registered holders of the referenced shares. Such portfolio managers and/or investment committee members expressly disclaim beneficial ownership of all shares held by such funds and accounts. The address of such funds and accounts, such subsidiaries and such portfolio managers and/or investment committee members is 60 State Street, 19th/20th Floor, Boston, MA 02109. Shares shown include only the securities being registered for resale and may not incorporate all shares deemed to be beneficially held by the registered holders or BlackRock, Inc.
- (8) StepStone Group LP (“**StepStone**”) is the investment manager of StepStone Master G, L.P. StepStone Group Holdings LLC (“**StepStone Group Holdings**”) is the general partner of StepStone, and StepStone Group Inc. is the sole managing member of StepStone Group Holdings. The business address of StepStone and StepStone Master G, L.P. is 4225 Executive Square, Suite 1600, La Jolla, CA 92037.
- (9) Affinity Asset Advisors, LLC (the “**Advisor**”) is the investment manager of Affinity Healthcare Fund, LP (the “**Fund**”) and exercises investment discretion with regard to the shares of Common Stock owned by the Fund. Michael Cho is the managing member of the Advisor. The Fund and the Advisor have the shared power to vote or to direct the vote and to dispose or direct the disposition of such shares of Common Stock of the Issuer owned by the Fund. The Advisor may be deemed to be the beneficial owner of such shares of Common Stock of the Issuer owned by the Fund by virtue of its position as investment manager of the Fund. The principal business address of each of the Fund and the Advisor is 767 Third Avenue, 15th Floor, New York, NY 10017.

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- (10) Altium Capital Management, LP, the investment manager of Altium Growth Fund, LP, has voting and investment power over these securities. Jacob Gottlieb is the managing member of Altium Capital Growth GP, LLC, which is the general partner of Altium Growth Fund, LP. Each of Altium Growth Fund, LP and Jacob Gottlieb disclaims beneficial ownership over these securities. The principal address of Altium Capital Management, LP is 152 West 57th Street, 20th Floor, New York, NY 10019.
- (11) Consists of 38,620 shares held by Boulder Ventures VIII, L.P. and 5,057 shares held by Boulder Ventures VIII (Annex), L.P. BV Partners VIII LLC (“**BV GP**”) is the general partner of Boulder Ventures VIII L.P. and Boulder Ventures VIII (Annex) L.P. BV GP has the discretionary authority to vote and dispose of the shares held by Boulder Ventures VIII L.P. and Boulder Ventures VIII (Annex) L.P. and, accordingly, BV GP may be deemed to have beneficial ownership of such shares. Kyle Lefkoff is a Managing Member of BV GP and, in his capacity as such, may be deemed to beneficially own the shares held by Boulder Ventures VIII L.P. and Boulder Ventures VIII (Annex) L.P. Mr. Lefkoff disclaims beneficial ownership of the shares held by Boulder Ventures VIII L.P. and Boulder Ventures VIII (Annex) L.P., except to the extent of his pecuniary interest therein. The business address for Mr. Lefkoff and Boulder Ventures is 1941 Pearl Street, Suite 300, Boulder, Colorado, 80302.
- (12) Consists of 35,379 shares held by BEMAP Master Fund LTD (“**BEMAP**”), 11,792 shares held by Mission Pure Alpha LP (“**Mission**”), 40,620 shares held by Monashee Pure Alpha SPV I LP (“**Pure Alpha**”) and 43,240 shares held by Blackstone CSP-MST FMAP Fund (“**FMAP**”). BEMAP, Mission, Pure Alpha, and FMAP are managed by Monashee Investment Management, LLC (“**Monashee Management**”). Jeff Muller is CCO of Monashee Management and has voting and investment control over Monashee Management and, accordingly, may be deemed to have beneficial ownership of the shares held by BEMAP, Pure Alpha, Mission, and FMAP. Jeff Muller, however, disclaims any beneficial ownership of the shares held by these entities. The business address of BEMAP, Pure Alpha, Mission, FMAP and Mr. Muller is c/o Monashee Investment Management, LLC, 75 Park Plaza, 4th Floor, Boston, Massachusetts 02116.
- (13) Sphera Biotech Master Fund LP (“**Sphera Biotech**”) has delegated its investment management authority to Sphera Global Healthcare Management LP (“**Sphera Management**”). Accordingly, Sphera Management may be deemed to have beneficial ownership of the shares held by Sphera Biotech. Sphera Management disclaims beneficial ownership of such shares, except to the extent of its pecuniary interest therein. Sphera Biotech and Sphera Management business address is 4 Yitzhak Sadeh, Building A, 29th Floor, Tel Aviv 6777520, Israel.
- (14) Shares listed under “Common Stock Beneficially Owned Prior to Offering” consist of (i) 258,882 shares held by Vestal Point Master Fund, LP and (ii) 257,828 shares held by an account separately managed by Vestal Point Capital, LP. The sole general partner of Vestal Point Master Fund, LP is Vestal Point Partners GP, LLC. The managing member of Vestal Point Partners GP, LLC is Ryan Wilder. The sole general partner of Vestal Point Capital, LP is Vestal Point Capital, LLC. The managing member of Vestal Point Capital, LLC is Mr. Wilder. As a result, Mr. Wilder may be deemed to have voting and investment power over the securities held by Vestal Point Master Fund, LP and the account separately managed by Vestal Point Capital, LP. Mr. Wilder disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein. The address of these entities and Mr. Wilder is c/o Vestal Point Capital, LP, 632 Broadway, Suite 602, New York, NY 10012.

Please see the sections titled “Certain Relationships, Related Party and Other Transactions” appearing elsewhere in this prospectus for information regarding material relationships with our selling securityholders within the past two years.

## DESCRIPTION OF SECURITIES

The following description of our capital stock and provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws are summaries and are qualified by reference to our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and applicable provisions of Delaware corporate law.

### Authorized Capital Stock

The total number of authorized shares of capital stock consists of (i) 210,000,000 shares of common stock, par value \$0.0001 per share, of which 200,000,000 shares are designated Class A Common Stock and 10,000,000 shares are designated Class B Common Stock and (ii) 10,000,000 shares of preferred stock, par value \$0.0001 per share.

### Class A Common Stock

#### *Voting*

Holders of shares of Class A Common Stock are entitled to one vote for each share held of record on all matters on which stockholders are entitled to vote generally, except that holders of shares of Class A Common Stock will have no voting power with respect to, and will not be entitled to vote on, any amendment to the Amended Certificate of Incorporation (including any certificate of designations relating to any series of Preferred Stock) that relates solely to the terms of any outstanding preferred stock if the holders of such preferred stock are entitled to vote as a separate class thereon under the Amended Certificate of Incorporation or under the DGCL. The holders of Class A Common Stock do not have cumulative voting rights in the election of directors.

#### *Dividends*

Holders of shares of Class A Common Stock are entitled to receive dividends when, as and if declared by the board of directors out of funds legally available therefor, subject to any statutory or contractual restrictions on the payment of dividends and to any restrictions on the payment of dividends imposed by the terms of any outstanding preferred stock.

#### *Distributions on Liquidation*

Upon its liquidation, dissolution or winding up and after payment in full of all amounts required to be paid to creditors and to the holders of preferred stock having liquidation preferences, if any, the holders of shares of Class A Common Stock will be entitled to receive pro rata the remaining assets available for distribution.

#### *Other Rights*

Holders of our common stock have no preemptive, subscription, redemption or conversion rights and no sinking fund provisions are applicable to our common stock. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

### Class B Common Stock

Except as expressly set forth below with respect to voting rights and conversion rights only, the Class B Common Stock has the same rights and powers of, ranks equally to, shares ratably with and is identical in all respects and as to all matters to Class A Common Stock. If we in any manner subdivide or combine the shares of Class A Common Stock, then the shares of Class B Common Stock will be subdivided or combined in the same

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proportion and manner, and if we in any manner subdivide or combine the shares of Class B Common Stock, then the outstanding shares of Class A Common Stock will be subdivided or combined in the same proportion and manner.

### ***Voting Rights***

Holders of shares of Class B Common Stock shall have no voting rights and are not entitled to vote on any matter, including the election of directors, at any time.

### ***Conversion Rights***

Shares of Class B Common Stock are convertible into a corresponding number of fully paid and nonassessable shares of Class A Common Stock upon written notice by the holder thereof. Notwithstanding anything to the contrary in the Amended Certificate of Incorporation, no holder of Class B Common Stock shall be entitled to receive, and we shall not deliver to any such holder, any Class A Common Stock upon conversion of the Class B Common Stock to the extent (but only to the extent) that, after such receipt, such converting holder and its affiliates (together, the “Related Holders”) would beneficially own in the aggregate, directly or indirectly, shares of Class A Common Stock in excess of the Beneficial Ownership Limitation Percentage (as defined below) (this provision, the “Beneficial Ownership Limitation”). For the avoidance of doubt, in the event that the Related Holders beneficially own in the aggregate, directly or indirectly, shares of Class A Common Stock equal to or in excess of the Beneficial Ownership Limitation Percentage without taking into account the conversion of Class B Common Stock, then none of the Class B Common Stock shall be convertible into shares of Class A Common Stock until such time as the Related Holders no longer beneficially own in the aggregate, directly or indirectly, shares of Class A Common Stock equal to or in excess of the Beneficial Ownership Limitation Percentage. The “Beneficial Ownership Limitation Percentage” means initially 9.9% of the then-outstanding shares of Class A Common Stock. Any holder of Class B Common Stock may increase the Beneficial Ownership Limitation Percentage with respect to such holder upon 61 days’ prior written notice (but, prior to the Restriction Lapse Date (as defined below), not above 9.9% of the then-outstanding shares of Class A Common Stock) and may decrease the Beneficial Ownership Limitation Percentage at any time upon providing written notice of such election; provided, however, that no holder may make such an election to change the Beneficial Ownership Limitation Percentage with respect to such holder unless all holders managed by the same investment advisor as such electing holder make the same election. “Restriction Lapse Date” means the date that the original recipient of Class B Common Stock (the “Original Recipient”) issued Class B Common Stock as merger consideration pursuant to the Merger Agreement, and the Original Recipient’s affiliates cease to hold any shares of Class B Common Stock.

### **Preferred Stock**

Our board of directors is authorized, without action by the stockholders, to designate and issue up to an aggregate of 10,000,000 shares of preferred stock in one or more series. Our board of directors can designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of the Company, which might harm the market price of our common stock. Our board of directors will make any determination to issue such shares based on its judgment as to our best interests and the best interests of our stockholders.

### **Annual Stockholder Meetings**

Our Amended Bylaws provide that annual stockholder meetings will be held at a date, time and place, if any, as may be designated by the board of directors. To the extent permitted under applicable law, we may conduct meetings by remote communication as provided by the DGCL.

### **Anti-Takeover Effects of the Certificate of Incorporation, Amended Bylaws and Certain Provisions of Delaware Law**

Our Amended Certificate of Incorporation, our Amended Bylaws and certain provisions of the DGCL contain provisions, which are summarized in the following paragraphs, that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors. These provisions are intended to avoid costly takeover battles, reduce our vulnerability to a hostile or abusive change of control and enhance the ability of the board of directors to maximize stockholder value in connection with any unsolicited offer to acquire us. However, these provisions may have an anti-takeover effect and may delay, deter or prevent a merger or acquisition of us by means of a tender offer, a proxy contest or other takeover attempt that a stockholder might consider in its best interest, including those attempts that might result in a premium over the prevailing market price for the shares held by stockholders.

#### *Authorized but Unissued Capital Stock*

Delaware Law does not require stockholder approval for any issuance of shares that are authorized and available for issuance. However, the listing requirements of Nasdaq, which would apply so long as Class A Common Stock remains listed on Nasdaq, require stockholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power of our capital stock or then outstanding number of shares of Class A Common Stock. These additional shares may be used for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions.

The board of directors will be authorized to generally issue shares of one or more series of preferred stock on terms calculated to discourage, delay or prevent a change of control of the Company or the removal of its management. Moreover, our authorized but unissued shares of preferred stock will be available for future issuances in one or more series without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, to facilitate acquisitions and employee benefit plans.

One of the effects of the existence of authorized and unissued and unreserved Class A Common Stock or preferred stock may be to enable our Board to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of its management and possibly deprive its stockholders of opportunities to sell their shares of Class A Common Stock at prices higher than prevailing market prices.

#### *Vacancies and Newly Created Directorships*

The Amended Certificate of Incorporation and Amended Bylaws provide that, subject to any rights of any series of preferred stock that may be designated, any vacancies on the board of directors, and any newly created directorships, will be filled only by the affirmative vote of a majority of the remaining directors then in office, even if less than a quorum, and any director so chosen will hold office until the earlier expiration of the term of office of the director whom he or she has replaced or his or her successor shall be duly elected and qualified or until such director's earlier death, disqualification, resignation or removal. No decrease in the number of directors shall shorten the term of any director then in office.

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### *Removal of Directors*

Under the Amended Bylaws, subject to the right of any series of preferred stock, any or all members of the board of directors may be only removed for cause by at least a 66 2/3% vote of the shares then entitled to vote generally in the election of directors, voting together as a single class.

### *No Cumulative Voting*

Under Delaware Law, the right to vote cumulatively does not exist unless the certificate of incorporation specifically authorizes cumulative voting. The Amended Certificate of Incorporation does not authorize cumulative voting. Therefore, stockholders holding a majority in voting power of the shares of Class A Common Stock entitled to vote generally in the election of directors will be able to elect all directors.

### *Special Stockholder Meetings*

The Amended Certificate of Incorporation and the Amended Bylaws provide that special meetings of stockholders may be called only by the chair of the board of directors, the chief executive officer or at the direction of the board of directors pursuant to a written resolution adopted by a majority of the total number of directors that the Company would have if there were no vacancies. Any business transacted at a special meeting of stockholders will be limited to matters set forth in the notice of the special meeting. These provisions may have the effect of deterring, delaying or discouraging hostile takeovers, or changes in control or management.

### *Director Nominations and Stockholder Proposals*

The Amended Bylaws contain advance notice procedures with respect to stockholder nominations for the election as directors. In order for any matter to be “properly brought” before a meeting, a stockholder will have to comply with advance notice requirements and provide us with certain information. Generally, to be timely, a stockholder’s notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the immediately preceding annual meeting of stockholders. The Amended Bylaws also specify requirements as to the form and content of a stockholder’s notice. The Amended Bylaws allow the chair of the meeting at a meeting of the stockholders to adopt rules and regulations for the conduct of meetings which may have the effect of precluding the conduct of certain business at a meeting if the rules and regulations are not followed. These provisions may also defer, delay or discourage a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to influence or obtain control of the Company.

### *Stockholder Action by Written Consent*

Pursuant to Section 228 of the DGCL, any action required to be taken at any annual or special meeting of the stockholders may be taken without a meeting, without prior notice and without a vote if a consent or consents in writing, setting forth the action so taken, is or are signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares of stock entitled to vote thereon were present and voted, unless the certificate of incorporation provides otherwise. The Amended Certificate of Incorporation precludes stockholder action by written consent.

These provisions may have the effect of deterring hostile takeovers or delaying or preventing changes in control of the Company or its management, such as a merger, reorganization or tender offer. These provisions are intended to enhance the likelihood of continued stability in the composition of the board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of the board of directors. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions are also intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares



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and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. Such provisions may also have the effect of preventing changes in management.

### *Amendments to Governing Documents*

Pursuant to the Amended Certificate of Incorporation and Amended Bylaws, the board of directors is expressly empowered to adopt, amend or repeal the Amended Bylaws. Any adoption, amendment or repeal of the Amended Bylaws by the board of directors shall require the approval of a majority of the authorized number of directors. Our stockholders also have power to adopt, amend or repeal the Amended Bylaws; provided, however, that, in addition to any vote of the holders of any class or series of stock required by law, such action by stockholders shall require the affirmative vote of the holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the capital stock entitled to vote generally in the election of directors, voting together as a single class.

### **DGCL Section 203**

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, those provisions prohibit a Delaware corporation, including those whose securities are listed for trading on Nasdaq, from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

- the transaction is approved by the board of directors before the date the interested stockholder attained that status;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced; or
- on or after such time the business combination is approved by the board of directors and authorized at a meeting of stockholders by at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, exchange, mortgage or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of directly or indirectly increasing the proportionate share of the stock of any class or series, or securities convertible into the stock of any class or series, of the corporation beneficially owned by the interested stockholder; or
- the direct or indirect receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

Generally, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.



### **Dissenters' Rights of Appraisal and Payment**

Under the DGCL, with certain exceptions, including the circumstances where the Common Stock is, at the effective date of a merger or consolidation, either listed on a national securities exchange or held of record by more than 2,000 holders, our stockholders will have appraisal rights in connection with a merger or consolidation of the Company. Pursuant to the DGCL, stockholders who properly request and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

### **Stockholders' Derivative Actions**

Under the DGCL, any stockholders may bring an action in our name to procure a judgment in our favor, also known as a derivative action, provided that the stockholder bringing the action is a holder of our shares at the time of the transaction to which the action relates or such stockholder's stock thereafter devolved by operation of law.

### **Exclusive Forum**

The Amended Certificate of Incorporation provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for any (i) derivative action or proceeding brought on behalf of the Company, (ii) action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or our stockholders, (iii) action asserting a claim arising pursuant to any provision of the DGCL or the Amended Certificate of Incorporation or Amended Bylaws, or (iv) action asserting a claim governed by the internal affairs doctrine. This provision does not apply to any actions arising under the Securities Act. Any person or entity purchasing or otherwise acquiring or holding any interest in any security of the Company shall be deemed to have notice of and consented to the forum provisions in the Amended Certificate of Incorporation. However, the enforceability of similar forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be unenforceable. Additionally, 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 and stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

### **Limitations on Liability and Indemnification of Officers and Directors**

The DGCL authorizes corporations to limit or eliminate the personal liability of directors and officers to corporations and their stockholders for monetary damages for breaches of directors' and officers' fiduciary duties, subject to certain exceptions. The Amended Certificate of Incorporation will include a provision that eliminates the personal liability of directors and officers for monetary damages to the corporation or its stockholders for any breach of fiduciary duty as a director or an officer. The effect of these provisions is to eliminate the rights of the Company and our stockholders, through stockholders' derivative suits on our behalf, to recover monetary damages from a director or an officer for breach of fiduciary duty as a director or an officer, including breaches resulting from grossly negligent behavior. However, exculpation will not apply to any breaches of a director's or officer's duty of loyalty, acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, or for any transaction from which such director or officer derived an improper personal benefit.

The Amended Certificate of Incorporation and the Amended Bylaws generally provide that we must defend, indemnify and advance expenses to our directors and officers to the fullest extent permitted or required by the DGCL. We are expressly authorized to carry directors' and officers' liability insurance providing indemnification for our directors, officers and certain employees for some liabilities. We believe that these indemnification and advancement provisions and insurance are useful to attract and retain qualified directors and executive officers.

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The limitation of liability, indemnification and advancement provisions in the Amended Certificate of Incorporation and Amended Bylaws may discourage stockholders from bringing a lawsuit against directors or officers for breach of their fiduciary duties. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit the Company and our stockholders.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our Class A Common Stock is Equiniti Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

### **Listing**

Our Class A Common Stock is listed on the Nasdaq Global Market under the symbol "OKUR."

## PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- in settlement of short sales;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- through the distribution of the common stock by any selling stockholder to its partners, members or stockholders;
- directly to one or more purchasers;
- through delayed delivery requirements;
- by pledge to secured debts and other obligations;
- a combination of any such methods of sale; and
- any other method permitted by applicable law.

In addition, a selling stockholder that is an entity may elect to make a pro rata in-kind distribution of shares to its members, partners or stockholders pursuant to the registration statement of which this prospectus is a part by delivering a prospectus with a plan of distribution. Such members, partners or stockholders would thereby receive freely tradeable securities pursuant to the distribution through a registration statement.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the

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pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended (the “Securities Act”), amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling stockholders for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule, or another available exemption from the registration requirements of the Securities Act.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be “underwriters” within the meaning of Section 2(a)(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. (it being understood that the Selling Stockholders shall not be deemed to be underwriters solely as a result of their participation in this offering). Selling stockholders who are “underwriters” within the meaning of Section 2(a)(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934, as amended, may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, to the extent applicable, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

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We will pay all expenses of the registration of the shares pursuant to the registration rights agreement with the selling stockholders dated October 4, 2024 (the “Registration Rights Agreement”), including, without limitation, SEC filing fees and expenses of compliance with state securities or “Blue Sky” laws; provided, however, that we will not be responsible for any underwriting fees, discounts or commissions attributable to the sale of the shares and any legal fees and expenses of counsel to the selling stockholders. We have agreed pursuant to the Registration Rights Agreement to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholders pursuant to the Registration Rights Agreement to use commercially reasonable efforts to cause the registration statement of which this prospectus constitutes a part to be declared or otherwise become effective and to remain continuously effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with such registration statement or (2) the date that all the shares covered by this prospectus cease to be Registrable Securities as defined in the Registration Rights Agreement.

There can be no assurance that any selling stockholder will sell any or all of the shares registered pursuant to the registration statement, of which this prospectus forms a part. Once sold hereunder, the shares will be freely tradable in the hands of persons, other than our affiliates.

## **LEGAL MATTERS**

The validity of the securities offered hereby has been passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation.

## **EXPERTS**

The consolidated financial statements of Reneo Pharmaceuticals, Inc. at December 31, 2023 and 2022, and for each of the two years in the period ended December 31, 2023, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The financial statements of OnKure, Inc. as of December 31, 2023 and 2022, and for each of the years in the two year period then ended, have been included herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

The audit report covering the December 31, 2023 financial statements contains an explanatory paragraph that states that OnKure, Inc.'s recurring losses from operations and an accumulated deficit raise substantial doubt about OnKure, Inc.'s ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of that uncertainty.

## **WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act that registers the shares of our Class A Common Stock to be sold in this offering. The registration statement, including the attached exhibits and schedules, contains additional relevant information about us and our capital stock. The rules and regulations of the SEC allow us to omit from this prospectus certain information included in the registration statement. For further information about us and the Securities, you should refer to the registration statement and the exhibits and schedules filed with the registration statement. With respect to the statements contained in this prospectus regarding the contents of any agreement or any other document, in each instance, the statement is qualified in all respects by the complete text of the agreement or document, a copy of which has been filed as an exhibit to the registration statement.

We are subject to the informational reporting requirements of the Exchange Act. We file reports, proxy statements and other information with the SEC under the Exchange Act. Our SEC filings are available over the Internet at the SEC's website at <http://www.sec.gov>. Our website address is <https://onkuretherapeutics.com/>. The information on, or that can be accessed through, our website is not part of this prospectus.

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders  
OnKure, Inc.:

*Opinion on the Financial Statements*

We have audited the accompanying balance sheets of OnKure, Inc. (the Company) as of December 31, 2023 and 2022, the related statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2023, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

*Going Concern*

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*Basis for Opinion*

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the relevant ethical requirements relating to our audits.

We conducted our audits in accordance with the auditing standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2021.

Boulder, Colorado  
May 13, 2024

**ONKURE, INC.**  
**BALANCE SHEETS**  
(in thousands, except share and per share data)

	<u>December 31,</u>	
	<u>2023</u>	<u>2022</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 29,876	\$ 11,543
Prepaid clinical trials	3,192	1,240
Prepaid expenses and other current assets	698	840
Total current assets	33,766	13,623
Property and equipment, net	1,432	1,604
Operating lease right-of-use asset	478	443
Other assets	58	329
Total assets	<u>\$ 35,734</u>	<u>\$ 15,999</u>
<b>Liabilities, Convertible Preferred Stock, and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 3,417	\$ 2,520
Accrued expenses	3,660	2,871
Operating lease liability, current portion	208	151
Total current liabilities	7,285	5,542
Operating lease liability, net of current portion	466	486
Total liabilities	7,751	6,028
Commitments and contingencies		
Convertible preferred stock	129,825	64,389
Stockholders' deficit:		
Common stock, Class A, \$0.0001 par value; 78,000,000 and 40,000,000 shares authorized; 13,296,584 and 7,745,744 shares issued and outstanding as of December 31, 2023 and 2022, respectively.	1	1
Common stock, Class B, \$0.0001 par value; 9,589,983 shares authorized; 0 shares issued and outstanding.	—	—
Additional paid-in capital	208	2,655
Accumulated deficit	(102,051)	(57,074)
Total stockholders' deficit	(101,842)	(54,418)
Total liabilities, convertible preferred stock, and stockholders' deficit	<u>\$ 35,734</u>	<u>\$ 15,999</u>

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

**ONKURE, INC.**  
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(in thousands, except share and pre share data)**

	Year Ended	
	December 31,	
	2023	2022
<b>Operating expenses:</b>		
Research and development	\$ 32,115	\$ 25,862
General and administrative	4,819	3,904
Total operating expenses	<u>36,934</u>	<u>29,766</u>
<b>Loss from operations</b>	<u>(36,934)</u>	<u>(29,766)</u>
Other income:		
Interest income	1,623	254
Total other income	<u>1,623</u>	<u>254</u>
<b>Net loss and comprehensive loss</b>	<u><u>\$ (35,311)</u></u>	<u><u>\$ (29,512)</u></u>

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

**ONKURE, INC**  
**STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**  
(in thousands, except share information)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
<b>Balance as of December 31, 2021</b>	15,870,584	\$ 38,264	6,917,439	\$ 1	\$ 2,267	\$ (27,562)	\$ (25,294)
Issuance of Series B Preferred Stock under a stock purchase agreement, net of issuance costs of \$1.4 million	9,951,868	26,125	—	—	—	—	—
Issuance of Class A Common Stock for cash upon the exercise of stock options	—	—	828,305	—	340	—	340
Share-based compensation expense	—	—	—	—	48	—	48
Net loss	—	—	—	—	—	(29,512)	(29,512)
<b>Balance as of December 31, 2022</b>	<u>25,822,452</u>	<u>\$ 64,389</u>	<u>7,745,744</u>	<u>\$ 1</u>	<u>\$ 2,655</u>	<u>\$ (57,074)</u>	<u>\$ (54,418)</u>
Issuance of Series C Preferred Stock under a stock purchase agreement, net of issuance costs of \$0.7 million	19,463,456	53,059	—	—	—	—	—
Issuance of Class A Common Stock and Series C Preferred Stock in exchange for Series A, A-1, and Series B Preferred Stock under a stock purchase agreement	1,957,898	12,377	5,402,428	—	(2,711)	(9,666)	(12,377)
Issuance of Class A Common Stock for cash upon the exercise of stock options	—	—	148,412	—	65	—	65
Share-based compensation expense	—	—	—	—	199	—	199
Net loss	—	—	—	—	—	(35,311)	(35,311)
<b>Balance as of December 31, 2023</b>	<u>47,243,806</u>	<u>\$129,825</u>	<u>13,296,584</u>	<u>\$ 1</u>	<u>\$ 208</u>	<u>\$ (102,051)</u>	<u>\$ (101,842)</u>

*See accompanying notes are an integral part of these financial statements.*

**ONKURE, INC.**  
**STATEMENTS OF CASH FLOWS**  
**(in thousands)**

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$(35,311)	\$(29,512)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	199	48
Depreciation and amortization	417	229
Amortization of right-of-use asset	143	158
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,497)	(332)
Accounts payable and accrued liabilities	1,713	2,650
Lease liability	(210)	(194)
Net cash used in operating activities	<u>(34,546)</u>	<u>(26,953)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(246)	(1,134)
Net cash used in investing activities	<u>(246)</u>	<u>(1,134)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of Convertible Preferred Stock	53,783	27,500
Payment of issuance costs associated with the issuance of preferred stock	(723)	(1,375)
Proceeds from issuance of common stock in connection with equity plans	65	340
Net cash provided by financing activities	<u>53,125</u>	<u>26,465</u>
Net increase (decrease) in cash and cash equivalents	18,333	(1,622)
Cash and cash equivalents at beginning of period	11,543	13,165
Cash and cash equivalents at end of period	<u>\$ 29,876</u>	<u>\$ 11,543</u>
<b>Supplemental disclosure of non-cash financing activities:</b>		
Right-of-use asset obtained in exchange for new operating lease liability	\$ 219	\$ 562
Issuance of Series C Preferred Stock conversion	<u>\$ 23,313</u>	<u>—</u>

*The accompanying notes are an integral part of these financial statements*

**ONKURE, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

**(1) DESCRIPTION OF BUSINESS**

OnKure, 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. The Company is using its structure-based drug design platform to build a robust pipeline of tumor-agnostic candidates that are designed to achieve optimal efficacy and tolerability. OnKure is currently developing OKI-219, a selective PI3K $\alpha$ <sup>H1047R</sup> inhibitor, as its lead program. OnKure aims to become the leader in targeting oncogenic PI3K $\alpha$  and has multiple programs to enable optimal targeting of this critical oncogene.

*Risks and Uncertainties*

The board of directors of the Company discusses with management macroeconomic and geopolitical developments, including inflation, instability in the banking and financial services sector, tightening of the credit markets, international conflicts, COVID-19, cybersecurity, and sanctions so that the Company can be prepared to react to new developments as they arise. The board of directors and the management of the Company are carefully monitoring these developments and the resulting economic impact on its financial condition and results of operations.

*Liquidity and Capital Resources*

The Company had recurring losses from operations, an accumulated deficit of \$102.1 million and cash and cash equivalents of \$29.9 million as of December 31, 2023. 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. As a result, the Company has determined that substantial doubt about the Company’s ability to continue as a going concern for a period of at least 12 months from the date of the issuance of these financial statements does exist.

The Company’s ability to secure capital is dependent upon 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 may be unable to realize value from the Company’s assets or discharge liabilities in the normal course of business, which may, among other alternatives, cause the Company to delay, substantially reduce, or discontinue operational activities to conserve cash, which could have a material adverse effect on the Company’s ability to achieve its intended business objectives.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. 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. The Company believes that the \$29.9 million of cash and cash equivalents on hand as of December 31, 2023, will not be sufficient to fund its operations in the normal course of business and meet its liquidity needs through at least the next 12 months from the issuance of these financial statements. As such, the Company will need to raise additional capital to finance its operations and the ability to do so is uncertain. As a result, the Company has determined there is substantial doubt about the Company’s ability to continue as a going concern for a period of at least 12 months from the date of the issuance of these financial statements.

Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on the Company’s financial condition and its ability to discover and develop its product candidates. Changing

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circumstances may cause the Company to consume capital significantly faster or slower than currently anticipated. If the Company is unable to acquire additional capital or resources, it will be required to modify its operational plans. 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 financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

### **(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

#### *Basis of Presentation*

The accompanying financial statements as of and for the year ended December 31, 2023, and as of December 31, 2022, include the accounts of OnKure, Inc.

The financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) and include all adjustments necessary for the fair presentation of the Company’s financial position, results of operations, and cash flows for the periods presented.

#### *Segment Information*

The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein. All equipment and other fixed assets are physically located within the United States.

#### *Use of Estimates*

The preparation of the financial statements in accordance with U.S. 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 external research and development expenses, and the fair value of stock options and restricted stock awards and 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, benefits, share-based compensation, fees for acquiring and maintaining licenses under third-party license agreements, consulting fees, costs of research and development activities conducted by third parties on the Company’s behalf, costs to manufacture or have manufactured clinical trial materials, depreciation, and facilities and overhead costs.

#### *Accrued Research and Development Expenses*

The Company records research and development expenses in the period in which the Company receives or takes ownership of the applicable goods or when the applicable services are performed. The Company is required to

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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, which 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 the 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 estimate. 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.

### *Patent Costs*

The Company expenses all costs as incurred in connection with patent applications (including direct application fees and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the statements of operations and comprehensive loss.

### *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 6)

### *Common Stock Valuation*

Due to the lack of marketability for the Company's common stock, the Company utilizes methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants' Audit and Accounting Practice Guide: Valuation of Privately-Held Company Equity Securities Issued as Compensation to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the fair value of the common stock as of the grant date. The fair value of the common stock has been determined based upon a variety of factors, including the prices at which the Company sold shares of its



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convertible preferred stock to outside investors in arms-length transactions, and the superior rights, preferences and privileges of the preferred stock relative to the common stock at the time of each grant; the progress of the Company's research and development programs, including their stages of development, and the Company's business strategy; external market and other conditions affecting the biotechnology industry, and trends within the biotechnology industry; the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results; the lack of an active public market for the Company's common stock; and the market performance of peer companies in the biopharmaceutical industry.

Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation 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 Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 820, *Fair Value Measurements and Disclosures* ("ASC 820"), establishes a hierarchy of inputs used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are those 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. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of financial instruments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1 —Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 —Valuations are based on quoted prices for similar assets or liabilities in active markets, or quoted prices in markets that are not active for which significant inputs are observable, either directly or indirectly. The Company had no Level 2 valuations for the year ended December 31, 2023 and 2022, respectively.

Level 3 —Valuations are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. Inputs reflect management's best estimate of what market participants would use in valuing the asset or liability at the measurement date. The Company had no Level 3 valuations for the year ended December 31, 2023 and 2022, respectively.

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 \$29.9 million and \$11.5 million as of December 31, 2023, and 2022, 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 above

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federally insured limits of \$250,000 as of December 31, 2023, and 2022. 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.

### *Property and Equipment*

The Company carries its property and equipment at cost, less accumulated depreciation, amortization and impairment, if any. Expenditures for renewals or betterments that materially extend the useful life of an asset or increase its productivity, such as leasehold improvements, are capitalized. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three to seven years. Leasehold improvements are amortized over the shorter of the life of the lease (including any renewal periods that are deemed to be reasonably assured) or the estimated useful life of the assets. Repair and maintenance costs are expensed as incurred and expenditures for major improvements are capitalized.

The following summarizes the components of property and equipment (in thousands):

	December 31,	
	2023	2022
Lab equipment	\$ 706	\$ 669
Leasehold improvements	1,090	1,004
Computer hardware and software	141	84
Furniture and fixtures	160	95
Property and equipment, gross	2,097	1,852
Less: accumulated depreciation and amortization	(665)	(248)
Property and equipment, net	<u>\$1,432</u>	<u>\$1,604</u>

### *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 from 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.

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.

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### *Impairment of Long-lived Assets*

The Company assesses the carrying amount of its property and equipment whenever events or changes in circumstances indicate the carrying amount of such assets may not be recoverable. No impairment charges were recorded during the years ended December 31, 2023, and 2022.

### *Income Taxes*

Income taxes are provided for the tax effects of transactions reported in the financial statements and consist of taxes currently payable and deferred taxes. The Company accounts for income taxes using the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, and operating losses and tax credit carryforwards.

A valuation allowance is recorded to the extent it is more likely than not that some portion of a deferred tax asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. The Company's significant deferred tax assets are net operating loss carryforwards, tax credits, and accruals. The Company has provided a valuation allowance equal to its net deferred tax assets since inception as, due to its history of operating losses, the Company has concluded that it is more likely than not that most of its deferred tax assets will not be realized.

Accounting for uncertain tax positions requires a more likely than not threshold for recognition in the financial statements. The Company recognizes a tax benefit based on whether it is more likely than not that a tax position will be sustained. The Company records a liability to the extent that a tax position taken or expected to be taken on a tax return exceeds the amount recognized in the financial statements.

The Company has no unrecognized tax benefits as of December 31, 2023, and 2022. The Company classifies interest and penalties arising from the underpayment of income taxes in the statements of operations as general and administrative expenses. No such expenses have been recognized during the years ended December 31, 2023, and 2022.

### *Employee Benefit Plan*

The Company established a qualified 401(k) plan in June 2021 which covers all employees who meet eligibility requirements. The Company matches its employee contributions up to a maximum amount of 4% of the participant's compensation. During the years ended December 31, 2023, and 2022, the Company made matching contributions of approximately \$294,000 and \$220,000, respectively.

### *Recently Issued Accounting Pronouncements*

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* to update reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and information used to assess segment performance. This update is effective beginning with the Company's 2024 fiscal year annual reporting period, with early adoption permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its financial statements.

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

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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. 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) LEASES

The Company leases office and lab facilities in Boulder, Colorado under non-cancellable operating leases with rights to extend. Right-of-use assets and lease liabilities for operating leases as included in the Company's financial statements are as follows (in thousands):

	December 31,	
	2023	2022
Operating lease right-of-use assets	\$478	443
Current operating lease liabilities	208	151
Noncurrent operating lease liabilities	466	486
Total lease liabilities	\$674	637

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

	December 31,	
	2023	2022
Operating lease cost	\$173	152
Variable lease expense	201	150
Short-term lease expense	—	—

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

	December 31,	
	2023	2022
Weighted-average remaining lease term – operating leases (years)	2.92	3.85
Weighted-average discount rate – operating leases	4.50%	4.50%
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	\$ 210	\$ 194

The aggregate maturities of the Company's operating lease liabilities were as follows as of December 31, 2023 (in thousands):

2024	\$233
2025	240
2026	247
Total future minimum lease payments	720
Less: imputed interest	(46)
Total	\$674

#### (4) COMMON STOCK

##### *Common Stock*

The Company is authorized to issue 87,589,983 shares of common stock, of which 78,000,000 shares have been designated as Class A Common Stock and 9,589,983 shares have been designated as Class B Common Stock, both with a par value of \$0.0001 per share.

The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of a majority of the Company's stock who are entitled to vote. Each share of Class A Common Stock is entitled to one vote. Class B Common Stock is not entitled to vote on any matter on which the holders of Class A Common Stock or Preferred Stock are entitled to vote. All holders of common stock are entitled to receive dividends when and as declared or paid by the Company's board of directors, subject to the preferential rights of the holders of preferred stock.

Class B Common Stock is convertible into a corresponding number of shares of Class A Common Stock upon written notice of the holder, subject to defined beneficial ownership limitations.

#### (5) CONVERTIBLE PREFERRED STOCK

Convertible preferred stock consisted of the following (in thousands) except for share information:

	December 31,	
	2023	2022
Convertible preferred stock, Series A, \$0.0001 par value; 2,758,788 shares issued and outstanding at December 31, 2022, liquidation preference of \$5,222 as of December 31, 2022	—	4,975
Convertible preferred stock, Series A-1, \$0.0001 par value; 2,413,906 shares issued and outstanding at December 31, 2022, liquidation preference of \$5,198 as of December 31, 2022	—	5,162
Convertible preferred stock, Series B, \$0.0001 par value; 20,649,758 shares issued and outstanding at December 31, 2022, liquidation preference of \$57,061 as of December 31, 2022	—	54,252
Convertible preferred stock, Series C, \$0.0001 par value; 51,141,064 authorized; 47,243,806 shares issued and outstanding at December 31, 2023; liquidation preference of \$195,823 as of December 31, 2023.	129,825	—

As of December 31, 2023 and 2022, the Company's Preferred Stock is classified as temporary equity in the accompanying balance sheets given that the holders of the convertible preferred stock could cause certain events to occur that are outside of the Company's control whereby the Company could be obligated to redeem the convertible preferred stock. The carrying value of the convertible preferred stock is not adjusted to the redemption value until the contingent redemption events are considered probable to occur.

##### Series A, Series A-1, and Series B Preferred Stock

As of December 31, 2022, the Company was authorized to issue 25,828,896 shares of preferred stock, of which 2,758,788 shares were designated as Series A Preferred Stock, 2,413,906 shares were designated as Series A-1 Preferred Stock, and 20,656,202 shares were designated as Series B Preferred Stock. Per the Series C Preferred Stock Purchase Agreement ("Series C Purchase Agreement") in March 2023, all shares of Series A Preferred

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Stock, Series A-1 Preferred Stock, and Series B Preferred Stock (“Prior Preferred”) were converted into shares of Class A Common Stock and some of the shares of Class A Common Stock were subsequently exchanged for shares of Series C Preferred Stock.

Prior Preferred stock:	
Series A Preferred Stock	2,758,788
Series A-1 Preferred Stock	2,413,906
Series B Preferred Stock	20,649,758
Total Prior Preferred stock	<u>25,822,452</u>
Shares issued for Prior Preferred:	
Series C Preferred Stock	27,780,350
Class A Common Stock	5,402,428
Total shares issued in exchange for Prior Preferred	<u>33,182,778</u>

As of December 31, 2023, no shares of the prior preferred were authorized for issue or outstanding.

### Series C Preferred Stock

As of December 31, 2023, the Company is authorized to issue 51,141,064 shares of Series C Preferred Stock.

In March 2023, the Company entered into a Series C Purchase Agreement pursuant to which the Company issued 19,463,456 shares of Series C Preferred Stock at a purchase price of \$2.76 per share, which resulted in gross proceeds of approximately \$53.8 million, as well as the conversion of all Series A Preferred Stock, Series A-1 Preferred Stock, and Series B Preferred Stock.

The Company’s convertible preferred stock had the following characteristics as of December 31, 2023.

### *Conversion of Preferred Stock into Common Stock*

Each share of preferred stock, at the option of the holder, is convertible into a number of shares of common stock as determined by multiplying the number of shares of preferred stock being converted by the conversion rate. The conversion rate in effect at any time for conversion of preferred stock is determined by dividing the Original Issue Price by the Conversion Price. The Original Issue Price for the Series C Preferred Stock is \$2.76 per share. The Conversion Price is subject to certain adjustments as provided in the Company’s restated certificate of incorporation.

The preferred stock will automatically convert to common stock upon the closing of an initial public offering of the Company’s common stock in which the per-share price is at least \$5.53 and gross proceeds of not less than \$75 million, or the date and time specified by vote or the written consent of the holders of at least a majority of the then outstanding shares of Series C Preferred Stock voting or consenting as a separate class on an as-converted basis.

### *Voting Rights*

Each preferred stockholder is entitled to the number of votes equal to the number of shares of Class A Common Stock into which such holder’s shares are convertible. At any time when a defined number of shares of Series C Preferred Stock are outstanding, the Company is restricted from certain actions described in the Company’s restated certificate of incorporation without the vote or written consent of the holders of a majority of the then outstanding shares of Series C Preferred Stock voting or consenting as a separate class on an as-converted basis.

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### *Dividends*

The Company cannot declare, pay or set aside any dividends on any shares of any other class or series of capital stock unless each holder of the preferred stock first receives a dividend based upon a formula in the Company's restated certificate of incorporation. No dividends were declared as of December 31, 2023.

### *Liquidation Preference*

Upon any liquidation, dissolution or winding up of the Company, certain qualifying mergers, sales or transactions with a special purpose acquisition companies, and other deemed liquidation events as defined in the Company's restated certificate of incorporation, unless the holders of a majority of the then outstanding shares of Series C Preferred Stock, voting as a separate class on an as-converted basis, elect otherwise, prior to and in preference to any distribution to the holders of common stock, holders of Series C Preferred Stock are entitled to be paid out of the assets of the Company legally available for distribution, or the consideration received in such transaction, an amount per share of Series C Preferred Stock equal to the greater of: i) 1.50 times the Series C Original Issuance Price plus all declared and unpaid dividends on Series C Preferred Stock or ii) such amount per share that would have been payable had all shares of Series C Preferred Stock been converted into common stock immediately prior to such event. If upon liquidation, dissolution, or winding up of the Company, the assets and funds of the Company are insufficient to permit the payment of the full preferential amounts to the holders of preferred stock, then the holders shall share ratably in any distribution of the assets available for distribution, in proportion to the respective amounts which would otherwise be payable in respect of the shares held by the preferred stockholders.

After the payment of all preferential amounts required to be paid to the holder of shares of preferred stock, the remaining assets available for distribution to its stockholders are to be distributed to the holders of shares of common stock, pro rata based on the number of shares held by each holder.

## **(6) SHARE-BASED COMPENSATION**

The Company had share-based compensation plans which are described below:

### *2011 Equity Incentive Plan*

In October 2011, the Company established an equity incentive plan (the "2011 Plan"). The 2011 Plan provides for the grant of stock options and restricted stock awards ("RSA") to employees, non-employee directors, advisors, and consultants. The aggregate number of shares of common stock that may be issued under the 2011 Plan will not exceed 1,266,000 shares. Shares are no longer available for issuance under the 2011 Plan, which was subsequently terminated in March 2023.

### *2021 Equity Incentive Plan*

In February 2021, the Company established an equity incentive plan (the "2021 Plan"). The 2021 Plan provides for the grant of stock options and RSA to employees, non-employee directors, advisors, and consultants. The aggregate number of shares of common stock that may be issued under the 2021 Plan will not exceed 4,326,997 shares.

### *2023 RSU Equity Incentive Plan*

In September 2023, the company established an equity incentive plan (the "2023 Plan"). The 2023 Plan provides for the grant of restricted stock units ("RSU") to employees, directors, and consultants. The aggregate number of shares of common stock that may be issued under the 2023 Plan will not exceed 2,000,000 shares.

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### *Stock Options*

Options granted under the Company's equity incentive plans have an exercise price equal to or in excess of the market value of the Class A Common Stock at the date of grant and expire no more than 10 years from the date of grant. Generally, options vest 25% on the first anniversary of the vesting commencement date and 75% ratably in equal monthly installments over the remaining 36 months. Stock options granted to non-employees generally vest quarterly over two to three years.

As of December 31, 2023, there were 1,521,745 options available for issuance under the 2021 Plan.

A summary of common stock option activity is as follows:

	<u>Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (Years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Outstanding as of December 31, 2021	2,795,205	\$ 0.46	8.72	\$ —
Granted	1,240,168	\$ 0.53		
Exercised	(828,305)	\$ 0.41		
Canceled	(105,764)	\$ 0.50		
Outstanding as of December 31, 2022	3,101,304	\$ 0.50		\$ 243
Granted	4,368,378	\$ 0.33		
Exercised	(148,412)	\$ 0.44		
Canceled	(123,719)	\$ 0.54		
Outstanding as of December 31, 2023	7,197,551	\$ 0.40	8.88	\$ 16
Options exercisable as of December 31, 2023	2,585,640	\$ 0.44	8.26	\$ 16
Options vested and expected to vest as of December 31, 2023	6,903,294	\$ 0.40	8.86	\$ 16

As of December 31, 2023, the Company had unrecognized compensation cost for unvested stock options of \$452,000, expected to be recognized over a weighted-average period of approximately 2.6 years.

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 December 31, 2023.

The weighted-average grant-date fair value of options granted for the years ended December 31, 2023, and 2022 was \$0.13 and \$0.10, respectively.

From time to time, the Company grants performance-based stock options. As of December 31, 2023, the Company granted 358,089 performance-based shares. The company recognized \$13,000 in performance-based compensation expense and 250,063 performance-based shares were outstanding for the year ended December 31, 2023, respectively. No performance-based shares were granted and no performance-based expense was recognized for the year ended December 31, 2022.

### *Restricted Stock Awards and Restricted Stock Units*

RSA typically vests 25% on the first anniversary of the issuance date and incrementally vest monthly for the three-year period thereafter. In the event of a termination of services, all unvested shares are forfeited, and the Company has the option to purchase all outstanding vested shares at their fair market value.



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RSU vests based on a service-based requirement and a liquidity event plus service requirement. No RSU had vested as of December 31, 2023.

As of December 31, 2023, there were 523,285 options available for issuance under the 2023 Plan.

A summary of restricted stock award and restricted stock unit activity are as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested balance as of December 31, 2021	111,413	\$ 0.09
Vested (RSA)	76,682	\$ 0.08
Unvested balance as of December 31, 2022	34,731	\$ 0.10
Granted (RSU)	1,487,689	\$ 0.33
Vested (RSA)	30,324	\$ 0.10
Forfeited	(10,974)	\$ 0.33
Unvested balance as of December 31, 2023	<u>1,481,122</u>	\$ 0.33

As of December 31, 2023, the Company had unrecognized compensation cost for unvested RSU awards of \$455,000, expected to be recognized over a weighted-average period of approximately 3.2 years.

### *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):

	Year ended December 31,	
	2023	2022
Research and development	\$ 98	\$ 34
General and administrative	\$101	\$ 14
Total share-based compensation	<u>\$199</u>	<u>\$ 48</u>

The fair value was determined using the Black-Scholes option pricing model and the following weighted-average assumptions:

	Year ended December 31,	
	2023	2022
Expected term (years)	5.73	5.97
Expected volatility	32.0%	36.6%
Risk-free interest rate	4.31%	2.51%
Expected dividend yield	—	—

[Table of Contents](#)**(7) ACCRUED EXPENSES**

Accrued expenses consisted of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Accrued contract manufacturing costs	\$1,627	\$ 434
Accrued compensation	1,663	1,456
Accrued other	370	981
Total accrued expenses	<u>\$3,660</u>	<u>\$2,871</u>

**(8) INCOME TAXES**

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which the temporary differences are expected to be recovered or settled.

The components of the income tax benefit are as follows:

	Year Ended December 31,	
	2023	2022
Federal tax at statutory rate	21.0%	21.0%
State taxes, net of federal deduction	3.6%	3.6%
R&D credits	0.2%	2.4%
Other	(0.1)%	(0.2)%
Change in valuation allowance	(24.7)%	(27.2)%
Effective income tax rate	<u>—</u>	<u>—</u>

Significant components of deferred income taxes are as follows (in thousands):

	As of December 31,	
	2023	2022
Net operating loss carryforward	\$ 9,027	\$ 6,212
R&D Tax credit	837	836
Deferred R&D expenses	11,123	5,198
Accrued expenses	783	881
Share-based compensation	104	91
Other	337	281
Total net deferred tax asset	22,211	13,499
Valuation allowance	(22,211)	(13,499)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2023, the Company had approximately \$1.5 million of net operating loss carryforwards (“NOLs”) and \$0.8 million of research and experimental credits which expire through 2037, and approximately \$35.2 million of federal and state net operating loss carryforwards which have an indefinite life.

Pursuant to Internal Revenue Code (“IRC”) Sections 382 and 383, the Company’s ability to use NOLs and research tax credit carry forwards to offset future taxable income may be limited if the Company experiences a cumulative change in ownership of more than 50% within a three-year testing period. The Company has not

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completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of NOLs and research tax carryforwards available to offset future taxable income and income tax liabilities in future years may be significantly restricted or eliminated. Further, deferred tax assets associated with such NOLs and research tax credits could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. Management considers projected future taxable income and tax planning strategies in making this assessment.

The Company's federal and state income tax returns for all years will remain open to examination by federal and state tax authorities for three years from the date of utilization of any net operating loss carryforwards.

### **(9) COMMITMENTS AND CONTINGENCIES**

#### *Clinical Trial Collaboration and Supply Agreement with Pfizer*

In August 2020, the Company entered into a clinical trial collaboration and supply agreement under which Pfizer Inc. ("Pfizer") agreed to supply drug product in connection with a clinical trial. The agreement continues until the earlier of the completion of all obligations of the parties or the termination of the contract by either party as defined in the agreement. The Company may terminate the agreement if the clinical trial is deemed to be unsafe, regulatory authorities raise concerns, or if Pfizer does not uphold its obligations outlined in the agreement.

#### *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 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 December 31, 2023.

### **(10) SUBSEQUENT EVENTS**

The Company has evaluated subsequent events through May 13, 2024, the date the financials were available to be issued.

In May 2024, the Company entered into a definitive merger agreement with Reneo Pharmaceuticals, Inc. (Nasdaq: RPHM) ("Reneo") to combine the Company with Reneo in an all-stock transaction. The combined company will focus on advancing OnKure's pipeline candidates. Upon completion of the transaction, the combined company is expected to operate under the name OnKure Therapeutics, Inc., and trade on the Nasdaq Global Market under the ticker symbol "OKUR".

In connection with the transaction, Reneo has entered into a subscription agreement for a \$65 million private investment in public equity (PIPE) financing expected to close concurrently with the closing of the merger, with a group of institutional investors.

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Pre-merger Reneo stockholders are expected to own approximately 31% of the combined company, and pre-merger Company stockholders are expected to own approximately 69% of the combined company, upon the closing of the merger, exclusive of the PIPE financing.

The transaction is expected to close in 2024, subject to customary closing conditions, including approval by the stockholders of each company.

## Independent Auditors' Review Report

Board of Directors and Stockholders  
OnKure, Inc.:

### *Results of Review of Interim Financial Information*

We have reviewed the financial statements of OnKure, Inc. (the Company), which comprise the balance sheet as of June 30, 2024, and the related statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders' deficit, and cash flows for the three- and six-month periods ended June 30, 2024 and 2023, and the related notes (collectively referred to as the interim financial information).

Based on our reviews, we are not aware of any material modifications that should be made to the accompanying interim financial information for it to be in accordance with U.S. generally accepted accounting principles.

### *Basis for Review Results*

We conducted our reviews in accordance with auditing standards generally accepted in the United States of America (GAAS) applicable to reviews of interim financial information and in accordance with the auditing standards of the Public Company Accounting Oversight Board (United States) (PCAOB). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. A review of interim financial information is substantially less in scope than an audit conducted in accordance with GAAS and in accordance with the auditing standards of the PCAOB, the objective of which is an expression of an opinion regarding the financial information as a whole, and accordingly, we do not express such an opinion. We are required to be independent of the Company and to meet our other ethical responsibilities in accordance with the relevant ethical requirements relating to our reviews. We believe that the results of the review procedures provide a reasonable basis for our conclusion.

### *Substantial Doubt About the Entity's Ability to Continue as a Going Concern*

The accompanying interim financial information has been prepared assuming that the Company will continue as a going concern. Note 1 of the Company's audited financial statements as of December 31, 2023, and for the year then ended, includes a statement that substantial doubt exists about the Company's ability to continue as a going concern. Note 1 of the Company's audited financial statements also discloses the events and conditions, management's evaluation of the events and conditions, and management's plans regarding these matters, including the fact that the Company has recurring losses from operations and an accumulated deficit as of December 31, 2023. Our auditors' report on those financial statements includes a separate section referring to the matters in Note 1 of those financial statements. As indicated in Note 1 of the accompanying interim financial information as of June 30, 2024, and for the three and six months then ended, the Company still has recurring losses from operations and an accumulated deficit as of June 30, 2024, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. The accompanying interim financial information does not include any adjustments that might result from the outcome of this uncertainty.

### *Responsibilities of Management for the Interim Financial Information*

Management is responsible for the preparation and fair presentation of the interim financial information in accordance with U.S. generally accepted accounting principles and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of interim financial information that is free from material misstatement, whether due to fraud or error.

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*Report on Balance Sheet as of December 31, 2023*

We have previously audited, in accordance with GAAS and in accordance with the auditing standards of the PCAOB, the balance sheet as of December 31, 2023, and the related statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders' deficit, and cash flows for the year then ended (not presented herein); and we expressed an unmodified audit opinion on those audited financial statements in our report dated May 13, 2024. In our opinion, the accompanying balance sheet of the Company as of December 31, 2023 is consistent, in all material respects, with the audited financial statements from which it has been derived.

/s/ KPMG LLP

Boulder, Colorado  
August 19, 2024

**ONKURE, INC.**  
**BALANCE SHEETS**  
(in thousands, except share and per share data)

	June 30, 2024 (Unaudited)	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 18,633	\$ 29,876
Prepaid expenses and other current assets	5,163	3,890
Total current assets	<u>23,796</u>	<u>33,766</u>
Property and equipment, net	1,223	1,432
Operating lease right-of-use asset	405	478
Other assets	49	58
Total assets	<u>\$ 25,473</u>	<u>\$ 35,734</u>
<b>Liabilities, Convertible Preferred Stock, and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 8,261	\$ 3,417
Accrued expenses	4,507	3,660
Operating lease liabilities, current portion	216	208
Total current liabilities	<u>12,984</u>	<u>7,285</u>
Convertible notes payable, net of debt issuance costs	5,858	—
Operating lease liabilities, net of current portion	357	466
Other long-term liabilities	26	—
Total liabilities	<u>19,225</u>	<u>7,751</u>
Commitments and contingencies		
Convertible preferred stock, Series C, \$0.0001 par value; 51,141,064 shares authorized; 47,243,806 shares issued and outstanding at June 30, 2024 and December 31, 2023; liquidation preference of \$195,823 as of June 30, 2024 and December 31, 2023, respectively	129,825	129,825
Stockholders' deficit:		
Common stock, Class A, \$0.0001 par value; 78,000,000 and 40,000,000 Shares authorized; 13,386,958 and 13,296,584 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively.	1	1
Common stock, Class B, \$0.0001 par value; 9,589,983 shares authorized; no shares issued and outstanding.	—	—
Additional paid-in capital	2,148	208
Accumulated deficit	<u>(125,726)</u>	<u>(102,051)</u>
Total stockholders' deficit	<u>(123,577)</u>	<u>(101,842)</u>
Total liabilities, convertible preferred stock, and stockholders' deficit	<u>\$ 25,473</u>	<u>\$ 35,734</u>

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

**ONKURE, INC.**  
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(in thousands)**  
**(Unaudited)**

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
<b>Operating expenses:</b>				
Research and development	\$ 10,752	\$ 7,514	\$ 19,318	\$ 15,037
General and administrative	3,591	1,120	4,857	2,349
Total operating expenses	<u>14,343</u>	<u>8,634</u>	<u>24,175</u>	<u>17,386</u>
<b>Loss from operations</b>	<u>(14,343)</u>	<u>(8,634)</u>	<u>(24,175)</u>	<u>(17,386)</u>
Other income and (expense):				
Interest income	230	451	526	524
Interest expense	(26)	—	(26)	—
<b>Total other income</b>	<u>204</u>	<u>451</u>	<u>500</u>	<u>524</u>
<b>Net loss and comprehensive loss</b>	<u>\$ (14,139)</u>	<u>\$ (8,183)</u>	<u>\$ (23,675)</u>	<u>\$ (16,862)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.06)</u>	<u>\$ (0.62)</u>	<u>\$ (1.77)</u>	<u>\$ (1.56)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>13,370,466</u>	<u>13,265,671</u>	<u>13,339,473</u>	<u>10,791,145</u>

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



**ONKURE, INC**  
**STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**  
(in thousands, except share information)  
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
<b>Balances as of December 31, 2023</b>	47,243,806	\$ 129,825	13,296,584	\$ 1	\$ 208	\$ (102,051)	\$ (101,842)
Issuance of Class A Common Stock for cash upon the exercise of stock options	—	—	42,476	—	10	—	10
Share-based compensation expense	—	—	—	—	107	—	107
Net loss	—	—	—	—	—	(9,536)	(9,536)
<b>Balances as of March 31, 2024</b>	47,243,806	\$ 129,825	13,339,060	\$ 1	\$ 325	\$ (111,587)	\$ (111,261)
Issuance of Class A Common Stock for cash upon the exercise of stock options	—	—	47,898	—	10	—	10
Share-based compensation expense	—	—	—	—	1,813	—	1,813
Net loss	—	—	—	—	—	(14,139)	(14,139)
<b>Balances as of June 30, 2024</b>	47,243,806	\$ 129,825	13,386,958	\$ 1	\$ 2,148	\$ (125,726)	\$ (123,577)
<b>Balances as of December 31, 2022</b>	25,822,452	\$ 64,389	7,745,744	\$ 1	\$ 2,655	\$ (57,074)	\$ (54,418)
Issuance of Series C Preferred Stock under a stock purchase agreement, net of issuance costs of \$0.7 million	19,463,456	53,068	—	—	—	—	—
Issuance of Class A Common Stock and Series C Preferred Stock in exchange of Series A, A-1, and Series B Preferred Stock under a stock purchase agreement	1,957,898	12,376	5,402,428	—	(2,711)	(9,666)	(12,377)
Issuance of Class A Common Stock for cash upon the exercise of stock options	—	—	96,666	—	41	—	41
Share-based compensation expense	—	—	—	—	15	—	15
Net loss	—	—	—	—	—	(8,679)	(8,679)
<b>Balance as of March 31, 2023</b>	47,243,806	\$ 129,833	13,244,838	\$ 1	—	\$ (75,419)	\$ (75,418)
Issuance of Class A Common Stock for cash upon the exercise of stock options	—	—	10,833	—	5	—	5
Share-based compensation expense	—	—	—	—	17	—	17
Net loss	—	—	—	—	—	(8,183)	(8,183)
<b>Balances as of June 30, 2023</b>	47,243,806	\$ 129,825	13,255,671	\$ 1	\$ 22	\$ (83,602)	\$ (83,579)

*The accompanying notes are an integral part of these financial statements*

**ONKURE, INC.**  
**STATEMENTS OF CASH FLOWS**  
**(in thousands)**  
**(Unaudited)**

	Six Months Ended June 30,	
	2024	2023
<b>Cash flows from operating activities:</b>		
Net loss	\$(23,675)	\$(16,862)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,920	32
Depreciation and amortization	226	197
Amortization of right-of-use assets	73	86
Amortization of debt issuance costs	1	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,264)	547
Accounts payable, accrued and other liabilities	5,718	454
Lease liabilities	(101)	(100)
Net cash used in operating activities	(17,102)	(15,646)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(19)	(71)
Net cash used in investing activities	(19)	(71)
<b>Cash flows from financing activities:</b>		
Proceeds from the sale of Series C Preferred Stock	—	53,783
Payment of issuance costs associated with the issuance of Series C Preferred Stock	—	(724)
Proceeds from the issuance of convertible notes payable	6,000	—
Payment of issuance costs associated with issuance of convertible notes payable	(142)	—
Proceeds from the issuance of common stock	20	47
Net cash provided by financing activities	5,878	53,106
Net increase (decrease) in cash and cash equivalents	(11,243)	37,389
Cash and cash equivalents at beginning of period	29,876	11,543
Cash and cash equivalents at end of period	\$ 18,633	\$ 48,932
<b>Supplemental disclosure of non-cash financing activities:</b>		
Issuance of Series C Preferred Stock on conversion of prior Preferred Stock	\$ —	\$ 23,313

*The accompanying notes are an integral part of these financial statements*

**ONKURE, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(Unaudited)**

**(1) DESCRIPTION OF BUSINESS**

OnKure, 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 robust pipeline of small molecule drugs designed to selectively target specific mutations thought to be key drivers of cancer.

*Liquidity and Capital Resources*

The Company had recurring losses from operations, an accumulated deficit of \$125.7 million and cash and cash equivalents of \$18.6 million as of June 30, 2024. 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. As a result, the Company has determined that substantial doubt about the Company’s ability to continue as a going concern for a period of at least 12 months from the date of the issuance of these financial statements does exist.

The Company’s ability to secure capital is dependent upon 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 may be unable to realize value from the Company’s assets or discharge liabilities in the normal course of business, which may, among other alternatives, cause the Company to delay, substantially reduce, or discontinue operational activities to conserve cash, which could have a material adverse effect on the Company’s ability to achieve its intended business objectives.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. 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. The Company believes that the \$18.6 million of cash and cash equivalents on hand as of June 30, 2024, will not be sufficient to fund its operations in the normal course of business and meet its liquidity needs through at least the next 12 months from the issuance of these financial statements. As such, the Company will need to raise additional capital to finance its operations and the ability to do so is uncertain. As a result, the Company has determined there is substantial doubt about the Company’s ability to continue as a going concern for a period of at least 12 months from the date of the issuance of these financial statements.

Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on the Company’s financial condition and its ability to discover and develop its product candidates. Changing circumstances may cause the Company to consume capital significantly faster or slower than currently anticipated. If the Company is unable to acquire additional capital or resources, it will be required to modify its operational plans. 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 financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

## **(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### *Basis of Presentation*

The Company has prepared the accompanying unaudited financial statements in accordance with U.S. generally accepted accounting principles (“GAAP”). The Company recommends that these unaudited financial statements be read in conjunction with the audited financial statements and the notes thereto included in the Company’s audited financial statements for the year ended December 31, 2023.

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

### *Summary of Significant Accounting Policies*

The significant accounting policies used in the preparation of these financial statements for the period ended June 30, 2024 are consistent with those discussed in Note 3 to the financial statements in the Company’s audited financial statements for the year ended December 31, 2023.

### *Use of Estimates*

The preparation of the financial statements in accordance with U.S. 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 external research and development expenses, and the fair value of stock options and restricted stock awards and units.

### *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 Financial Accounting Standards Board (“FASB”) Accounting Standard Codification (“ASC”) Topic 820, *Fair Value Measurements and Disclosures* (“ASC 820”), establishes a hierarchy of inputs used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are those 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. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of financial instruments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1 — Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 — Valuations are based on quoted prices for similar assets or liabilities in active markets, or quoted prices in markets that are not active for which significant inputs are observable, either directly or indirectly. The Company had no Level 2 valuations for the periods ended June 30, 2024, or year ended December 31, 2023, respectively.

Level 3 — Valuations are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. Inputs reflect management’s best estimate of what market participants would use in valuing the asset or liability at the measurement date. The Company had no Level 3 valuations for the periods ended June 30, 2024, or year ended December 31, 2023, respectively.

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

### *Recently Issued Accounting Pronouncements*

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* to update reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and information used to assess segment performance. This update is effective beginning with the Company's 2024 fiscal year annual reporting period, with early adoption permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its financial statements.

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. 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) LEASES**

The Company leases office and lab facilities in Boulder, Colorado under non-cancellable operating leases.

Other information related to the Company's operating leases are as follows:

	As of June 30,	
	2024	2023
Weighted-average remaining lease term (years)	2.5	3.5
Weighted-average discount rate	4.50%	4.50%
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases (in thousands)	\$ 101	\$ 100

The aggregate maturities of the Company's operating lease liabilities were as follows as of June 30, 2024 (in thousands):

2024	\$ 118
2025	240
2026	247
Total future minimum lease payments	605
Less: Imputed interest	(32)
Total	<u>\$573</u>

**(4) SHARE-BASED COMPENSATION**

The Company had share-based compensation plans which are described below:

*2011 Equity Incentive Plan*

In October 2011, the Company established an equity incentive plan (the “2011 Plan”). The 2011 Plan provides for the grant of stock options and restricted stock awards (“RSA”) to employees, non-employee directors, advisors, and consultants. The aggregate number of shares of common stock that may be issued under the 2011 Plan will not exceed 1,266,000 shares. Shares are no longer available for issuance under the 2011 Plan, which was subsequently terminated in March 2023.

*2021 Equity Incentive Plan*

In February 2021, the Company established an equity incentive plan (the “2021 Plan”). The 2021 Plan provides for the grant of stock options and RSA to employees, non-employee directors, advisors, and consultants. The aggregate number of shares of common stock that may be issued under the 2021 Plan will not exceed 4,326,997 shares.

*2023 RSU Equity Incentive Plan*

In September 2023, the company established an equity incentive plan (the “2023 Plan”). The 2023 Plan provides for the grant of restricted stock units (“RSU”) to employees, directors, and consultants. The aggregate number of shares of common stock that may be issued under the 2023 Plan will not exceed 2,000,000 shares.

*Stock Options*

Options granted under the Company’s equity incentive plans have an exercise price equal to or in excess of the market value of the Class A Common Stock at the date of grant and expire no more than 10 years from the date of grant. Generally, options vest 25% on the first anniversary of the vesting commencement date and 75% ratably in equal monthly installments over the remaining 36 months. Stock options granted to non-employees generally vest quarterly over two to three years.

As of June 30, 2024, there were 687,274 options available for issuance under the 2021 Plan, of which the Company is restricted from granting stock awards for 361,600 shares of its common stock under certain conditions.

A summary of common stock option activity is as follows:

	<u>Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (Years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Outstanding as of December 31, 2023	7,197,551	\$ 0.40	8.88	\$ 16
Granted	854,795	\$ 0.33		
Exercised	(90,374)	\$ 0.21		
Canceled	(20,324)	\$ 0.54		
Outstanding as of June 30, 2024	<u>7,941,648</u>	<u>\$ 0.39</u>	<u>7.46</u>	<u>\$ 2</u>
Options exercisable as of June 30, 2024	<u>4,289,295</u>	<u>\$ 0.41</u>	<u>6.22</u>	<u>\$ 2</u>
Options vested and expected to vest as of June 30, 2024	<u>7,710,235</u>	<u>\$ 0.39</u>	<u>7.40</u>	<u>\$ 2</u>

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As of June 30, 2024, the Company had unrecognized compensation cost for unvested stock options of \$365,000, expected to be recognized over a weighted-average period of approximately 2.6 years.

From time to time, the Company grants performance-based stock options. As of June 30, 2024, the Company had granted 358,089 performance-based shares. The company recognized \$9,000 and \$30,000 in performance-based compensation expense for the three and six months ended June 30, 2024, respectively. No performance-based shares were outstanding as of June 30, 2024. No performance-based shares were granted and no performance-based expense was recognized for the three and six months ended June 30, 2023. These performance-based stock options are not included in the table above.

### *Restricted Stock Awards and Restricted Stock Units*

RSA typically vests 25% on the first anniversary of the issuance date and incrementally vest monthly for the three-year period thereafter. In the event of termination of services, all unvested shares are forfeited, and the Company has the option to purchase all outstanding vested shares at their fair market value.

RSU vests based on a service-based requirement and a liquidity event plus service requirement.

As of June 30, 2024, there were 523,285 RSUs available for issuance under the 2023 Plan.

A summary of restricted stock awards and restricted stock units activity are as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested balance as of December 31, 2023	1,481,122	\$ 0.33
Vested outstanding (RSA)	4,407	\$ 0.12
Unvested balance as of June 30, 2024	1,040,204	\$ 0.33
Vested outstanding (RSU) as of June 30, 2024	436,511	\$ 0.33

As of June 30, 2024, the Company had unrecognized compensation cost for unvested RSU awards of \$328,000, expected to be recognized over a weighted-average period of approximately 2.7 years.

### *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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	\$ 1,518	\$ 15	\$1,555	\$ 27
General and administrative	295	2	365	5
Total share-based compensation	<u>\$ 1,813</u>	<u>\$ 17</u>	<u>\$1,920</u>	<u>\$ 32</u>

The Company recorded accelerated share-based compensation expenses related to modifications of RSUs under certain separation agreements of \$1.7 million during the three and six months ended June 30, 2024.

The fair value was determined using the Black-Scholes option pricing model and the following weighted-average assumptions for the six months ended June 30, 2024: expected term 6.07 years, expected volatility 31.94%, risk-free interest rate 4.05% and 0% expected dividend yield. No options were granted in the three months ended June 30, 2024. No options were granted for the three and six months ended June 30, 2023, respectively.

**(5) NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS 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 exercise of all outstanding stock options and restricted stock units were excluded from the diluted net loss per share calculation for the three and six months ended June 30, 2024 and 2023 because such shares are anti-dilutive.

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

	As of June 30,	
	2024	2023
Options to purchase common stock	8,299,737	2,991,710
Restricted stock units	1,476,715	—
<b>Total</b>	<b>9,776,452</b>	<b>2,991,710</b>

**(6) PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current assets consisted of the following (in thousands):

	As of June 30, 2024 (Unaudited)	As of December 31, 2023
Prepaid clinical trials	\$ 1,494	\$ 3,192
Deferred recapitalization costs	656	—
Other receivables	2,045	273
Prepaid other	968	425
<b>Total prepaid expenses</b>	<b>\$ 5,163</b>	<b>\$ 3,890</b>

**(7) PROPERTY AND EQUIPMENT, NET**

The following summarizes the components of property and equipment (in thousands):

	As of June 30, 2024 (Unaudited)	As of December 31, 2023
Lab equipment	\$ 706	\$ 706
Leasehold improvements	1,090	1,090
Computer hardware and software	158	141
Furniture and fixtures	160	160
Property and equipment, gross	2,114	2,097
Less: Accumulated depreciation and amortization	(891)	(665)
<b>Property and equipment, net</b>	<b>\$ 1,223</b>	<b>\$ 1,432</b>

Depreciation expense for the three and six months ended June 30, 2024 was \$115,000 and \$228,000, respectively. Depreciation expense for the three and six months ended June 30, 2023 was \$99,000 and \$197,000, respectively.



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### **(8) ACCRUED EXPENSES**

Accrued expenses consisted of the following (in thousands):

	As of June 30, 2024 (Unaudited)	As of December 31, 2023
Accrued contract manufacturing costs	\$ 864	\$ 1,627
Accrued compensation	1,707	1,663
Accrued legal	1,171	—
Accrued other	765	370
Total accrued expenses	<u>\$ 4,507</u>	<u>\$ 3,660</u>

### **(9) COMMITMENTS AND CONTINGENCIES**

#### *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 members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs because of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its financial statements as of June 30, 2024.

### **(10) PROPOSED MERGER**

In May 2024, the Company entered into a definitive merger agreement with Reneo Pharmaceuticals, Inc. (Nasdaq: RPHM) (“Reneo”) to combine the Company with Reneo in an all-stock transaction. The combined company will focus on advancing OnKure’s pipeline candidates. Upon completion of the transaction, the combined company is expected to operate under the name OnKure Therapeutics, Inc., and trade on the Nasdaq Global Market under the ticker symbol “OKUR”.

In connection with the transaction, Reneo has entered into a subscription agreement for a \$65 million private investment in public equity (PIPE) financing expected to close concurrently with the closing of the merger, with a group of institutional investors.

Pre-merger Reneo stockholders are expected to own approximately 31% of the combined company, and pre-merger OnKure stockholders are expected to own approximately 69% of the combined company, upon the closing of the merger, exclusive of the PIPE financing. The expected relative ownership percentages of pre-Mergers OnKure stockholders and pre-Mergers Reneo stockholders of the combined company are calculated using the treasury stock method, as described in the merger agreement, on a fully diluted basis prior to giving effect to the concurrent PIPE investments and excluding any shares reserved for future grants.

The transaction is expected to close in the second half of 2024, subject to customary closing conditions, including requisite approvals by the stockholders of each company and the receipt of required regulatory approvals (to the extent applicable).

**(11) CONVERTIBLE PROMISSORY NOTES**

In June 2024, the Company entered into convertible promissory note agreements with certain of its existing investors for up to \$12.0 million. At close, the company received total proceeds of \$6.0 million and may draw up to an additional \$6.0 million in the event the merger with Reno has not closed by September 30, 2024. The notes bear interest rates from 6% to 8% per annum. All unpaid principal and accrued interest are due in December 2025, unless earlier converted. No principal or interest is due until maturity. The Company incurred \$142,000 of debt issuance costs related to the convertible promissory notes during the three and six months ended June 30, 2024. Debt issuance costs are amortized as a component of interest expense over the term of the related debt using the straight-line method, which approximates the interest method. The Company recognized \$1,000 in interest expense related to the amortization of the debt issuance costs for the three and six months ended June 30, 2024.

The unpaid notes will automatically convert into shares issued in the concurrent PIPE financing at the price per share paid by investors in the concurrent PIPE financing. In the event that the notes have not been converted before a certain date, the note holders have the option to convert the outstanding notes into Series C Preferred stock at a discount. In the event that the company completes a qualified financing, as defined, and the notes have not been converted before a certain date the notes will automatically convert on a qualified financing at a discount.

**(12) SUBSEQUENT EVENTS**

The Company evaluates subsequent events up until the date the financial statements are issued.

**Report of Independent Registered Public Accounting Firm**

To the Stockholders and the Board of Directors of Reneo Pharmaceuticals, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Reneo Pharmaceuticals, Inc. (the “Company”) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

**Basis for Opinion**

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2018.

San Diego, California  
March 28, 2024  
except for the last paragraph of Note 1 as to which the date is  
October 23, 2024

**RENEO PHARMACEUTICALS, INC.**  
**Consolidated Balance Sheets**  
**(In thousands, except par value and share data)**

	<u>December 31,</u>	
	<u>2023</u>	<u>2022</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 27,632	\$ 19,927
Short-term investments	75,331	81,246
Prepaid expenses and other current assets	3,659	5,180
Total current assets	<u>106,622</u>	<u>106,353</u>
Property and equipment, net	134	453
Right-of-use assets	599	1,292
Other non-current assets	81	84
Total assets	<u>\$ 107,436</u>	<u>\$ 108,182</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 8,717	\$ 1,893
Accrued expenses	9,129	4,827
Operating lease liabilities, current portion	331	404
Total current liabilities	<u>18,177</u>	<u>7,124</u>
Operating lease liabilities, less current portion	642	1,059
Performance award	7	29
Total liabilities	<u>18,826</u>	<u>8,212</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized at December 31, 2023 and December 31, 2022; 3,342,080 and 2,469,955 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	307,076	236,696
Accumulated deficit	(218,474)	(136,683)
Accumulated other comprehensive income (loss)	8	(43)
Total stockholders' equity	<u>88,610</u>	<u>99,970</u>
Total liabilities and stockholders' equity	<u>\$ 107,436</u>	<u>\$ 108,182</u>

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

**RENEO PHARMACEUTICALS, INC.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
**(In thousands, except share and per share data)**

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Operating expenses:		
Research and development	\$ 56,613	\$ 37,705
General and administrative	26,440	16,143
Total operating expenses	<u>83,053</u>	<u>53,848</u>
Loss from operations	(83,053)	(53,848)
Other income	5,665	1,893
Net loss	<u>(77,388)</u>	<u>(51,955)</u>
Unrealized gain (loss) on short-term investments	51	(77)
Comprehensive loss	<u>\$ (77,337)</u>	<u>\$ (52,032)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ 25.23</u>	<u>\$ 21.21</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>3,067,645</u>	<u>2,449,642</u>

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

**RENEO PHARMACEUTICALS, INC.**
**Consolidated Statements of Changes in Stockholders' Equity**  
**(In thousands, except share data)**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balances, December 31, 2021</b>	<b>2,445,539</b>	<b>\$—</b>	<b>\$231,905</b>	<b>\$ 34</b>	<b>\$ (84,728)</b>	<b>\$ 147,211</b>
Stock based compensation	—	—	4,320	—	—	4,320
Issuance of common stock in connection with at-the-market facility, net of issuance costs	9,208	—	193	—	—	193
Issuance of common stock in connection with equity plans	15,208	—	278	—	—	278
Other comprehensive loss	—	—	—	(77)	—	(77)
Net loss	—	—	—	—	(51,955)	(51,955)
<b>Balances, December 31, 2022</b>	<b>2,469,955</b>	<b>\$—</b>	<b>\$236,696</b>	<b>\$ (43)</b>	<b>\$ (136,683)</b>	<b>\$ 99,970</b>
Stock based compensation	—	—	5,112	—	—	5,112
Issuance of common stock in public offering, net of offering costs	790,625	—	58,862	—	—	58,862
Issuance of common stock in private placement, net of offering costs	62,500	—	4,667	—	—	4,667
Issuance of common stock in connection with at-the-market facility, net of issuance costs	40,787	—	1,009	—	—	1,009
Issuance of common stock in connection with equity plans	35,857	—	730	—	—	730
Repurchase and retirement of common stock in connection with common stock repurchase agreement	(57,644)	—	—	—	(4,403)	(4,403)
Other comprehensive income	—	—	—	51	—	51
Net loss	—	—	—	—	(77,388)	(77,388)
<b>Balances, December 31, 2023</b>	<b>3,342,080</b>	<b>\$—</b>	<b>\$307,076</b>	<b>\$ 8</b>	<b>\$ (218,474)</b>	<b>\$ 88,610</b>

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

**RENEO PHARMACEUTICALS, INC.**  
**Consolidated Statements of Cash Flows**  
**(In thousands)**

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Cash flows from operating activities		
Net loss	\$ (77,388)	\$ (51,955)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,112	4,320
Depreciation and amortization	170	88
Amortization/accretion on short-term investments	(4,777)	(817)
Changes in the fair value of performance award	(22)	(415)
Non-cash lease expense	355	441
Right-of-use and leasehold improvement impairment expenses	650	17
Changes in operating assets and liabilities:		
Prepaid and other assets	1,524	878
Accounts payable and accrued expenses	11,118	518
Operating lease liabilities	(424)	(437)
Net cash used in operating activities	<u>(63,682)</u>	<u>(47,362)</u>
Cash flows from investing activities		
Purchases of property and equipment	(221)	(346)
Purchase of available-for-sale short-term investments	(231,257)	(101,596)
Proceeds from maturities of available-for-sale short-term investments	242,000	44,100
Net cash provided by (used in) investing activities	<u>10,522</u>	<u>(57,842)</u>
Cash flows from financing activities		
Proceeds from public offering of common stock, net of offering costs	58,862	—
Proceeds from private placement of common stock, net of offering costs	4,667	193
Repurchase of common stock in connection with common stock repurchase agreement	(4,403)	—
Proceeds from issuance of common stock under the at-the-market facility, net of offering costs	1,009	—
Proceeds from issuance of common stock in connection with equity plans	730	278
Net cash provided by financing activities	<u>60,865</u>	<u>471</u>
Net increase (decrease) in cash and cash equivalents	7,705	(104,733)
Cash and cash equivalents, beginning of year	19,927	124,660
Cash and cash equivalents, end of year	<u>\$ 27,632</u>	<u>\$ 19,927</u>
<b>Noncash operating activities:</b>		
Right-of-use assets obtained in exchange for lease obligations	\$ —	\$ 1,733

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

**RENEO PHARMACEUTICALS, INC.**  
**Notes to Consolidated Financial Statements**

**1. Organization and Business**

***Organization***

Renoo Pharmaceuticals, Inc. (Renoo or the Company) commenced operations on September 22, 2014 as a pharmaceutical company and has historically focused on the development of therapies for patients with rare genetic mitochondrial diseases. In December 2017, the Company in-licensed mavodelpar (REN001), a novel oral peroxisome proliferator-activated receptor delta (PPAR $\delta$ ) agonist.

***Risks and Uncertainties***

On December 14, 2023, the Company announced that its pivotal STRIDE study, a global, randomized, double-blind, placebo-controlled Phase 2b trial of mavodelpar in adult patients with primary mitochondria myopathy due to mitochondrial DNA defects, did not meet its primary or secondary efficacy endpoints. As a result, the Company suspended the development activities of its only product candidate, mavodelpar, and implemented cash preservation activities, including substantial workforce reduction. In December 2023, the Company implemented a workforce reduction and recognized approximately \$2.5 million in severance and continuation of benefit expenses for the year ended December 31, 2023.

The Company is subject to a number of risks similar to other pharmaceutical companies including, but not limited to, dependency on the clinical and commercial success of the Company's potential product candidates, ability to obtain regulatory approval of any such potential product candidates, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians, consumers and third-party payors, significant competition and untested manufacturing capabilities, and dependence on key individuals and sole source suppliers.

***Liquidity***

From its inception in 2014, the Company has incurred significant losses and negative cash flows from operations and expects to continue to incur net losses into the foreseeable future and may never become profitable. As of December 31, 2023, the Company had cash, cash equivalents and short-term investments of \$103.0 million to fund future operations. Since inception through December 31, 2023, the Company has funded its operations primarily through the issuance and sale of equity securities. Management has prepared cash flow forecasts which indicate that, based on the Company's current cash resources available and working capital, the Company will have sufficient resources to fund its operations for at least one year after the date the consolidated financial statements are issued.

Future capital requirements will depend on many factors, including the timing and extent of spending on its operations and there can be no assurance that the Company will be successful in obtaining additional funding, that the Company's projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could negatively impact the Company's business, results of operations, and future prospects.

***Public Offerings***

In May 2022, the Company entered into an at-the-market equity offering sales agreement with Leerink Partners LLC (Leerink), previously SVB Securities LLC (2022 ATM Facility), under which it could offer and



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sell from time to time at its sole discretion, up to \$20.0 million in shares of its common stock. On November 13, 2023, concurrent with entering into the 2023 ATM Facility (defined below), the Company and Leerink terminated the 2022 ATM Facility. The Company had sold an aggregate of \$1.2 million under the 2022 ATM Facility as of the termination date.

In May 2023, the Company completed a public offering in which it sold an aggregate of 790,625 shares of common stock, which included the full exercise of the underwriters' option to purchase an additional 103,125 shares of common stock, at a price of \$80.00 per share. The Company received total net proceeds from the offering of approximately \$58.9 million, after deducting underwriting discounts and commissions and offering expenses.

Also, in May 2023, the Company completed a concurrent private placement in which it sold an aggregate of 62,500 shares of common stock to Abingworth Bioventures 8 L.P., a holder of more than 5% of the Company's common stock, at a price of \$80.00 per share. The Company received total net proceeds of approximately \$4.7 million, after deducting advisor fees and other estimated fees and expenses.

On November 13, 2023, the Company entered into an at-the-market equity offering sales agreement (Sales Agreement) with Leerink under which it may offer and sell, from time to time, at its sole discretion, up to \$100.0 million in shares of its common stock (2023 ATM Facility). As of December 31, 2023, the Company had not sold any shares of its common stock under the 2023 ATM Facility and on March 25, 2024, the Company provided notice to Leerink of its election to terminate the Sales Agreement, effective as of April 8, 2024.

On October 4, 2024, the Company effected a 1-for-10 reverse stock split of its common stock. The par value and the authorized shares of the common stock were not adjusted as a result of the reverse stock split. The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

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

### ***Basis of Presentation and Consolidation***

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (GAAP) and reflect the operation of the Company and its wholly owned subsidiary. All intercompany balances and transactions among the consolidated entities have been eliminated in consolidation.

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

The preparation of the Company's consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure in the Company's consolidated financial statements and accompanying notes. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments with original maturities of three months or less, when purchased, to be cash equivalents. As of December 31, 2023 and 2022, the Company had cash balances deposited at major financial institutions. Cash balances are subject to minimal credit risk as the balances are with high credit quality financial institutions. Cash and cash equivalents include cash in readily available checking, money market accounts and repurchase agreements.

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### ***Short-term Investments***

The Company accounts for short-term investments in accordance with Accounting Standard Codification (ASC) Topic 320, *Investments – Debt and Equity Securities*. Management determines the appropriate classification of its investments at the time of purchase and reevaluates such determinations at each reporting period.

At December 31, 2023, the Company's investments comprised of U.S. treasury securities and commercial paper classified as available-for-sale securities. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses on sales of investments are included in interest income and are derived using the specific identification method for determining the cost of securities.

When the fair value of an available-for-sale debt security falls below the amortized cost basis it is evaluated to determine if any of the decline in value is attributable to credit loss. Decreases in fair value attributable to credit loss are recorded directly to earnings with a corresponding allowance for credit losses, limited to the amount that the fair value is less than the amortized cost basis. If the credit quality subsequently improves the allowance is reversed up to a maximum of the previously recorded credit losses. When the Company intends to sell an impaired available-for-sale debt security, or if it is more likely than not that the Company will be required to sell the security prior to recovering the amortized cost basis, the entire fair value adjustment will immediately be recognized in earnings with no corresponding allowance for credit losses. The Company did not recognize any credit losses on its short-term investments during the years ended December 31, 2023 and 2022.

Money market account balances are included as cash and cash equivalents on the consolidated balance sheets, which are also disclosed in Note 4, *Fair Value Measurements*.

### ***Concentration of Credit Risk***

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash, cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

### ***Property and Equipment, Net***

Property and equipment are stated at cost, less accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. Maintenance and repairs are expensed as incurred.

The following estimated useful lives were used to depreciate or amortize the Company's assets:

	<u>Estimated Useful Life</u>
Furniture and fixtures	5 years
Computers and software	3 years
Leasehold improvements	Shorter of useful life or remaining lease term

### ***Impairment of Long-Lived Assets***

Long-lived assets consist primarily of property and equipment. Long-lived assets are evaluated for impairment when events and circumstances indicate the assets might be impaired by first comparing the estimated future undiscounted cash flows of the asset or asset group to the carrying value. If the carrying value

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exceeds the estimated future undiscounted cash flows, an impairment loss is recognized based on the amount that the carrying value exceeds the fair value of the asset or asset group. As a result of suspending development activities of the Company's only product candidate, mavodelpar, the Company recognized \$0.3 million and \$0.4 million in impairment losses of right-of-use assets and leasehold improvements, respectively, for the year ended December 31, 2023. The Company recognized an immaterial amount in impairment related to its leases for the year ended December 31, 2022.

### ***Leases***

The Company determines if an arrangement includes a lease at inception. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company's lease terms may include options to extend or terminate a lease when it is reasonably certain that it will exercise that option. The Company combines lease and non-lease components when determining lease payments.

Right-of-use (ROU) assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term, unless there is a transfer of title or purchase option the Company is reasonably certain to exercise. For leases where an implicit rate is not readily determinable, the Company uses its incremental borrowing rate based on information available at the lease commencement date to determine the present value of future lease payments. Lease expense for operating leases is recognized on a straight-line basis over the expected lease term.

### ***Research and Development Costs and Accruals***

All research and development costs are expensed as incurred. Research and development costs consist primarily of costs associated with manufacturing drug substance and drug product, costs associated with preclinical studies, clinical trials managed through contract research organizations (CROs) and other third parties, license fees, salaries and employee benefits.

The Company bases its expense accruals related to clinical trials on its estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on its behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under certain contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing costs, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. 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 expense in the period that the related goods are consumed, or services are performed.

To date, the Company has not experienced significant changes in its estimates of accrued research and development expenses after a reporting period.

### ***License Fees***

The Company expenses amounts paid to acquire licenses associated with products under development when the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Acquisitions of technology licenses are charged to expense or capitalized based upon management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. The Company has determined that technological feasibility for its product candidate would be reached when the requisite regulatory approvals are obtained to make the product available for sale. Contingent milestone payments are recognized when the related contingency is resolved, and the amounts are paid or become payable. These amounts are expensed to research and development if there is no alternative future use associated with the license or capitalized as an intangible asset if alternative future use of the license exists.

### ***Income Taxes***

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to unrecognized tax benefits.

The Company is subject to taxation in the United States and the United Kingdom (UK). As of December 31, 2023, the Company's tax years since inception are subject to examination by taxing authorities in the United States, and the UK tax returns from 2018 forward are subject to examination.

### ***Stock-Based Compensation***

The Company recognizes stock-based compensation expense for grants under its 2014 and 2021 Equity Incentive Plans and employee stock purchase plan (ESPP). The Company accounts for all stock-based awards granted to employees and directors at their fair value and recognizes compensation expense over the award's vesting period. Determining the amount of stock-based compensation to be recorded requires the Company to develop estimates of fair values of stock options as of the grant date. The Company calculates the grant date fair values of stock options using the Black-Scholes valuation model, which requires the input of subjective assumptions, including but not limited to expected stock price volatility over the term of the awards and the expected term of stock options. The fair value of restricted stock awards granted to employees is based on the quoted closing market price per share on grant date.

The Company granted restricted stock awards with performance conditions that are based upon the achievement of pre-specified clinical development or regulatory performance events. As the outcome of each event has inherent risks and uncertainties, and a positive outcome may not be known until the event is achieved, the Company will begin to recognize the value of the performance-based restricted stock awards when the achievement of each performance condition is deemed probable, a determination that requires significant judgment by management. Compensation cost is recognized under the accelerated method and is adjusted in future periods for subsequent changes in the expected outcome of the performance-related conditions.

The Company granted restricted stock awards with market conditions. The Company measures the fair value of stock-based awards with market-based vesting conditions on the date of grant using a Monte Carlo simulation model. In accordance with accounting guidance for awards with market conditions, the stock-based compensation expense will be recognized over the derived service period regardless of whether the award achieves the market condition and will only be adjusted to the extent the service condition is not met.

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### ***Foreign Currency Transactions***

The functional currency of Reneo Pharma Ltd, the Company's wholly owned subsidiary in the UK, is the U.S. dollar. All foreign exchange transactional and remeasurement gains and losses are recognized in the consolidated statements of operations and comprehensive loss. For the years ended December 31, 2023 and 2022, total foreign currency gains and losses were immaterial.

### ***Comprehensive Income or Loss***

Comprehensive income or loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources.

### ***New Accounting Pronouncements***

#### *Recently Adopted Accounting Pronouncements*

In June 2016, the Financial Accounting Standard Board (FASB) issued Accounting Standard Update (ASU) 2016-13, *Financial Instruments - Credit Losses (ASC 326), Measurement of Credit Losses on Financial Instruments*. The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in the carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. This new guidance was effective for the Company as of January 1, 2023. The Company adopted the guidance as of January 1, 2023, with no material impact on its consolidated financial statements and related disclosures.

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

In December 2023, the FASB issued ASU 2023- 09, *Income Taxes (ASC 740), Improvements to Income Tax Disclosures*. The standard will require more detailed information in the rate reconciliation table and for income taxes paid, among other enhancements. The standard is effective for years beginning after December 15, 2025 and early adoption is permitted. The Company is evaluating the impact of this standard on its consolidated financial statements.

### **3. 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 exercise of all outstanding stock options and vesting of restricted stock units were excluded from the diluted net loss per share calculation for the years ended December 31, 2023 and 2022 because such shares are anti-dilutive.

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

	As of December 31,	
	2023	2022
Common stock options outstanding	530,125	587,774
Unvested restricted stock units	32,650	32,950
<b>Total</b>	<b>562,775</b>	<b>620,724</b>

#### 4. Fair Value Measurements

ASC Topic 820, *Fair Value Measurement*, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and 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. Commercial paper and U.S. treasury securities are categorized as Level 2, using significant other observable inputs. 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.

Investments are reviewed periodically to identify possible other-than-temporary impairments. As the Company has the ability and intends to hold these investments with unrealized losses for a reasonable period of time sufficient for the recovery of fair value, which may be maturity, the Company does not consider these investments to be other-than-temporarily impaired for any of the periods presented.

In connection with the Company's chief executive officer's (CEO) employment agreement, he is entitled to receive a special performance bonus in the amount of \$7.5 million (Performance Award), payable in cash, common stock or a combination of cash and common stock, at the election of the Company, based on achievement of certain conditions as described in more detail in Note 9. The Company estimated the fair value of the Performance Award using a Monte Carlo simulation, which incorporates the stock price at the date of the valuation and utilizes Level 3 inputs such as volatility, probabilities of success, and other inputs that are not observable in active markets. The Performance Award is required to be measured at fair value on a recurring basis each reporting period, with changes in the fair value recognized in general and administrative expense in the consolidated statements of operations and comprehensive loss over the derived service period of the award.

No assets or liabilities were transferred into or out of their classifications during the years ended December 31, 2023 and 2022.

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

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

The recurring fair value measurement of the Company's assets and liabilities measured at fair value at December 31, 2022 consisted of the following (in thousands):

	Quoted Prices in Active Markets For Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
<b>Assets</b>				
<i>Cash and cash equivalents:</i>				
Money market investments	\$ 9,365	\$ —	\$ —	\$ 9,365
Commercial paper	—	4,978	—	4,978
<i>Short-term investments:</i>				
U.S. treasury securities	—	76,253	—	76,253
Commercial paper	—	4,993	—	4,993
Total	<u>\$ 9,365</u>	<u>\$ 86,224</u>	<u>\$ —</u>	<u>\$ 95,589</u>
<b>Liabilities</b>				
Performance award	\$ —	\$ —	\$ 29	\$ 29
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 29</u>	<u>\$ 29</u>

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

	Performance Award
Balance as of January 1, 2023	\$ 29
Change in fair value	(22)
Balance as of December 31, 2023	<u>\$ 7</u>

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### 5. Marketable Debt Securities

The Company's investments in debt securities are carried at fair value and classified as current assets available-for-sale and represent the investment of funds available for current operations. Unrealized gains and losses on available-for-sale debt securities are included in other comprehensive income or loss, and charged to income or expense in the period when realized. The following tables summarize the gross unrealized gains and losses of the Company's available-for-sale securities (in thousands):

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

	As of December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
<b>Available-for-sale securities:</b>				
U.S. treasury securities	\$ 76,297	\$ 2	\$ (46)	\$76,253
Commercial paper	4,993	—	—	4,993
Total	<u>\$ 81,290</u>	<u>\$ 2</u>	<u>\$ (46)</u>	<u>\$81,246</u>

### 6. Property and Equipment, Net

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

	As of December 31,	
	2023	2022
Computer, software and office equipment	\$ 254	\$ 300
Leasehold improvements*	—	255
Total property and equipment, gross	254	555
Less: accumulated depreciation and amortization	(120)	(102)
Total property and equipment, net	<u>\$ 134</u>	<u>\$ 453</u>

\* All leasehold improvements were fully impaired and written off. For further information see Note 13.

### 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2023	2022
Accrued clinical and regulatory	\$3,661	\$1,872
Accrued contract manufacturing cost	1,100	1,583
Accrued compensation*	3,948	807
Accrued other	420	565
Total accrued expenses	<u>\$9,129</u>	<u>\$4,827</u>

\* Accrued compensation includes severance costs. For further information see Note 13.



## 8. Leases

The Company's headquarters are located in Irvine, California, where it leases office space under a lease agreement that expires in November 2026. The Company leases additional office space located in Sandwich, UK under a lease agreement that expires in October 2027 (UK lease), with an option to early terminate in October 2025 with no termination fee. In January 2024, the Company exercised its early termination option. The Company concluded that its current leases are impaired and recognized approximately \$0.3 million of ROU assets impairment expense for the year ended December 31, 2023. For further information, see Note 13.

At December 31, 2023, the weighted average incremental borrowing rate was 5% and the weighted average remaining lease term was 3.8 years for the operating leases held by the Company. For the years ended December 31, 2023 and 2022, cash paid for amounts included for the measurement of lease liabilities was \$0.5 million. For the years ended December 31, 2023 and 2022, operating lease expense was \$0.4 million and \$0.5 million, respectively.

Maturities of lease liabilities by fiscal year for the Company's operating leases are as follows:

	<u>As of December 31, 2023</u>
2024	\$ 381
2025	367
2026	285
Total lease payments	1,033
Less: Imputed interest	(60)
Present value of lease liabilities	<u>\$ 973</u>

## 9. Stock-Based Compensation

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

Under the 2014 Plan, certain employees were granted the ability to early exercise their options. The shares of common stock issued pursuant to the early exercise of unvested stock options are restricted and continue to vest over the requisite service period after issuance. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. The shares purchased by the employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest. As of December 31, 2023, there were no unvested shares of common stock outstanding that were issued pursuant to the early exercise of stock options.

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### *Shares Reserved for Future Issuance*

As of December 31, 2023, the Company had reserved shares of its common stock for future issuance as follows:

	<b>Shares Reserved</b>
Common stock options outstanding	530,125
Unvested restricted stock units	32,650
Available for future grants under the 2021 Equity Incentive Plan	210,922
Available for future grants under the 2021 Employee Stock Purchase Plan	44,589
Total shares of common stock reserved	<u>818,286</u>

### *Stock Options*

A summary of the Company's stock option activity and related information for the year ended December 31, 2023 is as follows:

	<b>Options Outstanding</b>	<b>Weighted- Average Exercise Price</b>	<b>Weighted- Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value (in thousands)</b>
Outstanding at December 31, 2022	587,774	\$ 44.68	8.2	\$ 907
Granted	57,891	68.54		
Exercised	(17,382)	23.11		
Forfeited/Expired	(98,158)	46.86		
Outstanding at December 31, 2023	<u>530,125</u>	<u>\$ 47.59</u>	<u>6.9</u>	<u>\$ —</u>
Vested at December 31, 2023	322,834	\$ 49.14	6.1	\$ —
Exercisable at December 31, 2023	359,212	\$ 49.12	6.2	\$ —

Options exercisable at December 31, 2023 include vested options and options eligible for early exercise. All outstanding options as of December 31, 2023 are expected to vest.

Unrecognized stock-based compensation expense at December 31, 2023 was \$5.9 million, which is expected to be recognized over a weighted-average vesting term of 2.0 years.

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. The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Risk-free interest rate	4.0%	3.4%
Expected volatility	88.6%	84.8%
Expected term (in years)	5.9	6.0
Expected dividend yield	— %	— %

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*Risk-free interest rate.* The Company bases the risk-free interest rate assumption on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

*Expected volatility.* The expected volatility assumption was based on the volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.

*Expected term.* The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

*Expected dividend yield.* The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends.

### **Restricted Stock Units (RSUs)**

RSUs consist of time-based units (TSUs), performance-based units (PSUs) and market-based units (MSUs).

The following table summarizes RSU activities during the year ended December 31, 2023:

	<b>Number of RSUs</b>	<b>Weighted- Average Grant Date Per Share Value</b>
Unvested at December 31, 2022	32,950	\$ 56.70
Granted	13,700	58.19
Cancelled	(14,000)	53.54
Unvested at December 31, 2023	<u>32,650</u>	\$ 58.98

### *Time-Based Units*

TSUs typically vest over four years, with 25% vesting on the one-year anniversary of the employee's hire date and the remainder vesting monthly or quarterly over the following three years subject to the employee's continued employment with the Company through the vesting dates. The fair value of the awards was based on the value of the Company's common stock at the grant date of the award and expense is recognized on a straight-line basis. The Company had 5,700 unvested shares underlying TSUs as of December 31, 2023. The stock-based compensation expense related to such TSUs for the year ended December 31, 2023 was immaterial. Unrecognized stock-based compensation expense at December 31, 2023 was \$0.3 million, which is expected to be recognized over a weighted-average vesting term of 1.3 years.

### *Performance-Based Units*

The vesting of the PSUs is based on the Company achieving certain regulatory milestones and is subject to the employee's continued employment with the Company through the achievement date. The fair value of the awards was based on the value of the Company's common stock at the grant date of the award and expense recognition is based on the probability of achieving the performance conditions. Stock-based compensation expense is adjusted in future periods for subsequent changes in the expected outcome of the performance conditions. The Company had 14,950 unvested shares underlying PSUs as of December 31, 2023. The Company concluded that achievement of the performance conditions was not probable as of December 31, 2023 and 2022, and therefore no stock-based compensation expense was recognized for the years ended December 31, 2023 and 2022 in connection with the PSUs. As of December 31, 2023, there was \$1.1 million of unrecognized stock-based compensation expense related to PSUs that were deemed not probable of vesting.

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### *Market-Based Units*

The vesting of the MSUs is based on the Company's closing stock price trading above \$200 per share for 30 consecutive trading days subject to the employee's continued employment with the Company through the date of achievement. The share price of the Company's common stock on the date of issuance of the MSUs was \$27.80 per share. The fair value was based on Monte Carlo simulation model on the grant date. Stock-based compensation expense is recognized over the derived service period of approximately 3 years. The Company had 12,000 unvested shares underlying MSUs as of December 31, 2023. Stock-based compensation expense related to the MSUs during the years ended December 31, 2023 and 2022 was immaterial. As of December 31, 2023, unrecognized stock-based compensation expense related to the MSUs was immaterial.

### *Performance Award*

In connection with the CEO's employment agreement, he is entitled to receive a Performance Award in the amount of \$7.5 million, payable in cash, common stock or a combination of cash and common stock, at the election of the Company, in the event that (i) the Company's market value exceeds \$750.0 million utilizing the volume-weighted average of the closing sale price of its common stock on the Nasdaq Stock Market or other principal exchange for each of the 30 trading days immediately prior to the measurement date, or (ii) the fair market value of the net proceeds available for distribution to the Company's stockholders in connection with a change in control as defined in the Company's severance benefit plan, as determined in good faith by its Board of Directors, exceeds \$750.0 million. The Company has determined that the Performance Award is subject to ASC 718, *Compensation – Stock Compensation* and includes both market and performance conditions. Since the Company's initial public offering (IPO), neither of the events have yet been satisfied. The Company estimated the fair value of the Performance Award at each reporting period using the Monte Carlo simulation (Note 4), which is recognized as stock-based compensation expense over the derived service period. For the years ended December 31, 2023 and 2022, the Company reversed approximately \$22,000 and \$0.4 million in stock-based compensation expenses, respectively, as a direct result of the decreased value of the Performance Award caused by a decline in the Company's common stock price.

### *2021 Employee Stock Purchase Plan*

In March 2021, the Company's Board of Directors adopted the ESPP, which became effective immediately prior to the execution of the underwriting agreement in connection with the Company's IPO. As of December 31, 2023, 28,846 shares have been issued under the ESPP.

In September 2021, the compensation committee of the Company's Board of Directors adopted the Company's 2021 UK Sharesave Sub-plan (SAYE). An allocation of 2,587 shares of common stock from the ESPP reserve pool was approved and reserved for issuance under the SAYE. No shares have been issued under the SAYE through December 31, 2023.

The stock-based compensation expense related to the ESPP and the SAYE for the years ended December 31, 2023 and 2022, was \$0.4 million and \$0.2 million, respectively.

### *Stock-Based Compensation Expense*

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

	Year Ended December 31,	
	2023	2022
Research and development	\$ 1,815	\$ 1,593
General and administrative	3,297	2,727
Total	\$ 5,112	\$ 4,320

## 10. License Agreement

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

To date, the Company has paid a \$3.0 million upfront payment, \$2.0 million in milestone payments and issued an aggregate of 57,643 shares of its common stock to vTv Therapeutics.

On October 30, 2023, the Company repurchased from vTv Therapeutics all 57,643 shares of its common stock previously issued to vTv Therapeutics under the vTv License Agreement for an aggregate purchase price of approximately \$4.4 million in a private, non-underwritten transaction.

Upon the achievement of certain pre-specified development and regulatory milestones, the Company is also required to pay vTv Therapeutics milestone payments totaling up to \$64.5 million. The Company is also required to pay vTv Therapeutics up to \$30.0 million in total sales-based milestones upon achievement of certain sales thresholds of the licensed product. As of December 31, 2023, the Company has paid an aggregate of \$2.0 million in development and regulatory milestone payments. In addition, the Company is obligated to make royalty payments to vTv Therapeutics at mid-single digit to low teen percentage royalty rates, based on tiers of annual net sales of licensed products, subject to certain customary reductions. There were no milestone payments achieved or recorded for the years ended December 31, 2023 and 2022.

## 11. Income Taxes

The Company's net loss was generated in the following jurisdictions (in thousands):

	<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
Domestic	\$ (78,132)	\$ (51,994)
Foreign	744	39
Net loss	<u>\$ (77,388)</u>	<u>\$ (51,955)</u>

The components of net deferred taxes consisted of the following (in thousands):

	<u>As of December 31,</u>	
	<u>2023</u>	<u>2022</u>
<b>Deferred tax assets:</b>		
NOL carryforwards	\$ 23,490	\$ 16,381
Capitalized research and development expenses	15,274	7,465
Credit carryforwards	6,111	4,061
Intangible assets	2,902	3,202
Compensation accruals	1,885	989
Operating lease liabilities	245	316
Depreciation	89	78
Other	2	2
<b>Gross deferred tax assets</b>	49,998	32,494
Less valuation allowance	(49,872)	(32,214)
<b>Total deferred tax assets</b>	126	280
<b>Deferred tax liabilities:</b>		
ROU assets	(126)	(280)
<b>Net deferred tax assets (liabilities)</b>	<u>\$ —</u>	<u>\$ —</u>

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For the years ended December 31, 2023 and 2022, the Company recorded no provision for income taxes. A reconciliation of the effective tax rate to the amount computed by applying the statutory federal income tax rate to the loss from operations is summarized for the years ended December 31, 2023 and 2022, as follows:

	As of December 31,	
	2023	2022
U.S. federal statutory income tax rate	21.0%	21.0%
Tax credits, net	2.5%	3.4%
Return-to-provision adjustment	0.1%	0.5%
Other	(0.1)%	(0.8)%
GILTI inclusion	(0.4)%	(0.3)%
Foreign Rate Differential	(0.1)%	—
Valuation allowance	(23.0)%	(23.8)%
U.S. federal effective tax rate	0.0%	0.0%

The Company had federal net operating loss (NOL) carryforwards available of approximately \$110.9 million as of December 31, 2023, before consideration of limitations under Section 382 of the Internal Revenue Code of 1986, as amended (Section 382), as further described below. The federal NOLs generated after 2017 of \$109.3 million will carry forward indefinitely. NOLs generated prior to 2018 of \$1.6 million will begin to expire in 2034. Additionally, the Company had state NOL carryforwards available of \$1.8 million as of December 31, 2023. The state NOLs may be used to offset future taxable income and will begin to expire in 2034. The Company has generated UK NOLs of \$0.2 million which carryforward indefinitely.

At December 31, 2023, the Company had federal and state tax credit carry forwards of approximately \$16.9 million and \$0.7 million, respectively. The Company has not performed a formal research and development credit study with respect to these credits. The federal credits will begin to expire in 2034, if unused, and the state credits carry forward indefinitely.

The future utilization of the Company's NOL and tax credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of changes in ownership by stockholders that hold 5% or more of the Company's common stock. An assessment of such ownership changes under Section 382 was not completed through December 31, 2023. To the extent that an assessment is completed in the future, the Company's ability to utilize tax attributes could be restricted on a year-by-year basis and certain attributes could expire before they are utilized. The Company will examine the impact of any potential ownership changes in the future.

The Company has elected to record the inclusion related to the Global Intangible Low-Taxed Income (GILTI) in the period incurred. The estimated GILTI inclusion generated by the Company's wholly-owned controlled foreign corporation in the UK for the year ended December 31, 2023 was \$1.5 million. This amount is included in the income tax provision, however, has zero impact to the provision due to the full valuation allowance.

The Company has established a full valuation allowance for its deferred tax assets due to uncertainties that preclude it from determining that it is more likely than not that the Company will be able to generate sufficient taxable income to realize such assets. Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2023. Such objective evidence limits the ability to consider other subjective evidence such as the Company's projections for future growth. Based on this evaluation, as of December 31, 2023, a full valuation allowance of \$49.9 million has been recorded against the Company net deferred tax assets, as the Company has determined that none of the Company's balance of deferred tax assets is more likely than not to be

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realized. The amount of the deferred tax assets considered realizable, however, could be adjusted in the future if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence, such as estimates of future taxable income during carryforward periods and the Company's projections for growth.

The following table summarizes the changes to unrecognized tax benefits (in thousands):

	Year Ended December 31,	
	2023	2022
Beginning balance of unrecognized tax benefits	\$ 7,094	\$ 2,999
Additions based on tax positions related to the current year	4,331	4,095
Ending balance of unrecognized tax benefits	\$ 11,425	\$ 7,094

The amount of the unrecognized tax benefits that would impact the effective tax rate, absent the valuation allowance, would be \$11.0 million. Due to the full valuation allowance, the impact, however, is zero. At December 31, 2023 and 2022, the Company has not accrued any interest or penalties related to uncertain tax positions. The Company does not anticipate that there will be a significant change in the amount of unrecognized tax benefits over the next 12 months. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

The Company is subject to taxation in the United States and the UK. The Company's federal and state returns since inception are subject to examination due to the carryover of net operating losses. The Company has not been, nor is it currently, under examination by any tax authorities. The UK tax returns from 2018 forward are subject to examination by the UK tax authorities.

## 12. Commitments and Contingencies

### *Legal Proceedings*

The Company is currently not a party to any legal proceedings, nor is the Company aware of any threatened or pending litigation. However, 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.

### *401(k) Plan*

The Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. Matching contributions to the 401(k) plan are made for certain eligible employees to meet non-discrimination provisions of the plan. During the years ended December 31, 2023 and 2022, the expense recorded by the Company was \$0.2 million and immaterial, respectively.

## 13. Financial Impact of Suspension of Mavodelpar Development Activities

On December 14, 2023, the Company announced that its pivotal STRIDE study did not meet its primary or secondary efficacy endpoints. As a result, the Company suspended the development activities of its only product candidate, mavodelpar, and implemented cash preservation activities, including substantial workforce reductions.

In December 2023, the Company implemented a workforce reduction and recognized approximately \$2.5 million in severance and continuation of benefit expenses for the year ended December 31, 2023.

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In addition, the Company assessed the impairment of its ROU and fixed assets due to the suspension of mavodelpar's development activities and concluded that its current leases and leasehold improvements were impaired. The Company recognized approximately \$0.3 million and \$0.4 million of impairment expenses for ROU and leasehold improvements for the year ended December 31, 2023, respectively.

**14. Subsequent Events**

In February 2024, the Company implemented a second workforce reduction. As a result of this workforce reduction, the Company will recognize approximately \$1.6 million in severance and continuation of benefit expenses in first quarter of 2024.



**RENEO PHARMACEUTICALS, INC.**  
**Consolidated Balance Sheets**  
**(In thousands, except share and par value data)**

	<b>June 30, 2024</b>	<b>December 31, 2023</b>
	<b>(Unaudited)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 35,970	\$ 27,632
Short-term investments	40,704	75,331
Prepaid expenses and other current assets	1,316	3,659
Total current assets	77,990	106,622
Property and equipment, net	81	134
Right-of-use assets	493	599
Other non-current assets	153	81
Total assets	<u>\$ 78,717</u>	<u>\$ 107,436</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 64	\$ 8,717
Accrued expenses	953	9,129
Operating lease liabilities, current portion	331	331
Total current liabilities	1,348	18,177
Operating lease liabilities, less current portion	492	642
Performance award	8	7
Total liabilities	1,848	18,826
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized at June 30, 2024 and December 31, 2023; 3,342,080 shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Additional paid-in capital	309,143	307,076
Accumulated deficit	(232,261)	(218,474)
Accumulated other comprehensive (loss) income	(13)	8
Total stockholders' equity	76,869	88,610
Total liabilities and stockholders' equity	<u>\$ 78,717</u>	<u>\$ 107,436</u>

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

**RENEO PHARMACEUTICALS, INC.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
**(In thousands, except share and per share data)**  
**(Unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 590	\$ 14,400	\$ 5,533	\$ 25,389
General and administrative	5,774	6,639	10,396	11,771
Total operating expenses	<u>6,364</u>	<u>21,039</u>	<u>15,929</u>	<u>37,160</u>
Loss from operations	(6,364)	(21,039)	(15,929)	(37,160)
Other income	1,003	1,508	2,142	2,522
Net loss	(5,361)	(19,531)	(13,787)	(34,638)
Unrealized (loss) gain on short-term investments	(1)	(43)	(21)	12
Comprehensive loss	<u>\$ (5,362)</u>	<u>\$ (19,574)</u>	<u>\$ (13,808)</u>	<u>\$ (34,626)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.60)</u>	<u>\$ (6.46)</u>	<u>\$ (4.13)</u>	<u>\$ (12.53)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>3,342,080</u>	<u>3,021,532</u>	<u>3,342,080</u>	<u>2,764,017</u>

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

**RENEO PHARMACEUTICALS, INC.**  
**Consolidated Statements of Changes in Stockholders' Equity**  
(In thousands, except share data)  
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balances, December 31, 2023</b>	<b>3,342,080</b>	<b>\$ —</b>	<b>\$307,076</b>	<b>\$ 8</b>	<b>\$ (218,474)</b>	<b>\$ 88,610</b>
Stock based compensation	—	—	1,078	—	—	1,078
Other comprehensive loss	—	—	—	(20)	—	(20)
Net loss	—	—	—	—	(8,426)	(8,426)
<b>Balances, March 31, 2024</b>	<b>3,342,080</b>	<b>\$ —</b>	<b>\$308,154</b>	<b>\$ (12)</b>	<b>\$ (226,900)</b>	<b>\$ 81,242</b>
Stock based compensation	—	—	989	—	—	989
Other comprehensive loss	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	(5,361)	(5,361)
<b>Balances, June 30, 2024</b>	<b>3,342,080</b>	<b>\$ —</b>	<b>\$309,143</b>	<b>\$ (13)</b>	<b>\$ (232,261)</b>	<b>\$ 76,869</b>
<b>Balances, December 31, 2022</b>	<b>2,469,955</b>	<b>\$ —</b>	<b>\$236,696</b>	<b>\$ (43)</b>	<b>\$ (136,683)</b>	<b>\$ 99,970</b>
Stock based compensation	—	—	1,157	—	—	1,157
Issuance of common stock in connection with at-the-market facility, net of issuance costs	40,787	—	1,009	—	—	1,009
Other comprehensive income	—	—	—	55	—	55
Net loss	—	—	—	—	(15,107)	(15,107)
<b>Balances, March 31, 2023</b>	<b>2,510,742</b>	<b>\$ —</b>	<b>\$238,862</b>	<b>\$ 12</b>	<b>\$ (151,790)</b>	<b>\$ 87,084</b>
Issuance of common stock in public offering, net of offering costs	790,625	—	58,862	—	—	58,862
Issuance of common stock in private placement, net of offering costs	62,500	—	4,667	—	—	4,667
Stock based compensation	—	—	1,207	—	—	1,207
Issuance of common stock in connection with equity plans	16,210	—	282	—	—	282
Other comprehensive loss	—	—	—	(43)	—	(43)
Net loss	—	—	—	—	(19,531)	(19,531)
<b>Balances, June 30, 2023</b>	<b>3,380,077</b>	<b>\$ —</b>	<b>\$303,880</b>	<b>\$ (31)</b>	<b>\$ (171,321)</b>	<b>\$ 132,528</b>

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

**RENEO PHARMACEUTICALS, INC.**  
**Consolidated Statements of Cash Flows**  
**(In thousands)**  
**(Unaudited)**

	Six Months Ended June 30,	
	2024	2023
Cash flows from operating activities		
Net loss	\$ (13,787)	\$ (34,638)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,067	2,364
Depreciation and amortization	28	83
Amortization/accretion on short-term investments	(1,644)	(2,011)
Changes in the fair value of performance award	1	847
Non-cash lease expense	129	241
Loss on disposal of fixed asset	27	3
Changes in operating assets and liabilities:		
Prepaid and other assets	2,360	1,542
Accounts payable and accrued expenses	(16,829)	6,690
Operating lease liabilities	(173)	(283)
Net cash used in operating activities	<u>(27,821)</u>	<u>(25,162)</u>
Cash flows from investing activities		
Purchases of property and equipment	(2)	(177)
Purchase of available-for-sale short-term investments	(67,750)	(132,327)
Proceeds from maturities of available-for-sale short-term investments	104,000	82,000
Net cash provided by (used in) investing activities	<u>36,248</u>	<u>(50,504)</u>
Cash flows from financing activities		
Payments of deferred costs in connection with private placement transaction	(89)	—
Proceeds from public offering of common stock, net of offering costs	—	58,862
Proceeds from private placement of common stock, net of offering costs	—	4,667
Proceeds from issuance of common stock under the at-the-market facility, net of offering costs	—	1,009
Proceeds from issuance of common stock in connection with equity plans	—	282
Net cash (used in) provided by financing activities	<u>(89)</u>	<u>64,820</u>
Net increase (decrease) in cash and cash equivalents	8,338	(10,846)
Cash and cash equivalents, beginning of period	27,632	19,927
Cash and cash equivalents, end of period	<u>\$ 35,970</u>	<u>\$ 9,081</u>
<b>Noncash investing and financing activities:</b>		
Property and equipment in accounts payable	\$ —	\$ 10

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

**RENEO PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements  
(Unaudited)**

**1. Organization and Business**

***Organization***

Reneo Pharmaceuticals, Inc. (Reneo or the Company) is a pharmaceutical company historically focused on the development and commercialization of therapies for patients with rare genetic mitochondrial diseases, which are often associated with the inability of mitochondria to produce adenosine triphosphate. The Company's only product candidate, mavodelpar, is a potent and selective agonist of the peroxisome proliferator-activated receptor delta (PPAR $\delta$ ). Mavodelpar has been shown to increase transcription of genes involved in mitochondrial function and increase fatty acid oxidation, and may increase production of new mitochondria.

On December 14, 2023, the Company announced that its pivotal STRIDE study, a global, randomized, double-blind, placebo-controlled Phase 2b trial of mavodelpar in adult patients with primary mitochondria myopathy due to mitochondrial DNA defects, did not meet its primary or secondary efficacy endpoints. As a result, the Company suspended the development activities for mavodelpar and implemented cash preservation activities, including a substantial workforce reduction. The Company implemented a reduction in workforce in December 2023 and February 2024, and currently has eight full-time employees remaining.

In January 2024, the Company's Board of Directors retained an independent financial advisor to initiate a formal process to evaluate potential strategic alternatives focused on maximizing stockholder value, including, but not limited to, a merger, sale, other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of its assets. The Company is no longer pursuing further clinical development of mavodelpar at this time.

On May 10, 2024, the Company entered into an Agreement and Plan of Merger (Merger Agreement and the transactions contemplated thereby, Proposed Transactions) with Radiate Merger Sub I, Inc., a Delaware corporation and its direct, wholly owned subsidiary (Merger Sub I), Radiate Merger Sub II, LLC, a Delaware limited liability company and its direct, wholly owned subsidiary (Merger Sub II), and OnKure, Inc., a Delaware corporation (OnKure), pursuant to which, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, (a) Merger Sub I will merge with and into OnKure (the First Merger), with Merger Sub I ceasing to exist and OnKure surviving the First Merger as its wholly owned subsidiary (Reneo following the First Merger, NewCo), and (b) as promptly as practicable following the First Merger, OnKure, as the surviving corporation of the First Merger, will merge with and into Merger Sub II, with OnKure ceasing to exist and Merger Sub II surviving the Second Merger as a wholly owned subsidiary of NewCo (the Second Merger, and together with the First Merger, the Mergers). At the effective time of the First Merger (the First Effective Time) and upon filing of an amendment to the Company's amended and restated certificate of incorporation to reclassify its common stock, each share of the Company's common stock existing and outstanding immediately prior thereto will be recapitalized and remain outstanding as a share of NewCo Class A common stock without any conversion or exchange thereof, subject to a proposed reverse stock split of all of the shares of the Company's common stock outstanding at the time of effectiveness thereof by a ratio to be determined by OnKure subject to the Company's approval (the Reverse Stock Split). Upon the First Effective Time, all shares of OnKure capital stock outstanding immediately prior to the First Effective Time, after giving effect to an assumed common stock exchange ratio of 0.024482 and an assumed preferred stock exchange ratio of 0.150062, will be converted into the right to receive approximately 7,695,878 shares of NewCo common stock in the aggregate, which is subject to adjustment as set forth in the Merger Agreement.

In connection with the Mergers, on May 10, 2024, the Company concurrently entered into a Subscription Agreement with certain existing OnKure stockholders and new investors (collectively, PIPE Investors) pursuant to which, among other things, the Company agreed to issue to the PIPE Investors shares of NewCo Class A

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common stock concurrently with the Mergers in a private placement transaction for an aggregate purchase price of \$65.0 million, which amount may be increased to up to \$85.0 million through additional subscriptions from additional PIPE Investors (the Concurrent PIPE Investments). The closing of the Concurrent PIPE Investments is conditioned upon the satisfaction or waiver of the conditions to the closing of the Mergers and the substantially concurrent closing of the Mergers, as well as certain other conditions.

Immediately after the Mergers, pre-Mergers OnKure stockholders are expected to own approximately 69.4% of NewCo on a fully-diluted basis and pre-Mergers Reneo stockholders are expected to own approximately 30.6% of NewCo on a fully-diluted basis. Following the completion of the Concurrent PIPE Investments, assuming a subscription amount of (a) \$65.0 million, pre-Mergers OnKure stockholders are expected to own approximately 54.8% of NewCo on a fully-diluted basis, pre-Mergers Reneo stockholders are expected to own approximately 24.2% of NewCo on a fully-diluted basis, and the PIPE Investors are expected to own approximately 21.0% of NewCo on a fully-diluted basis, and (b) \$85.0 million, pre-Mergers OnKure stockholders are expected to own approximately 51.5% of NewCo on a fully-diluted basis, pre-Mergers Reneo stockholders are expected to own approximately 22.7% of NewCo on a fully-diluted basis, and the PIPE Investors are expected to own approximately 25.8% of NewCo on a fully-diluted basis. The exchange ratios, and related pro forma ownership, will be adjusted (i) to account for the effect of the proposed Reverse Stock Split and (ii) to the extent that Reneo's net cash as of the close of business on the business day immediately preceding the closing date of the Mergers is less than \$59.0 million or greater than \$61.0 million (resulting in pre-Mergers Reneo stockholders owning less or more of NewCo, respectively). The expected relative ownership percentages of pre-Mergers OnKure stockholders and pre-Mergers Reneo stockholders of NewCo are calculated using the treasury stock method, as described in the Merger Agreement.

The Mergers, which have been approved by the Company's Board of Directors and the board of directors of OnKure, are expected to close in the second half of 2024, subject to the satisfaction or waiver of certain closing conditions, including the approval of the Company's stockholders. Certain stockholders of Reneo holding approximately 28.2% of the outstanding shares of its common stock entered into support agreements with Reneo and OnKure to vote all of their shares of the Company's common stock in favor of the Mergers, subject to the terms of the support agreements. Although the Company has entered into the Merger Agreement and intends to consummate the proposed Mergers, there is no assurance that the Company will be able to successfully consummate the proposed Mergers on a timely basis, or at all. If, for any reason, the proposed Mergers are not completed, the Company will reconsider its strategic alternatives and could pursue another strategic transaction similar to the proposed Mergers, potential collaborative, partnering or other strategic arrangements for the Company's assets, including a license, sale or divestiture of its assets, or liquidate and distribute available cash.

### ***Liquidity***

From its inception in 2014, the Company has incurred significant losses and negative cash flows from operations and expects to continue to incur net losses into the foreseeable future and may never become profitable. As of June 30, 2024, the Company had cash, cash equivalents and short-term investments of \$76.7 million, which the Company believes will be sufficient to fund the Company's current operating plan for at least the next 12 months from the date of issuance of these unaudited condensed financial statements.

On October 4, 2024, the Company effected a 1-for-10 reverse stock split of its common stock. The par value and the authorized shares of the common stock were not adjusted as a result of the reverse stock split. The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

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

### ***Basis of Presentation and Consolidation***

The Company has prepared the accompanying unaudited consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and note disclosures

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

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

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

### ***Summary of Significant Accounting Policies***

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

### ***New Accounting Pronouncements***

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

### **3. 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 exercise of all outstanding stock options and vesting of restricted stock units were excluded from the diluted net loss per share calculation for the three and six months ended June 30, 2024 and 2023 because such shares are anti-dilutive.

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

	As of June 30,	
	2024	2023
Common stock options outstanding	467,129	600,118
Unvested restricted stock units	31,150	36,450
Total	498,279	636,568

### **4. Fair Value Measurements**

ASC Topic 820, *Fair Value Measurement*, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and 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

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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. Commercial paper and U.S. treasury securities are categorized as Level 2, using significant other observable inputs. 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.

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

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



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

	Quoted Prices in Active Markets For Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
<b>Assets</b>				
<i>Cash and cash equivalents:</i>				
Money market investments	\$21,717	\$ —	\$ —	\$21,717
U.S. treasury securities	—	12,934	—	12,934
<i>Short-term investments:</i>				
U.S. treasury securities	—	40,611	—	40,611
Total	<u>\$21,717</u>	<u>\$ 53,545</u>	<u>\$ —</u>	<u>\$75,262</u>
<b>Liabilities</b>				
Performance award	\$ —	\$ —	\$ 8	\$ 8
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 8</u>	<u>\$ 8</u>

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

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

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

	Performance Award
Balance as of January 1, 2024	\$ 7
Change in fair value	1
Balance as of June 30, 2024	<u>\$ 8</u>

## 5. Marketable Debt Securities

The Company's investments in debt securities are carried at fair value and classified as current assets available-for-sale and represent the investment of funds available for current operations. Accretion of bond discount and interest income on marketable securities is included in other income as a separate component of other income (expense) on the statement of operations and comprehensive loss. Unrealized gains and losses on available-for-sale debt securities are included in other comprehensive income or loss, and charged to income or expense in the period when realized. The following tables summarize the gross unrealized gains and losses of the Company's available-for-sale securities (in thousands):

	As of June 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
<b>Available-for-sale securities:</b>				
U.S. treasury securities	\$ 53,558	\$ —	\$ (13)	\$53,545
<b>Total</b>	<b>\$ 53,558</b>	<b>\$ —</b>	<b>\$ (13)</b>	<b>\$53,545</b>

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

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

## 6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of June 30, 2024	As of December 31, 2023
Accrued clinical and regulatory	\$ —	\$ 3,661
Accrued contract manufacturing cost	—	1,100
Accrued compensation	386	3,948
Accrued other	567	420
<b>Total accrued expenses</b>	<b>\$ 953</b>	<b>\$ 9,129</b>

## 7. Leases

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

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

	As of June 30,	
	2024	2023
Weighted incremental borrowing rate	5%	5%
Weighted average remaining lease term (in years)	2.3	3.7
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	\$194	\$142
Lease expense (in thousands)	\$148	\$241

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

	As of June 30, 2024
2024 (remaining six months)	\$ 195
2025	371
2026	285
Total lease payments	851
Less: Imputed interest	(28)
Present value of lease liabilities	<u>\$ 823</u>

## 8. Stock-Based Compensation

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

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

### *Shares Reserved for Future Issuance*

As of June 30, 2024, the Company had reserved shares of its common stock for future issuance as follows:

	Shares Reserved
Common stock options outstanding	467,129
Unvested restricted stock units	31,150
Available for future grants under the 2021 Equity Incentive Plan	442,366
Available for future grants under the 2021 Employee Stock Purchase Plan	78,009
Total shares of common stock reserved	<u>1,018,654</u>

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### **Stock Options**

A summary of the Company's stock option activity and related information for the six months ended June 30, 2024 is as follows:

	<b>Options Outstanding</b>	<b>Weighted- Average Exercise Price</b>	<b>Weighted- Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value (in thousands)</b>
Outstanding at December 31, 2023	530,125	\$ 47.60	6.9	\$ —
Forfeited/Expired	(62,996)	\$ 49.05		
Outstanding at June 30, 2024	<u>467,129</u>	\$ 47.39	6.9	\$ —
Vested at June 30, 2024	334,861	\$ 50.38	6.5	\$ —
Exercisable at June 30, 2024	351,698	\$ 50.31	6.5	\$ —

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

Unrecognized stock-based compensation expense as of June 30, 2024 was \$4.4 million, which is expected to be recognized over a weighted-average vesting term of 1.8 years.

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. The Company did not grant any stock options during the six months ended June 30, 2024.

### **Restricted Stock Units (RSUs)**

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

	<b>Number of RSUs</b>	<b>Weighted- Average Grant Date Per Share Value</b>
Unvested at December 31, 2023	32,650	\$ 59.00
Cancelled	(1,500)	\$ 69.79
Unvested at June 30, 2024	<u>31,150</u>	\$ 58.46

### **Time-Based Units**

TSUs typically vest over four years, with 25% vesting on the one-year anniversary of the employee's hire date and the remainder vesting monthly or quarterly over the following three years subject to the employee's continued employment with the Company through the vesting dates. The fair value of the awards was based on the value of the Company's common stock at the grant date of the award and expense is recognized on a straight-line basis. The Company had 5,700 unvested shares underlying TSUs as of June 30, 2024. The stock-based compensation expense related to such TSUs for the three and six months ended June 30, 2024 was immaterial. No stock-based compensation expense related to such TSUs was recognized for the three and six months ended June 30, 2023. Unrecognized stock-based compensation expense as of June 30, 2024 was \$0.3 million, which is expected to be recognized over a weighted-average vesting term of 3.1 years.

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### *Performance-Based Units*

The vesting of the PSUs is based on the Company achieving certain regulatory milestones and is subject to the employee's continued employment with the Company through the achievement date. The fair value of the awards was based on the value of the Company's common stock at the grant date of the award and expense recognition is based on the probability of achieving the performance conditions. Stock-based compensation expense is adjusted in future periods for subsequent changes in the expected outcome of the performance conditions. The Company had 13,450 unvested shares underlying PSUs as of June 30, 2024. The Company concluded that achievement of the performance conditions was not probable as of June 30, 2024 and 2023, and therefore no stock-based compensation expense was recognized for the three and six months ended June 30, 2024 and 2023 in connection with the PSUs. As of June 30, 2024, there was \$1.1 million of unrecognized stock-based compensation expense related to PSUs that were deemed not probable of vesting.

### *Market-Based Units*

The vesting of the MSUs is based on the Company's closing stock price trading above \$200 per share for 30 consecutive trading days subject to the employee's continued employment with the Company through the date of achievement. The share price of the Company's common stock on the date of issuance of the MSUs was \$27.80 per share. The fair value was based on Monte Carlo simulation model on the grant date. Stock-based compensation expense is recognized over the derived service period of approximately 3 years. The Company had 12,000 unvested shares underlying MSUs as of June 30, 2024. Stock-based compensation expense related to the MSUs during the three and six months ended June 30, 2024 and 2023 was immaterial. As of June 30, 2024, unrecognized stock-based compensation expense related to the MSUs was immaterial.

### *Performance Award*

In connection with the CEO's employment agreement, he is entitled to receive a Performance Award in the amount of \$7.5 million, payable in cash, common stock or a combination of cash and common stock, at the election of the Company, in the event that (i) the Company's market value exceeds \$750.0 million utilizing the volume-weighted average of the closing sale price of its common stock on the Nasdaq Stock Market or other principal exchange for each of the 30 trading days immediately prior to the measurement date, or (ii) the fair market value of the net proceeds available for distribution to the Company's stockholders in connection with a change in control as defined in the Company's severance benefit plan, as determined in good faith by its Board of Directors, exceeds \$750.0 million. The Company has determined that the Performance Award is subject to ASC 718, *Compensation – Stock Compensation* and includes both market and performance conditions. Since the Company's initial public offering (IPO), neither of the events have yet been satisfied. The Company estimated the fair value of the Performance Award at each reporting period using the Monte Carlo simulation (Note 4), which is recognized as stock-based compensation expense over the derived service period. For the three and six months ended June 30, 2024, stock-based compensation expense was immaterial. For the three and six months ended June 30, 2023, the Company recognized approximately \$0.6 million and \$0.8 million, respectively, in stock-based compensation expense as a direct result of the increased value of the Performance Award primarily caused by the increase in the Company's common stock price.

### **2021 Employee Stock Purchase Plan**

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

In September 2021, the compensation committee of the Company's Board of Directors (Compensation Committee) adopted the Company's 2021 UK Sharesave Sub-plan (SAYE). An allocation of 2,587 shares of common stock from the ESPP reserve pool was approved and reserved for issuance under the SAYE. The Compensation Committee terminated the SAYE in January 2024 and the reserved shares were returned to the ESPP reserve pool. No shares were issued under the SAYE prior to its termination.

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

### *Stock-Based Compensation Expense*

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	\$ 244	\$ 494	\$ 497	\$ 967
General and administrative	745	713	1,570	1,397
Total	<u>\$ 989</u>	<u>\$ 1,207</u>	<u>\$ 2,067</u>	<u>\$ 2,364</u>

## 9. License Agreement

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

Under the terms of the vTv License Agreement, the Company has paid vTv Therapeutics an initial upfront license fee of \$3.0 million and \$2.0 million of milestone payments and issued an aggregate of 57,643 shares of its common stock to vTv Therapeutics. On October 30, 2023, the Company repurchased from vTv Therapeutics all 57,643 shares of its common stock previously issued to vTv Therapeutics under the vTv License Agreement for an aggregate purchase price of approximately \$4.4 million in a private, non-underwritten transaction.

Upon the achievement of certain pre-specified development and regulatory milestones, the Company is also required to pay vTv Therapeutics milestone payments totaling up to \$64.5 million. The Company is also required to pay vTv Therapeutics up to \$30.0 million in total sales-based milestones upon achievement of certain sales thresholds of the licensed product. As of June 30, 2024, the Company has paid an aggregate of \$2.0 million in development and regulatory milestone payments. In addition, the Company is obligated to make tiered royalty payments to vTv Therapeutics at mid-single digit to low teen percentage royalty rates, based on tiers of annual net sales of licensed products, subject to certain customary reductions. There were no milestone payments achieved or recorded for the three and six months ended June 30, 2024 and 2023.

Although the Company has suspended development activities related to mavodelpar, it will continue to maintain and prosecute mavodelpar intellectual property.