Risk Factors Comparison 2024-04-01 to 2023-03-13 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

~~The risks~~ **If the reimbursement or pricing that we are able to obtain** and ~~uncertainties described below~~ **maintain for any product that we develop and commercialize is inadequate, is significantly delayed or is subject to overly restrictive conditions, our ability to generate revenue, attain profitability and / or commercialize our drug candidates** may ~~have~~ **be impaired and there could be** a material adverse effect on our business, ~~prospects,~~ financial condition **,** ~~or operating~~ results **of operations** ~~. In addition, we may be adversely affected by risks that we currently deem immaterial or by other risks that are not currently known to us. You should carefully consider these risks before making an~~ **and** ~~investment decision. The~~ **growth prospects and the** trading price of our ~~common~~ stock could decline ~~due to any of these risks and you may lose all or part of your investment~~ . ~~In assessing the risks described below, you should also refer to the other information contained in this Annual Report on Form 10- K. Risks Related to Our Products, Programs and Operations~~ Our ability to meet our future capital requirements is partially dependent on ~~the amount~~ **certain milestone** and ~~duration of~~ royalty ~~income~~ **payments that** we ~~expect~~ **are eligible** to receive ~~from~~ **based on** Rayner' s sales of OMIDRIA, and, if sales of OMIDRIA are less than anticipated **and / or Rayner is unable to expand sales of OMIDRIA outside the U. S.** , our financial condition and results of operations may be materially adversely affected, the price of our common stock may decline and we may be unable to access needed capital on favorable terms, or at all. ~~We currently are~~ **In February 2024, we sold to DRI an expanded interest in OMIDRIA royalties payable by Rayner. Pursuant to the Amendment with DRI, DRI is** entitled to receive **all** royalties on ~~Rayner' s~~ U. S. net sales of OMIDRIA ~~at~~ **between January 1, 2024 and December 31, 2031. Omeros retains** the **right to receive all royalties payable by Rayner on any net sales of OMIDRIA outside the U. S. payable from and after January 1, 2024, as well as all royalties on global net sales of OMIDRIA payable from and after December 31, 2031. We received $ 115. 5 million in cash upon closing of the Amendment. Additionally, we are eligible under the Amendment to receive two milestone payments of up to $ 27. 5 million each, payable in January 2026 and January 2028, respectively, based on achievement of certain thresholds for U. S. net sales of OMIDRIA. The royalty** rate **payable by Rayner on net sales** of **OMIDRIA is currently** 30 % ~~, which was reduced from 50~~ **in the United States and 15** % ~~following~~ **outside** the **U** ~~occurrence of the milestone event in late 2022 that resulted in our receipt of the $ 200~~ . **S** ~~0 million Milestone Payment~~ . The royalty rate is subject to further reduction to 10 % of U. S. net sales upon the occurrence of certain events, including during any specific period in which OMIDRIA is no longer eligible for separate payment. **The availability** ~~Additionally, we previously sold to DRI an interest in a portion~~ of ~~our future OMIDRIA royalty receipts and we are entitled to retain~~ royalties **from** ~~paid by~~ Rayner **and / or milestone** ~~in a given period only to the extent that such~~ payments **from** ~~exceed the specified amount to which~~ DRI is ~~entitled~~ **dependent on Rayner' s net sales of OMIDRIA and may be of lesser magnitude than anticipated** ~~for~~ **or** ~~such period~~ **may not become payable at all** . We cannot provide assurance that ~~our cash and investments on hand, together with~~ royalty income from Rayner **and / or milestone payments from DRI, if they become payable** , will be **a meaningful source of capital** ~~sufficient to fund our operations fully~~ in the future ~~. In the event that royalties from Rayner are insufficient now or in the future, we will need to generate substantially more royalty income from Rayner or generate other revenue such as through sales of future approved products to achieve and sustain profitability~~ . Sales- based royalty income **and milestone payments** may be affected by any number of factors, including: ● Rayner' s ability to successfully market and sell OMIDRIA in the U. S.; ● whether, and to what extent, **Rayner is able to expand** ~~if any, we derive royalties from the sale~~ **sales** of OMIDRIA outside the U. S.; ● pricing, coverage and reimbursement policies of government and private payers such as Medicare, Medicaid, the U. S. Department of Veterans Affairs, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators; ● a lack of acceptance by physicians, patients and other members of the healthcare community; ● interruptions in the supply of OMIDRIA; ● the availability, relative price and efficacy of the product as compared to alternative treatment options or branded, compounded or generic competing products; ● an unknown safety risk; and ● changed or increased regulatory restrictions in the U. S., EU and / or other foreign territories. ~~Failure to obtain and maintain regulatory approval in the U. S. or in foreign jurisdictions would prevent us from commercializing and marketing our drug candidates. The regulatory process is subject to substantial agency discretion and risks, including those described herein and elsewhere in these " Risk Factors. " In October 2021, we received a CRL from FDA regarding our BLA for narsoplimab for the treatment of HSCT- TMA. In the CRL, FDA expressed difficulty in estimating the treatment effect of narsoplimab in HSCT- TMA and asserted that additional information would be needed to support regulatory approval. We appealed FDA' s decision to issue the CRL through a formal dispute resolution process that concluded in late 2022. Although our appeal was denied, the decision identified a potential path for resubmission of the BLA based on inclusion of certain additional information and analyses, the specifics of which will be determined through further discussion with the FDA. We can provide no assurance that we will reach a satisfactory agreement with FDA regarding the additional information to be included with a resubmitted BLA, and the requirements for resubmission of our BLA may be costly, require significant time and may not result in approval. Ultimately, we cannot guarantee that FDA will ever approve narsoplimab for the treatment of HSCT- TMA or any other indication. We also intend to market outside the U. S. any of our drug candidates that are approved in the future. In order to market our products in non- U. S. jurisdictions, we or our partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The regulatory approval procedure varies among countries and can involve additional testing and data review. The requirements governing marketing authorization, the conduct of clinical trials, pricing and reimbursement vary from country to country. Approval by FDA does not ensure approval by the EMA, and approval by one foreign regulatory authority~~

~~does not ensure approval by regulatory agencies in other foreign countries or by FDA. The time required to obtain regulatory approval outside the U. S. and EU may differ from that required to obtain FDA or EU approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these " Risk Factors " and we may not obtain foreign regulatory approvals on a timely basis, or at all. In addition, even if we were able to obtain regulatory approval for a product in one or more foreign jurisdictions, we may need to complete additional requirements to maintain that approval and our ability to market the product in the applicable jurisdiction. If any product that we develop and commercialize does not receive adequate coverage or reimbursement from governments and / or private payers our prospects for revenue and profitability would suffer. The success of any product that we or our third- party business partners commercialize in the future will depend heavily on the pricing, availability and duration of adequate coverage or reimbursement for any such product from government, private and other third- party payers, both in the U. S. and in other countries. There may be significant delays in obtaining coverage or reimbursement for newly approved products, and we may not be able to provide data sufficient to be granted adequate coverage or reimbursement. Even when a payer determines that a product is eligible for reimbursement, coverage may be limited to the uses of a product that are either approved by FDA (or, in other countries, the relevant country' s regulatory agency) and / or appear in a recognized drug compendium, or other conditions may apply. Moreover, eligibility for coverage does not mean that any product will be reimbursed at a rate that allows us to make a profit or at a rate that covers our costs, including research, development, manufacturing, sales and distribution. Increasingly, government and private third- party payers that reimburse for healthcare services and products are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products, which could adversely impact the pricing of our products. Any reduction in reimbursement from Medicare, including as a result of the IRA (as discussed below), or other government programs may result in a similar reduction in payments from private payers. Pricing may also be adversely affected by changes in the terms, scope and / or complexity of government pricing requirements. Even if we achieve coverage or reimbursement for a product, the initial rate or method at which the product will be reimbursed could become unfavorable to us at the time reimbursement is initiated or in the future or may be of a limited duration. In addition, obtaining acceptable coverage and reimbursement from one payer does not guarantee that we will obtain similar acceptable coverage or reimbursement from another payer. 30On August 16, 2022, President Biden signed the IRA into law, which sets forth meaningful changes to drug product reimbursement by Medicare. Among other actions, the IRA permits HHS to engage in price- capped negotiation to set the price of certain drugs and biologics reimbursed under Medicare Part B and Part D. The IRA contains statutory exclusions to the negotiation program, including for certain orphan designated drugs for which the only approved indication (or indications) is for the orphan disease or condition. Should our product candidates be approved and covered by Medicare Part B or Part D, and fail to fall within a statutory exclusion, such as that for an orphan drug, those products could, after a period of time, be selected for negotiation and become subject to prices representing a significant discount from average prices to wholesalers and direct purchasers. The IRA also establishes a rebate obligation for drug manufacturers that increase prices of Medicare Part B and Part D covered drugs at a rate greater than the rate of inflation. The inflation rebates may require us to pay rebates if we increased the cost of a covered Medicare Part B or Part D approved product faster than the rate of inflation. In addition, the law eliminates the " donut hole " under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10 % of Part D enrollees' prescription costs for brand drugs below the out- of- pocket maximum and 20 % once the out- of- pocket maximum has been reached. Our cost- sharing responsibility for any approved product covered by Medicare Part D could be significantly greater under the newly designed Part D benefit structure compared to the pre- IRA benefit design. Additionally, manufacturers that fail to comply with certain provisions of the IRA may be subject to penalties, including civil monetary penalties. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices we can charge and reimbursement we can receive for our products, among other effects. In non- U. S. jurisdictions, we must obtain separate reimbursement approvals and comply with related foreign legal and regulatory requirements. In some countries, including those in the EU, our products may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time and expenditure of resources after the receipt of marketing approval for a product. We provide no assurances that the price of any product in one or more of these countries or regions will allow us to make a profit or cover our costs, including research, development, manufacturing, sales and distribution, and as a result we may decide to delay, potentially indefinitely, initiating sales in the particular country or region. If the reimbursement or pricing that we are able to obtain and maintain for any product that we develop and commercialize is inadequate, is significantly delayed or is subject to overly restrictive conditions, our ability to generate revenue, attain profitability and / or commercialize our drug candidates may be impaired and there could be a material adverse effect on our business, financial condition, results of operations and growth prospects and trading price of our stock could decline.~~ Our operating results are unpredictable and may fluctuate. Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including: ● the ~~level~~ **extent** and ~~timing~~ **magnitude** of ~~royalty income from~~ **certain payments to which we may be entitled based on** Rayner' s net sales of OMIDRIA ~~, which~~ may be affected by the extent of coverage and reimbursement for OMIDRIA, market acceptance of the product and Rayner' s ability to execute an effective sales strategy; ● the extent of any payments received from any collaboration agreements or development funding arrangements that we may enter into from time to time, as well as the extent of any payments that we are required to make under existing or future collaboration and license agreements, which may include sales- based royalties and milestone payments based on the achievement of development, regulatory and sales milestones and may vary significantly from quarter to quarter; ● the timing, cost and level of investment in our research and development activities as well as expenditures we may incur to acquire or develop additional technologies, drug candidates, or in preparation for potential commercialization of our drug candidates; ~~and~~31 -- **and** ● whether we are able to obtain marketing approval for any of our drug candidates, the extent and

timing of revenue from sales of any such approved product and the magnitude and timing of expenses associated with the manufacturing and sale of any such approved product. Any of these risk factors, should one or more occur, could adversely affect our results of operations and financial condition and cause the trading price of our stock to decline. **30We** ~~We have incurred cumulative operating losses since inception. If we are unable to raise additional capital when needed we may be unable to complete the development and commercialization of our drug candidates or to continue our other preclinical development programs. Our operations have consumed substantial amounts of cash since our incorporation, As of December 31, 2022, we had cash, cash equivalents and short- term investments of $ 194. 9 million and outstanding accounts receivable of $ 213. 2 million, substantially all of which have since been collected. Our cash used in operations was $ 86. 5 million and our net income for the year ended December 31, 2022 was $ 47. 4 million which included the $ 200. 0 million Milestone Payment. We expect to continue to spend substantial amounts to: ● initiate and conduct clinical trials and manufacture clinical and registration batches for our drug candidates; ● continue research and development in our programs; ● make principal, interest and fee payments as required under our 6. 25 % Convertible Senior Notes due 2023 (the " 2023 Notes ") and 5. 25 % Convertible Senior Notes due 2026 (the " 2026 Notes " and, together with the 2023 Notes, the " Convertible Notes "); and ● commercialize and launch drug candidates for which we may receive regulatory approval. We expect to continue to incur additional losses until such time as we generate significant revenue from the sale of other commercial products or partnerships. We are unable to predict the extent of any future losses and cannot provide assurance that we will generate sufficient revenue from commercial products in the future to fund our operations fully. If we are unable to generate sufficient revenue from commercialized products or partnership arrangements, we may never become and remain profitable and will be required to raise additional capital to continue to fund our operations. We cannot be certain that additional capital will be available to us on acceptable terms, if at all, when required. Adverse developments to our financial condition or business, as well as disruptions in the global equity and credit markets, may limit our ability to access capital. If we do not raise additional capital when needed through one or more funding avenues, such as debt or equity financings or corporate partnering, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our drug candidates or one or more of our preclinical programs or other research and development initiatives. In addition, we may be required to seek collaborators for one or more of our current or future products at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might be available or to relinquish or license on unfavorable terms our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves. We also may have insufficient funds or otherwise be unable to advance our preclinical programs to a point where they can generate revenue through partnerships, collaborations or other arrangements. Any of these actions could limit the amount of revenue we are able to generate and harm our business and prospects. We~~ are subject to extensive government regulation and the failure to comply with these regulations may have a material adverse effect on our operations and business. Both before and after approval of any product, we and our suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the U. S. and other countries, covering, among other things, testing, manufacturing, quality control, clinical trials, post- marketing studies, reporting, risk management plans, labeling, advertising, promotion, distribution, import and export, governmental pricing, price ~~32reporting~~ -- **reporting** and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions: warning letters; unanticipated expenditures; delays in approval or refusal to approve a drug candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties; adverse publicity; and disruptions to our business. Further, government investigations into potential violations of these laws would require us to expend considerable resources and face adverse publicity and the potential disruption of our business even if we are ultimately found not to have committed a violation. Obtaining FDA approval of our drug candidates requires substantial time, effort and financial resources and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on any of our drug candidates on a timely basis, if at all. As was the case with ~~the issuance with~~ our BLA for narsoplimab in ~~HSCT~~ **TA** - TMA, with respect to which FDA issued a CRL ~~indicating that certain additional information would be required to support approval~~ , even ~~if we discuss~~ **after collaborating closely** with ~~, and obtain feedback from,~~ FDA **or regulators with corollary responsibilities in jurisdictions outside the U. S.** regarding ~~our proposed clinical trials, clinical data collection protocols and nonclinical studies before initiating those~~ -- **the** ~~trials or studies, FDA~~ **contents of a marketing application a regulator** may decide that the design of our clinical trials or clinical data collection protocols as actually run, or our resulting data, are insufficient for approval of our drug candidates ~~and~~ **. FDA or other regulators** may require us to run additional preclinical, clinical or other studies or perform additional work related to chemistry, manufacturing and controls. In addition, we, FDA or an independent institutional review board or ethics committee may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are or would be exposed to an unacceptable health risk or because of the way in which the investigators on whom we rely carry out the trials. We are subject to extensive government regulation of the testing of our investigational products, including the requirement that we conduct all of our clinical trials in accordance with FDA' s GCP requirements and similar requirements outside of the U. S. If we are unable to comply with these requirements, if we are required to conduct additional trials or to conduct other testing of our drug candidates beyond that which we currently contemplate for regulatory approval, if we are unable to complete our clinical trials or other testing successfully, or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may face substantial additional expenses, be delayed in obtaining marketing approval for our drug candidates or may never obtain marketing approval. We are also required to comply with extensive governmental regulatory requirements after a product has received marketing authorization. Governing regulatory authorities may require post- marketing studies that may negatively impact the commercial viability of a product. Once on the market, a product may become associated with previously undetected adverse effects and / or may develop manufacturing difficulties. We are required to comply with other post- marketing requirements

including **cGMPs** ~~current Good Manufacturing Practices~~ , advertising and promotion restrictions, pharmacovigilance requirements including risk management activities, reporting and recordkeeping obligations, and other requirements. As a result of any of these or other problems or failure to comply with our regulatory obligations, a product' s regulatory approval could be withdrawn, which could harm our business and operating results. In addition, we must maintain an effective healthcare compliance program in order to comply with U. S. and other laws applicable to marketed drug products and, in particular, laws (such as the Anti- Kickback Statute, the False Claims Act and the Sunshine Act) applicable when drug products are reimbursed by a federal or state healthcare program. U. S. laws such as the Foreign Corrupt Practices Act prohibit the offering or payment of bribes or inducements to foreign public officials, including potentially physicians or other medical professionals who are employees of public healthcare entities in jurisdictions outside the U. S. In addition, many countries have their own laws similar to the healthcare compliance laws that exist in the U. S. Implementing and maintaining an effective compliance program requires the expenditure of significant time and resources. If we are found to be in violation of any of these laws, we may be subject to significant penalties, including but not limited to civil or criminal penalties, damages and fines as well as exclusion from government healthcare programs. We may face difficulties from changes to current regulations as well as future legislation. Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U. S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we ~~33are~~ -- **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. ~~Any~~ **31Any** reduction in reimbursement from Medicare resulting from the IRA or other legislative or policy changes or from other government programs may result in a similar reduction in payments from private payers. These healthcare reforms and the implementation of any future cost containment measures or other reforms may prevent us from being able to generate sufficient revenue, attain and / or maintain profitability or commercialize our drug candidates. We cannot be sure whether additional legislative changes will be enacted, **whether existing legislation will be** ~~or the effect of forthcoming guidance implementing~~ **implemented** ~~the IRA~~ , **interpreted or enforced as anticipated** or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on ~~OMIDRIA or the marketing approvals of~~ our drug candidates, if any, may be. We have no internal capacity to manufacture commercial or clinical supplies of our drug candidates and intend to continue to rely solely on third- party manufacturers **, which could significantly limit or delay our clinical trials or regulatory submissions and may negatively impact our financial conditions and results of operations** . If we are unable to establish relationships with contract manufacturers that have sufficient manufacturing capacity available to meet our needs, or if the contract manufacturers that we rely on experience difficulties manufacturing and supplying our drug candidates, or fail FDA or other regulatory inspections, then our clinical trials or regulatory submissions may be significantly limited or delayed or we may have inadequate supply to meet demand for any product that we commercialize in the future. We rely and intend to continue to rely on third- party manufacturers to produce quantities of clinical drug supplies of our drug candidates that are needed for clinical trials and to support NDAs, BLAs, or similar applications to regulatory authorities seeking marketing approval for our drug candidates, as well as to produce inventory of our drug candidates for commercial use in anticipation of marketing approval. Global demand for contract manufacturing is ~~high~~ **volatile** and the available supply of contract manufacturing capacity is limited **and unpredictable** . We cannot provide any assurance that we will be able to enter into or maintain these types of arrangements on commercially reasonable terms, or at all, or that manufacturing arrangements will meet our requirements **. Our contract manufacturers previously have and may in the future require us to place orders or make other financial commitments several years in advance of manufacturing commencement based on forecasts of our long-term commercial supply requirements for drug candidates that have not yet received, and may never receive, regulatory approval. We may be required to pay significant cancellation fees or other financial penalties in connection with the withdrawal or cancellation of any binding order for manufacturing that we later determine is not needed. The fees or other financial obligations that we may incur in connection with withdrawn or cancelled orders may be material and any such financial penalty would negatively impact our financial condition and results of operations** . If we or one of our manufacturers were to terminate one of these arrangements early, or the manufacturer was unable to supply product quantities sufficient to meet our requirements, we would be required to transfer manufacturing to an approved alternative facility and / or establish additional manufacturing and supply arrangements. We may also need to establish additional or replacement manufacturers, potentially with little or no notice, in the event that one of our manufacturers fails to comply with FDA and / or other pharmaceutical manufacturing regulatory requirements. Even if we are able to establish additional or replacement manufacturers, identifying these sources and entering into definitive supply agreements and obtaining regulatory approvals may require a substantial amount of time and cost and may create a shortage of the product. It can take several years to qualify and validate a new contract manufacturer, and we cannot guarantee that we would be able to complete in a successful and timely manner the appropriate validation processes or obtain the necessary regulatory approvals for one or more additional or replacement manufacturers. Such alternate supply arrangements may not be available on commercially reasonable terms, or at all. Additionally, if we are unable to engage multiple suppliers to manufacture our products, we may have inadequate supply to meet demand for our product. In addition, narsoplimab, OMS906 and OMS1029 are biologic drug products and other drug candidates from certain of our programs, including but not limited to MASP- 2 and MASP- 3, could be biologic drug products. We do not have the internal capability to produce biologics for use in clinical trials or on a commercial scale. There are only a limited number of manufacturers of biologic drug products and we may be unable to enter into agreements on commercially reasonable terms with a sufficient number of them to meet clinical or commercial demand, if at all. The regulatory requirements for commercial supply are more stringent than for clinical supply and we cannot guarantee that a contract manufacturer producing drug product for clinical trials will be able to complete successfully the appropriate validation processes or obtain the

necessary regulatory approvals for marketing approval and commercial supply in a timely manner or at all. ~~Our~~ **32Our** contract manufacturers may encounter difficulties with formulation, manufacturing, supply chain and / or release processes that could result in delays in clinical trials and / or regulatory submissions or that could impact adversely the commercialization of our products or drug candidates, as well as in the initiation of enforcement actions by FDA and other regulatory authorities. For example, our manufacturers are required to comply with FDA' s GMP requirements and ~~34are~~ -- **are** subject to periodic inspections by FDA. If our manufacturers are unable to comply with FDA requirements, they may be unable to meet our supply needs. These difficulties also could result in the recall or withdrawal of a product from the market or a failure to have adequate supplies to meet market demand. If the safety or manufacturing quality of any drug candidate supplied by contract manufacturers is compromised due to one or more of those contract manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to maintain regulatory approval to run clinical trials or to obtain and maintain regulatory approval for one or more of our drug candidates, which would harm our business and prospects significantly. Any significant delays in the manufacture and / or supply of clinical or commercial supplies could materially harm our business, financial condition, results of operations and prospects. Ingredients, excipients, test kits and other materials necessary to manufacture our drug candidates may not be available on commercially reasonable terms, or at all, which may adversely affect the development and commercialization of our drug candidates. We and our third- party manufacturers must obtain from third- party suppliers the APIs, excipients, and / or other raw materials plus primary and secondary packaging materials necessary for our contract manufacturers to produce our drug candidates for our clinical trials and, to the extent approved or commercialized, for commercial distribution. Although we have entered or intend to enter into agreements with third- party suppliers that will guarantee the availability and timely delivery of APIs, excipients, test kits and materials for our drug candidates, we have not entered into agreements for the supply of all such ingredients, excipients, test kits or materials, and we may be unable to secure all such supply agreements or guarantees on commercially reasonable terms, if at all. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients, excipients, test kits or materials in a timely manner or in the quantities required. Further, if we or our third- party manufacturers are unable to obtain APIs, excipients, test kits and materials as necessary for our clinical trials or for the manufacture of commercial supplies of our drug candidates, if approved, potential regulatory approval or commercialization would be delayed, which would materially and adversely affect our ability to generate revenue from the sale of our drug candidates. ~~Similarly, if Rayner or its third- party manufacturers experience difficulty obtaining the quantities of these ingredients, excipients or materials that are necessary for the manufacture of commercial supplies of OMIDRIA, the amount of royalty income we could expect to receive would be materially and adversely affected.~~ We may be unable to advance clinical development of narsoplimab for treatment of COVID- 19 and, even if successful, we may be unable to manufacture narsoplimab in sufficient quantities. Narsoplimab has been used to treat critically ill COVID- 19 patients under our compassionate use program with highly positive results and, in an analysis of the randomized population in the narsoplimab treatment arm of I- SPY COVID- 19 trial, the addition of narsoplimab to standard- of- care treatment of critically ill COVID- 19 patients resulted in a mortality benefit. Notwithstanding these results, we may determine not to continue clinical development of narsoplimab for COVID- 19 and / or further clinical evaluation of narsoplimab for the treatment of COVID- 19 may not be feasible as a result of a number of factors, including decreasing rates of severe illness in patients with COVID- 19 and the availability of alternative preventive or therapeutic agents for COVID- 19. Additionally, the results of the I- SPY- COVID- 19 trial may be not be viewed by regulators, government officials and others as strong evidence of narsoplimab' s efficacy in the treatment of severe COVID- 19 because the narsoplimab treatment arm of the I- SPY- COVID- 19 trial was terminated prior to accrual of the maximum of 125 patients on the basis of analysis in a pre- consented population in which substantial bias was detected. Also, contract manufacturing capacity and supplies of raw materials necessary for the production of narsoplimab are limited and we may be unable to secure the large- scale manufacturing capacity from third parties necessary to manufacture narsoplimab in sufficient quantities to enable broad availability of narsoplimab for COVID- 19 patients. These risks could limit our ability to develop or commercialize a therapeutic for COVID- 19. ~~35If~~ **33If** our clinical trials or clinical protocols are delayed, suspended or terminated, we may be unable to develop our drug candidates on a timely basis, which would adversely affect our ability to obtain regulatory approvals, increase our development costs and delay or prevent commercialization of approved products. We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials or clinical data collection protocols that will cause regulatory agencies, institutional review boards or ethics committees, or us to delay our clinical trials or suspend or delay the analysis of the data from those trials. Clinical trials and clinical data protocols **have been, and in the future** can be **,** delayed for a variety of reasons, including: ● discussions with FDA, the EMA or other foreign authorities regarding the scope or design of our clinical trials or clinical data collection protocols; ● delays or the inability to obtain required approvals from institutional review boards, ethics committees or other responsible entities at clinical sites selected for participation in our clinical trials; ● delays in enrolling patients into clinical trials, collecting data from enrolled patients or collecting historical control data for any reason including disease severity, trial or data collection protocol design, study eligibility criteria, patient population size (e. g., for orphan diseases or for some pediatric indications), proximity and / or availability of clinical trial sites for prospective patients, availability of competing therapies and clinical trials, regional differences in diagnosis and treatment, perceived risks and benefits of the product or drug candidate, disruptions due to external events or conditions affecting the localities or regions in which our clinical trials are conducted, such as **terrorism, political crises, natural disasters, war and wartime conditions,** such as ~~war~~ **those in Ukraine** , ~~terrorism~~ **which has affected the operation of our clinical trials of OMS906** , ~~political crises, natural disasters~~ or outbreaks of contagious disease such as the COVID- 19 pandemic, which previously slowed enrollment in our clinical trials of narsoplimab ~~in patients with IgA nephropathy~~ ; ● lower than anticipated retention rates of patients in clinical trials; ● the need to repeat or conduct additional clinical trials as a result of inconclusive or negative results, failure to replicate positive early clinical data in subsequent clinical trials, failure to deliver an efficacious dose

of a drug candidate, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol or to follow GCPs or other study requirements, an unacceptable study design or other problems; ● adverse findings in clinical or nonclinical studies related to the safety of our drug candidates in humans; ● an insufficient supply of drug candidate materials or other materials necessary to conduct our clinical trials; ● the need to qualify new suppliers of drug candidate materials for FDA and foreign regulatory approval; ● an unfavorable inspection or review by FDA or other regulatory authority of a clinical trial site or records of any clinical investigation; ● the occurrence of unacceptable drug- related side effects or adverse events experienced by participants in our clinical trials; ● the suspension by a regulatory agency of a trial by imposing a clinical hold; or ● the amendment of clinical trial or data collection protocols to reflect changes in regulatory requirements and guidance or other reasons as well as subsequent re- examination of amendments to clinical trial or data collection protocols by regulatory agencies, institutional review boards or ethics committees. ~~36In~~ **34In particular, because PNH and C3G, the indications for which our ongoing clinical trials are evaluating OMS906, are rare conditions, we have opened and expect to continue opening clinical sites in Ukraine and other countries that may be affected by armed conflict or political instability or that have not been traditionally established as centers for clinical research. Like Ukraine, some of these areas have been, and may continue to be, affected by such conflict, instability and / or health infrastructure challenges. Enrollment and retention of patients in, or the ability to receive results from, these clinical trials could be disrupted by the existing conditions in these areas or other geopolitical or macroeconomic developments. If patients withdraw from our trials, miss scheduled doses or follow- up visits or otherwise fail to follow trial protocols, if we are unable to resupply the drugs to clinical sites on schedule, or if our trial results are otherwise disrupted or disputed due to such conditions and developments, the integrity of data from our trials may be compromised or not accepted by FDA or other regulatory authorities, which would represent a significant setback for the development of this drug candidate. In** addition, our clinical trial or development programs have been, and in the future may be, suspended or terminated by us, FDA or other regulatory authorities, or institutional review boards or ethics committees due to a number of factors, including: ● failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; ● inspection of the clinical trial operations or trial sites by FDA or other regulatory authorities resulting in the imposition of a clinical hold; ● our failure to comply with our regulatory obligations as a sponsor of clinical research, such as adverse event reporting, control of study drug, adequate study monitoring, and other obligations; ● the failure to remove a clinical hold in a timely manner, if at all; ● unforeseen safety issues or any determination that a trial presents unacceptable health risks; ● inability to deliver an efficacious dose of a drug candidate; or ● lack of adequate funding to continue the clinical trial or development program, including as a result of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and / or increased expenses associated with the services of our contract research organizations (“ CROs ”), or other third parties. If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to file for regulatory approval or conduct additional clinical trials on the schedule we currently anticipate. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a drug candidate. Any delays in completing our clinical trials could increase our development costs, could slow down our product development and regulatory submission process, could delay our receipt of product revenue and could make it difficult to raise additional capital. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products, potentially harming our business. Because we have a number of drug candidates and development programs, we may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications for which there is a greater likelihood of obtaining regulatory approval and that may be more profitable, if approved. We have limited resources and must focus on the drug candidates and clinical and preclinical development programs that we believe are the most promising. As a result, we may forgo or delay the pursuit of opportunities with other drug candidates or other indications that later prove to have greater commercial potential and may not be able to progress development programs as rapidly as otherwise possible. Further, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug through collaboration, license or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. Our drug candidates may not successfully complete clinical development or be suitable for successful commercialization or generation of revenue through partnerships, and our preclinical programs may not produce drug candidates that are suitable for clinical trials. We must successfully complete preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before commencing clinical trials for any drug candidate. Many pharmaceutical and biological drug candidates do not successfully complete preclinical testing. There can be no assurance that positive results from preclinical studies will be predictive of results obtained from subsequent preclinical studies or clinical trials. ~~37Even~~ **35Even** if preclinical testing is successfully completed, we cannot be certain that any drug candidates that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials, and safety and / or efficacy outcomes of early clinical trials may not be consistent with outcomes of subsequent clinical trials. There can be no assurance that we will be able to successfully commercialize our current or future drug candidates or to meet our expectations with respect to revenues or profits from such products. We may incur substantial costs as a result of commercial disputes, claims, litigation or other legal proceedings relating to our business operations, especially with regard to patent and other intellectual property rights, and such costs or an adverse outcome in such a proceeding may adversely affect our financial condition, results of operations and / or stock price. Our business involves numerous commercial contractual arrangements, important intellectual property rights, potential product liability, uncertainties with respect to clinical development, manufacture and regulatory approvals and other aspects that create heightened risks of disputes, claims and legal proceedings. These include claims that may be faced in one or more jurisdictions

related to the safety of our drug candidates, the development of our drug candidates, our ability to obtain regulatory approval for our drug candidates, our expectations regarding product development and regulatory approval, sales and marketing practices, commercial disputes including with contract manufacturers, competition, environmental matters, employment matters and other matters. These matters could consume significant time and resources, even if we are successful. Many of our competitors and contractual counterparties are significantly larger than we are and, as a result, may be able to sustain the costs of complex litigation more effectively than we can because they have substantially greater resources. In addition, we may pay damage awards or settlements or become subject to equitable remedies that could, individually or in the aggregate, have a material negative effect on our financial condition, results of operations or stock price. Any uncertainties resulting from the initiation and continuation of any litigation also could have a material adverse effect on our ability to raise the capital necessary to continue our operations. We may initiate or become subject to litigation regarding patents and other intellectual property rights. Patent infringement litigation involves many complex technical and legal issues and its outcome is often difficult to predict and the risk involved in doing so can be substantial. ~~Generic drug manufacturers~~ **Manufacturers of generic or biosimilar drugs** could seek approval to market a generic **or biosimilar** version of our products or challenge our intellectual property rights with respect to our drug candidates. Further, our industry has produced a large number of patents and it is not always clear which patents cover various types of products or methods of use. A third party may claim that we or our contract manufacturers are using inventions covered by the third party' s patent rights and may go to court to stop us from engaging in the alleged infringing activity, including making, using or selling our drug candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we, or our contract manufacturers, are infringing the third party' s patents and would order us or our contractors to stop the activities covered by the patents. In addition, if we or our contract manufacturers are found to have violated a third party' s patent, we or our contract manufacturers could be ordered to pay damages to the other party. We have agreed ~~to~~ or may **in the future** agree to indemnify our contract manufacturers against certain patent infringement claims and thus may be responsible for any of their costs associated with such claims and actions. If we were sued for patent infringement, we would need to demonstrate that our drug candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we might be unable to do this. Proving invalidity, in particular, is difficult since it requires clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our drug candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third- party challenges. Our ability to protect our drug candidates from unauthorized making, using, selling, ~~38offering~~ **offering** to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities. ~~The~~ **36The** patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the U. S. and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the U. S. Patent and Trademark Office or by a court or other trier of fact in the U. S., or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third- party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third- party patents. We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the U. S. or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our drug candidates and / or materially harm our business. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. In addition, to the extent that we are unable to obtain and maintain patent protection for one of our drug candidates or in the event that such patent protection expires or is limited to method of use patent protection, it may no longer be cost- effective to extend our portfolio by pursuing additional development of a product or drug candidate for follow- on indications. We also may rely on trade secrets to protect our technologies or drug candidates, especially where we do not believe patent protection is appropriate or obtainable. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third- party entity illegally obtained and is using any of our trade secrets is expensive and time- consuming, and the outcome is unpredictable. In addition, courts outside the U. S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. Our indebtedness and liabilities could limit the cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations. As of December 31, ~~2022~~ **2023**, we had $ ~~320~~ **213**. ~~0~~ **2** million total aggregate principal amount of our ~~2023 Notes and~~ 2026 Notes outstanding, and we had approximately $ ~~0~~ **1**. ~~9~~ **3** million of outstanding finance lease obligations. We may incur additional indebtedness to meet future financing needs. Our existing and future indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things: ● requiring a

substantial portion of our cash flow from operations to service and repay our indebtedness, which will reduce the amount of cash available for other purposes; ● limiting our ability to obtain additional financing; ● limiting our flexibility to plan for, or react to, changes in our business; ~~39~~ **37** ● diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon any conversion of the Convertible Notes; ● placing us at a possible competitive disadvantage with competitors that are less leveraged than we are or have better access to capital; and ● increasing our vulnerability to adverse economic and industry conditions. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Convertible Notes, depends on our future performance, which is subject to many factors, including, economic, financial, competitive and other circumstances beyond our control. Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the Convertible Notes, and our cash needs may increase in the future. In addition, future indebtedness that we may incur may contain ~~,~~ financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full. Competitors may develop products that are less expensive, safer or more effective, or which may otherwise diminish or eliminate the success of any products that we may commercialize. We may not achieve commercial success if our competitors, many of which have significantly more resources and experience than we have, market products that are safer, more effective, less expensive or faster to reach the market than any products that we may develop and commercialize. Our competitors also may market a product that proves to be unsafe or ineffective, which may affect the market for future product we are developing, regardless of the safety or efficacy of our product. The failure of any future product that we may market to compete effectively with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, our financial condition and our results of operations. The loss of members of our management team could substantially disrupt our business operations. Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at- will employees, and we do not maintain any key- person life insurance policies other than on the life of Gregory A. Demopulos, M. D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, without having a readily available and appropriate replacement could delay the execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations. We rely on highly skilled personnel and, if we are unable to retain or motivate key personnel or hire qualified personnel, we may not be able to maintain our operations or grow effectively. Our performance is largely dependent on the talents and efforts of highly skilled individuals, many of whom possess specialized expertise that may be difficult to replace. Our future success depends on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization. If we are unable to hire and train a sufficient number of qualified employees for any reason, we may not be able to implement our current initiatives or grow effectively. We maintain a rigorous, highly selective and time- consuming hiring process. We believe that our approach to hiring has significantly contributed to our success to date. If we do not succeed in attracting qualified personnel and retaining and motivating existing personnel, our existing operations may suffer and we may be unable to grow effectively. ~~40We~~ **38We** may encounter difficulties managing our growth, which could delay our business plans or adversely affect our results of operations. To manage our future growth, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit, train and retain qualified personnel. We may not be able to implement necessary business processes and systems, recruit, train and retain additional qualified personnel and otherwise manage the growth of our enterprise due to factors such as limited financial resources and competition for qualified personnel within local, national and international markets. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Additionally, our inability to manage growth effectively could cause our operating costs to **exceed our forecasts** ~~grow even faster than we currently are anticipating~~ . Product liability claims may damage our reputation and, if insurance proves inadequate, these claims may harm our business. We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product' s safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with commercialization of our drug candidates. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain or maintain such insurance on acceptable terms for any product we bring to market. Further, our product liability insurance coverage may not provide coverage for or may be insufficient to reimburse us for any or all expenses or losses we may suffer. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage could have a material adverse effect on our business, financial condition and results of operations. We rely on third parties to conduct portions of our preclinical research and clinical trials. If these third parties do not perform as contractually required or otherwise expected, or if we fail to adequately supervise or monitor these parties, we may not be able to obtain regulatory approval for or commercialize our drug candidates. We rely on third parties, such as CROs, medical and research institutions and clinical investigators, to conduct a portion of our preclinical research, assist us in conducting our clinical trials or to conduct third party- sponsored clinical trials of our drug candidates. Nonetheless, we are responsible for confirming that our preclinical research and clinical trials are conducted in accordance with applicable regulations, the relevant trial protocol and within the context of approvals by an institutional review board or ethics committee, and we may not always be successful in ensuring such compliance. Our reliance on these third parties does not relieve us of responsibility for ensuring compliance with FDA and other regulations and standards for conducting, monitoring, recording and reporting the results of preclinical research and clinical trials to assure that data and reported results are credible and accurate

and that the trial participants are adequately protected. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical and clinical development processes may be extended, delayed, suspended or terminated, and we may not be able to commercialize or obtain regulatory approval for our drug candidates. ~~We may need~~ **If we are unable** to ~~maintain~~ **obtain** licenses ~~for active ingredients~~ from third parties ~~to develop and commercialize some of our drug candidates, which could increase our development costs and delay our ability to commercialize those drug candidates. Should we decide to use APIs in any of our drug candidates that are proprietary to one or more third parties, such as our PDE7 program (OMS527), we would need to maintain licenses to those active ingredients from those third parties. If we are unable to continue to access rights to these active ingredients prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate drug candidates from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these drug candidates. If we are unable to maintain continued access rights to the desired active 41ingredients~~ on commercially reasonable terms or **fail to comply with** ~~develop suitable alternate active ingredients, or~~ **our** ~~if we do not meet diligence or other~~ obligations under **such agreements** ~~the corresponding licenses~~ , ~~we may not~~ **our business could** be ~~able~~ **harmed. It may be necessary for us to use the patented or proprietary technology of third parties** to commercialize ~~drug candidates~~ **our products, in which case we would be required to obtain a license** from these **third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected products or product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation. Even if we are able to obtain a license, it may be non- exclusive, which could enable our competitors to obtain access to the same technologies licensed to us. If we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product or product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. As a non- accelerated filer, we are no longer required to comply with the auditor attestation requirements of the Sarbanes- Oxley Act. As of December 31, 2023, we are a non- accelerated filer under the Exchange Act and, therefore, we are no longer required to comply with the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley Act. Therefore, our internal controls over financial reporting will not receive the level of review provided by the process relating to the auditor attestation included in annual reports of issuers that are subject to the auditor attestation requirements. In addition, we cannot predict if investors will find our common stock less attractive because we are not required to comply with the auditor attestation requirements. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the trading price for our common stock may be negatively affected. Our share repurchase** ~~programs~~ **program could affect the price of our common stock and increase volatility and may be suspended or terminated at any time, which may result in a decrease in the trading price of our common stock . In November 2023, our board of directors authorized a share repurchase program to repurchase, from time to time, up to $ 50. 0 million of our outstanding shares of common stock in the open market, including under trading plans established pursuant to Rule 10b5- 1 and Rule 10b- 18 under the Exchange Act, or in privately negotiated transactions. The share repurchase program does not have a fixed expiration date, may be suspended or discontinued at any time, and does not obligate us to acquire any amount of our common stock. The timing, manner, price, and amount of any repurchases may be determined by us at our discretion and will depend on a variety of factors, including business, economic and market conditions, prevailing stock prices, corporate and regulatory requirements, and other considerations. As of March 26, 2024, approximately $ 33. 8 million remained available to repurchase of our outstanding shares of common stock under the share repurchase program. Repurchases pursuant to our share repurchase program could affect our stock price and increase its volatility. The existence of a share repurchase program could also cause our stock price to be higher than it would be in the absence of such a program and could potentially reduce the market liquidity for our common stock. There can be no assurance that any repurchases will enhance shareholder value, because the market price of our common stock may decline below the levels at which we repurchased our common stock. Although our share repurchase program is intended to enhance long- term shareholder value, short- term stock price fluctuations could reduce the share repurchase program' s effectiveness.** ~~General~~ **39General** Risk Factors Related to our ~~BusinessCyber~~ ----- **Business Cyber** - attacks or other failures in telecommunications or information technology systems could result in information theft, data corruption and significant disruption of our business operations. We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber- attacks or mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-

party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. **While we** ~~Any cyber- attack or destruction or loss of data could~~ have **not experienced any previous cybersecurity incidents that have had** a material adverse effect on **or company, we cannot provide assurance that a future cybersecurity incident will not occur or that it would not materially affect** our business ~~and prospects~~ **, results of operations or financial condition** . In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber- attacks or other data security breaches and may incur significant additional expense to implement further data protection measures. Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline. During the 12- month period ended December 31, ~~2022~~ **2023** , **the closing price of** our stock ~~traded~~ **ranged from** as high as $ 7. ~~46~~ **57** per share and as low as $ 1. ~~75~~ **08** per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to numerous factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company' s securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management' s attention and resources. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing shareholders would experience further dilution. To the extent that we raise additional funds in the future by issuing equity securities, our shareholders would experience dilution, which may be significant and could cause the market price of our common stock to decline significantly. In addition, approximately ~~13~~ **15** . ~~9~~ **3** million shares of common stock were subject to outstanding options ~~, awards and warrants~~ as of December 31, ~~2022~~ **2023** and may become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements. As of December 31, ~~2022~~ **2023** , we also had approximately ~~5~~ **8** . ~~0~~ **8** million additional shares of common stock reserved for future issuance under our employee benefit plans that are not subject to outstanding options. Further, to the extent we issue common stock upon conversion of the Convertible Notes, such conversion would dilute the ownership interests of existing stockholders despite the expected reduction of such dilution as a result of the capped call transactions that we entered into in connection with the original issuances of the Convertible Notes. If the holders of outstanding options or warrants elect to exercise some or all of them, or if the shares subject to our employee benefit plans are issued and become eligible for sale in the public market, or we issue common stock upon conversion of the Convertible Notes, our shareholders would experience dilution and the market price of our common stock could decline. ~~42~~ **40If we or the third parties upon whom we rely are adversely affected by natural disasters or other events, our business continuity and disaster recovery plans may not adequately protect us from such interruptions. Any unplanned event, such as flood, fire, explosion, earthquake, tsunami, extreme weather condition, power shortage, power outage, telecommunication failure, or other natural or man- made accidents or incidents could disrupt our operations. If a natural disaster or other event were to occur that prevents us from using all or a significant portion of our headquarters, that damages critical infrastructure, such as the manufacturing facilities of our third- party manufacturers, or that otherwise disrupts operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We may not carry sufficient business interruption insurance to compensate us for all losses that may occur. The disaster recovery and business continuity plans we have in place may not be adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of a natural disaster or other event, which could have a material adverse effect on our business, and we could potentially lose valuable data and other items. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition and results of operations. Anti- takeover provisions in our charter documents and under Washington law could make an acquisition of us, which may be beneficial to our shareholders, difficult and prevent attempts by our shareholders to replace or remove our current management. Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of shareholders to fill board vacancies and the ability of our board of directors to issue preferred stock without shareholder approval. In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B. 19 of the Washington Business Corporation Act, which, among other things, restricts the ability of shareholders owning 10 % or more of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management. We have never declared or paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future. Our business requires significant funding. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Therefore, we currently do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a rise in the market price of our common stock, which is uncertain and unpredictable, will be the sole source of potential gain for shareholders in the foreseeable future, and an investment in our common stock for dividend income should not be relied upon.**