Risk Factors Comparison 2025-03-12 to 2024-03-25 Form: 10-K

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Investing in our Series A common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as the other information in this Annual Report on Form 10- K, including our financial statements and the related notes appearing elsewhere in this Annual Report and" Management' s Discussion and Analysis of Financial Condition and Results of Operations". The following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and growth prospects. This Annual Report on Form 10- K also contains forward- looking statements and estimates that involve risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. Our actual results could differ materially from those anticipated in our forward- looking statements as a result of specific factors, including the risks and uncertainties described below. Risk Factors Summary ● We have incurred significant operating losses since our inception and we expect to incur significant operating losses for the foreseeable future. We may never become profitable or, if profitability is achieved, be able to sustain profitability. ● We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and / or eliminate one or more of our research and drug development programs or future commercialization efforts. ● Currently our business depends on the success of our lead drug candidate, denifanstat, which is still in clinical development. If we are unable to obtain regulatory approval for or successfully commercialize denifanstat, our business will be materially harmed. ● If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected. ● Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. If clinical trials or regulatory approval processes for our drug candidates are prolonged, delayed or suspended, we may be unable to seek regulatory approval for and commercialize our drug candidates on a timely basis, which would require us to incur additional costs and substantially harm our business. ● We may not be successful in our efforts to expand our pipeline, including by identifying additional indications for which to investigate denifanstat in the future. We may expend our limited resources to pursue a particular indication or formulation for denifanstat and fail to capitalize on drug candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success. ● We have conducted, are currently conducting, and may in the future conduct clinical trials for our drug candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials. ● Interim, top-line and preliminary data from our 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. ● We intend to develop certain of our drug candidates in combination with other approved and investigational therapies, which exposes us to additional risks. ● If we or third parties are unable to successfully develop technologies or establish tests for biomarkers that enable patient selection or monitoring for drug responses, or if we experience significant delays in doing so, we may not realize the full commercial potential of our drug candidates. ● The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed. ● Obtaining and maintaining regulatory approval for a drug candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that drug candidate in other jurisdictions. ● We may not be able to file INDs or IND amendments, or comparable foreign applications, to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or comparable foreign regulatory authorities may not permit us to proceed. ● Use of denifanstat or any future drug candidates could be associated with side effects, adverse events or other properties that could delay or prevent regulatory approval or result in significant negative consequences following marketing approval, if any. ● **Although we have received Breakthrough Therapy designation for denifanstat, this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood of receiving marketing approval in the United States.** ● We have received ~~fast~~ **Fast track** ~~track~~ **Track** designation for denifanstat for MASH and may seek such designation for our other drug candidates or for other indications, but we might not receive such designations, and even if we do, such designations may not actually lead to a faster development or regulatory review or approval process. ● Our drug candidates will remain subject to ongoing regulatory review even if they receive marketing approval, and if we fail to comply with continuing regulations, we could lose these approvals and the sale of any approved commercial products could be suspended. ● Our industry is highly competitive, and our drug candidates may become obsolete. ● We may attempt to seek approval from the FDA for one or more of our drug candidates through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained. ● Our employees, contractors and partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. ● If we fail to develop and commercialize other drug candidates, we may be unable to grow our business. ● If we are unable to successfully validate, develop and obtain regulatory approval for diagnostic tests for certain **of** our drug candidates that would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates. ● We may engage in strategic transactions that could increase our capital requirements, dilute our stockholders, cause us to incur debt or

assume contingent liabilities, subject us to other risks, adversely affect our liquidity, increase our expenses and present significant distractions to our management. ● ~~Any pandemic, epidemic, or outbreak of an infectious disease may materially and adversely affect our business and our financial results and could cause a disruption to the development of our drug candidates. ●~~ If we are unable to obtain, maintain and enforce sufficient patent protection for our drug candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our drug candidates successfully may be adversely affected. ● We may not be able to enforce our intellectual property rights throughout the world. ● ~~If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation or disputes could be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates. ●~~ We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property ~~. ● Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices, and our patent protection could be reduced or eliminated for non- compliance with these requirements~~ . ● We have licensed rights to denifanstat to Ascletis ~~, a significant stockholder~~ , for a territory that we refer to as " Greater China " throughout this Annual Report. Under the license agreement, Ascletis controls certain product development efforts in its territory, including conduct of clinical trials, which could have an impact on our clinical development programs. ● We rely on third parties to conduct our clinical trials of our drug candidates and expect to rely on third parties to conduct future clinical trials, as well as investigator- sponsored clinical trials of our drug candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed. ● We have relied on, and we expect to continue to rely on, third- party manufacturers to produce our drug candidates. Our manufacturers may experience manufacturing difficulties due to the ongoing effects of inflationary pressures, resource constraints, labor disputes or unstable political environments, which could delay the completion of our clinical trials, increase the costs associated with maintaining clinical trial programs and, significantly impact our ability to develop, obtain regulatory approval for, or market denifanstat and any future drug candidates. ● We currently have no marketing and sales organization and have no organizational experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell denifanstat and any future drug candidates, we may not be able to generate product revenues. ● A drug candidate may not achieve adequate market acceptance among physicians, patients, third- party payors and others in the medical community necessary for commercial success. ● Our ~~internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches and we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, loss of customers or sales, and other adverse consequences. ● Our~~ future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. ● Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. ~~60 ● Our principal stockholders and management own a significant percentage of our common stock and have the ability to exercise significant control over matters subject to stockholder approval. ●~~ Unfavorable global political or economic conditions could adversely affect our business, financial condition or results of operations. ~~Risks~~ **63Risks** related to our businessWe have incurred significant operating losses since our inception, and we expect to incur significant operating losses for the foreseeable future. We may never become profitable or, if profitability is achieved, be able to sustain profitability. We have incurred significant operating losses since our inception, and we expect to incur significant operating losses for the foreseeable future as we continue our clinical trials and development programs for denifanstat and other future drug candidates. Our net losses were $ **45. 6 million and $** 27. 9 ~~million and $ 30. 5~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. We had cash, cash equivalents and marketable securities of $ **158. 7 million and $** 94. 9 million ~~and $ 32. 3 million~~ as of December 31, **2024, and** 2023 ~~and 2022~~ , respectively. In the future, we intend to continue to conduct research and development, preclinical and clinical testing, regulatory compliance and, if denifanstat or other future drug candidates are approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in the incurrence of further significant operating losses for the foreseeable future. As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial- scale product, or conduct sales and marketing activities necessary for successful commercialization. We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant net losses since our inception. We may never be able to commercialize denifanstat or other future drug candidates. We may not be profitable even if we or any of our future development partners succeed in commercializing any of our drug candidates. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our preclinical and clinical development of, and seek regulatory approvals for, denifanstat and any future drug candidates. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. 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 revenues. Our prior net losses and expected future net losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses, or when, if at all, we will be able to achieve profitability. We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and / or eliminate one or more of our research and drug development programs or future commercialization efforts. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a

very time- consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of, and seek regulatory approval for, denifanstat and any future drug candidates. Because the design and outcome of our planned and anticipated preclinical studies and clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of denifanstat or any other drug candidate we develop. If we are required by the ~~U. S. Food and Drug Administration (~~FDA ~~)~~, or any comparable foreign regulatory authority to perform clinical trials or preclinical studies in addition to those that we currently anticipate, our expenses could increase. In addition, if we obtain regulatory approval to market denifanstat or any other drug candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Other unanticipated costs may also arise. Since our initial public offering of Series A common stock in July 2023 (IPO), we also have incurred, and expect to continue to incur, additional costs associated with operating as a public company. Accordingly, we will continue to need to obtain substantial additional funding in order to maintain our continuing operations. ~~61To~~ **To** date, we have financed our operations primarily through private equity and debt financings **, public equity financings** and our IPO. **In** ~~On January 30,~~ 2024, we completed an underwritten public offering of our Series A common stock pursuant to which we issued 9, 000, 000 shares of Series A common stock at $ 12. 50 per share for proceeds of $ 104. ~~9~~ **7** million, net of discounts and commissions. We currently have no outstanding debt obligations. We have incurred net losses and negative cash flows from operations since inception, including net losses of $ **45. 6 million and $** 27. 9 ~~million and $ 30. 5~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively. For the years ended December 31, **2024, and** 2023 ~~and 2022~~, we had negative cash flows from operations of $ **42. 4 million and $** 23. 8 ~~million and $ 24. 5~~ million, respectively. We had cash, cash equivalents ~~,~~ and marketable securities of $ **158. 7 million and $** 94. 9 million ~~and $ 32. 3 million~~ as of December 31, **2024 and** 2023 ~~and 2022~~, respectively. ~~We~~ **64We** expect to incur additional losses and negative cash flows from operations for at least the next 12 months. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities **as** ~~, together with the net proceeds~~ of **December 31, 2024** ~~our follow- on offering~~, will be sufficient for us to fund our operating expenses ~~and capital expenditure requirements~~ **for at least the next 12 months from the issuance of this Annual Report. We currently have insufficient funds to complete the Phase 3 program for denifanstat** through ~~the end of the fourth quarter of 2025~~ **topline data readout and are exploring various funding alternatives**. Our estimate as to how long we expect our current cash, cash equivalents and marketable securities to be able to continue to fund our operating expenses and capital expenditures requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business, global economic conditions and volatility in the credit and financial markets, inflationary pressures, the Russian invasion of Ukraine ~~and ,~~ the ~~recent~~ conflict in Israel **and other geopolitical conditions**. Our current cash, cash equivalents and marketable securities will not be sufficient to fund all of the activities that are necessary to complete the development and commercialization of our drug candidates. Until we can generate significant revenue from sales of our drug candidates, if ever, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research- stage programs, clinical trials or future commercialization efforts **, including the Phase 3 program for denifanstat**. Currently our business depends on the success of our lead drug candidate, denifanstat, which is still in clinical development. If we are unable to obtain regulatory approval for or successfully commercialize denifanstat, our business will be materially harmed. Currently, our product development is primarily focused on our lead drug candidate, denifanstat, for the potential treatment of ~~metabolic dysfunction- associated steatohepatitis (~~MASH ~~)~~, formerly known as ~~nonalcoholic steatohepatitis (~~NASH ~~)~~. Successful continued development and ultimate regulatory approval of denifanstat for MASH, or other indications that we may pursue, is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the preclinical and clinical development of denifanstat. We will need to raise sufficient funds to successfully complete the development program for denifanstat. The future regulatory and commercial success of denifanstat is subject to a number of risks, including the following: ● we may not have sufficient financial and other resources to complete the necessary clinical trials for denifanstat, including registrational clinical trials to obtain regulatory approval; ● the mechanism of action of denifanstat is complex and we do not know the degree to which it will translate into a therapeutic benefit, if any, in MASH or any other indication or to which it may contribute to long term safety issues or AEs, if any, when denifanstat is taken for prolonged periods such as in the treatment of MASH, or any other indication; ● patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to denifanstat, and there may be more uncertainty regarding relatedness to denifanstat if we pursue clinical trials of denifanstat in combination with other drugs or drug candidates, and this uncertainty could delay or prevent further clinical development; ● we may not be able to obtain adequate evidence from clinical trials of efficacy and safety for denifanstat in MASH, or any other indication; ● in our clinical programs for denifanstat, we may experience variability in patients, adjustments to clinical trial procedures and the need for additional clinical trial sites, which could delay our clinical trial progress; ~~62~~ ● the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval; ● the standards implemented by clinical or regulatory authorities may change at any time; **65** ● the FDA or comparable foreign regulatory authority may require efficacy endpoints for a Phase 3 clinical trial for the treatment of MASH, or any other indication, that

differ from the endpoints of our current or future trials, which may require us to conduct additional clinical trials; ● we do not know the degree to which denifanstat will be accepted as a therapy by physicians, patients and third- party payors, even if approved; ● if approved for MASH, denifanstat will likely compete with the off- label use of currently marketed drugs and other therapies in development that may reach approval for MASH prior to denifanstat; and ● we may not be able to obtain, maintain or enforce our patents and other intellectual property rights in a manner that prevents our competitors from developing and commercializing products similar or identical to denifanstat or that otherwise compete with denifanstat. Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a new drug application (NDA) to the FDA and even fewer are approved for commercialization. Furthermore, even if we receive regulatory approval to market denifanstat, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the drug. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development program for denifanstat, we may be unable to successfully develop or commercialize denifanstat. If we or any of our future development partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize denifanstat, we may not be able to generate sufficient revenue to continue our business. If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the trials until their conclusion. We may not be able to initiate, continue, or complete clinical trials that may be required by the FDA or comparable foreign regulatory authorities to obtain regulatory approval for denifanstat or any other future drug candidates if we are unable to locate, enroll and retain a sufficient number of eligible patients to participate in these clinical trials. Patient enrollment, a significant factor in the timing to conduct and complete clinical trials, is affected by many factors, including: ● the size and nature of the patient population; ● the severity of the disease under investigation; ● eligibility criteria for the trial; ● the proximity of patients to clinical sites; ● the design of the clinical protocol; ● the ability to obtain and maintain patient consents; ● the ability to recruit clinical trial investigators with the appropriate competencies and experience; ● the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our drug candidates or trial completion; ● the availability of competing clinical trials; ~~63~~ ● the availability of new drugs approved for the indication the clinical trial is investigating; ● clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies; ~~and~~ **and66** ● other factors outside of our control, such as the effects of any future pandemics, global economic conditions and volatility in the credit and financial markets, inflationary pressures, the Russian invasion of Ukraine and the ~~recent~~ conflict in Israel. In certain of our proposed MASH clinical trials, patient willingness to undergo a liver biopsy, particularly for trials of a longer duration, may also impact patient enrollment and retention. Potential patients for denifanstat or any other future drug candidates may not be adequately diagnosed or identified with the indications that we are targeting or may not meet the entry criteria for our trials. We also may encounter difficulties in identifying and enrolling MASH patients with a stage of disease appropriate for ongoing or future clinical trials. In addition, the process of finding and diagnosing patients may prove costly. Other pharmaceutical companies with more resources and greater experience in drug development and commercialization are targeting treatments for MASH, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is also limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites, and may delay or make it more difficult to fully enroll our clinical trials. We also rely on contract research organizations (CROs) and clinical trial sites to enroll subjects in our clinical trials and, while we have agreements governing their services, we will have limited influence over their actual performance. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost- effective manner. Delays in the completion of any clinical trials of our drug candidates will increase our costs, slow down our drug candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some 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 our drug candidates. Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. If clinical trials or regulatory approval processes for our drug candidates are prolonged, delayed or suspended, we may be unable to seek regulatory approval for and commercialize our drug candidates on a timely basis, which would require us to incur additional costs and substantially harm our business. Drug development has inherent risk. We will be required to demonstrate through adequate and well- controlled clinical trials that our drug candidates are safe and effective for use in their target indications before we can seek regulatory approvals for their commercial sale. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. Delay or failure can occur at any stage of development, including after commencement of any of our clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful, because later-stage clinical trials may be conducted in broader patient populations and involve different study designs. For instance, the results from our **Phase 2** FASCINATE- 1 **and** Phase **2b** ~~2 and~~ FASCINATE- 2 ~~Phase 2b~~ clinical trials of denifanstat in patients with MASH may not be predictive of the results from our ~~planned~~ Phase 3 **FASCINATE- 3 and FASCINIT clinical** ~~trial~~ **trials** of denifanstat for the treatment of MASH. Furthermore, our future trials will need to demonstrate sufficient safety and efficacy in larger patient populations for approval by regulatory authorities. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in the submission of an NDA to the FDA and even fewer are approved for commercialization. We cannot predict whether we will encounter problems with any completed, ongoing or planned clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to: ● inability

to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials. For example, carcinogenicity and reproductive toxicology studies may be required to support late- stage clinical trials and / or approval; ● reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; ~~64~~ ● difficulties obtaining regulatory authorization to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial; **67** ● reaching or failing to reach agreement on acceptable terms with prospective CROs, contract manufacturing organizations (CMOs), and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly; ● identifying, recruiting and training suitable clinical investigators; ● insufficient or inadequate supply or quality of our drug candidates or other materials necessary to conduct and complete our clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials; ● manufacturing, testing, releasing, validating or importing / exporting sufficient stable quantities of our drug candidates for use in clinical trials; ● difficulties obtaining institutional review board (IRB) approval or positive ethics committee opinions to conduct a clinical trial at a prospective site; ● recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post- treatment follow- up; ● changes to the clinical trial protocols; ● governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; ● serious and unexpected side effects related to the drug candidate being tested; ● lack of adequate funding to continue the clinical trial; ● severe adverse effects in clinical trials of the same class of agents conducted by other companies; ● changes in the standard of care on which a clinical development plan was based, which may require new or additional trials; ● selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; ● failure of our third- party vendors to perform manufacturing and distribution services in a timely manner or to sufficient quality standards; ● third- party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice (GCP), or other regulatory requirements; ● third- party contractors not performing data collection or analysis in a timely or accurate manner; ● third- party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; and ● failure of our third- party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner. We do not know whether our clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, if at all. Delays in the initiation, enrollment, or completion of our clinical trials will result in increased development costs for our drug candidates, and our financial resources may be insufficient to fund any incremental costs. If our clinical trials are delayed, our competitors may be able to bring products to market before we do and the commercial viability of our drug candidates could be limited. ~~65In~~ **In** addition, disruptions caused by any future pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing clinical trials. For example, we previously experienced delays ~~in~~ **68in** enrollment and temporary closures of clinical trial sites due to COVID- 19. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or relevant ethics committees of the institutions in which such trials are being conducted or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols or informed consents, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs, relevant ethics committees or competent authorities for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Further, conducting clinical trials in foreign countries, as our licensee, Ascletis, and its affiliate Gannex Pharma Co., Ltd. (Gannex), to whom Ascletis has assigned the license, are doing for denifanstat in China, and we may do in the future for our drug candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory frameworks, as well as political and economic risks relevant to such foreign countries. Moreover, principal investigators for our clinical trials may serve and have served as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of our drug candidates. We may not be successful in our efforts to expand our pipeline, including by identifying additional indications for which to investigate denifanstat in the future. We may expend our limited resources to pursue a particular indication or formulation for denifanstat and fail to capitalize on drug candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we are currently focused on developing denifanstat for MASH. In May 2023, Ascletis Pharma announced topline results from a Phase 2 clinical trial of denifanstat in 179 patients with moderate to severe acne in China. In December 2023, Ascletis Pharma announced the initiation of a randomized, double- blind, placebo- controlled, multicenter Phase 3 clinical

trial to evaluate the safety and efficacy of denifanstat for the treatment of moderate to severe acne vulgaris in 480 patients in China. Ascletis Pharma announced the dosing of the first patient in this trial in January **2024 and completion of enrollment in November** 2024. We have also identified other potential indications where fatty acid synthase (FASN) inhibition could have clinical benefit, including oncology. However, we may fail to generate additional clinical development opportunities for denifanstat or the other molecules in our catalog of FASN inhibitors for a number of reasons, including because denifanstat may in certain indications, on further study, be shown to have harmful side effects, limited to no efficacy, or other characteristics that suggest it is unlikely to receive marketing approval and achieve market acceptance in such additional indications. We plan to conduct several clinical trials for denifanstat in parallel over the next several years. If we make incorrect determinations regarding the viability or market potential of denifanstat or any of our other drug candidates or misread trends in MASH, acne or in the pharmaceutical, biopharmaceutical or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may forgo or delay pursuit of opportunities with other indications that could have had greater commercial potential or likelihood of success. For example, we may focus on or pursue one or more of our target indications over other potential indications and such development efforts may not be successful, which would cause us to delay the clinical development and approval of denifanstat. Furthermore, research programs to identify additional indications for denifanstat require substantial technical, financial, and human resources. 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 programs for specific indications may not yield any commercially viable products. ~~66We~~ **69We** have conducted, are currently conducting, and may in the future conduct clinical trials for our drug candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials. We have conducted and may in the future conduct one or more clinical trials of our current or future drug candidates outside the United States. For example, we conducted a cohort of our FASCINATE- 1 clinical trial in China **. We also plan to conduct a portion of our Phase 3 program for denifanstat in MASH in 16 countries outside the United States, inclusive of Canada, Germany, Spain, France, Canada, Mexico, and South Korea, among others** . The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U. S. population and U. S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical power, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, we would need to conduct additional trials, which could be costly and time- consuming. Interim, top- line and preliminary data from our 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 preliminary or top- line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and 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 different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. 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, top- line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim 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 disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Series A common stock. Others, including regulatory authorities, 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, the approvability or commercialization of the particular drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top- line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our drug candidates may be harmed, which could harm our business, operating results, prospects or financial condition. We intend to develop certain of our drug candidates in combination with other approved and investigational therapies, which exposes us to additional risks. We intend to develop certain of our drug candidates in combination with one or more other approved therapies. For example, we conducted a Phase 1 trial of denifanstat in patients with solid tumors, which included arms in combination with taxane- based chemotherapy. Our ability to develop and ultimately commercialize our drug candidates in combination with other therapies will

depend on our ability to access such therapies on commercially reasonable terms for the clinical trials and their availability for use with our drug ~~67candidate~~ **70candidate** . We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such therapies on commercially reasonable terms or at all. Any failure to maintain or enter into new successful commercial relationships or the expense of purchasing these therapies may delay our development timelines, increase our costs and jeopardize our ability to develop our current drug candidates. If any of these circumstances occur, our business, financial condition, operating results, stock price and prospects may be materially harmed. Moreover, the development of drug candidates for use in combination with another therapy may present challenges that are not faced for single agent drug candidates. The FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each drug candidate or therapy to any observed effects. It is possible that the results of such trials could show that any positive trial results are attributable to the other therapy and not our current drug candidates. Even if any drug candidate we develop were to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities outside of the United States could revoke or amend approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our drug candidates are replaced as the standard of care for the indications we choose for any of our drug candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. We also may choose to evaluate our current drug candidates and any other future drug candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell our current drug candidates or any drug candidate we develop in combination with any unapproved therapies for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our drug candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval. If the FDA or comparable foreign regulatory authorities do not approve these other products or revoke or amend their approval, or if safety, efficacy, quality, manufacturing or supply issues arise with the products we choose to evaluate in combination with our drug candidate, we may be unable to obtain approval of or market such combination therapy. If we or third parties are unable to successfully develop technologies or establish tests for biomarkers that enable patient selection or monitoring for drug responses, or if we experience significant delays in doing so, we may not realize the full commercial potential of our drug candidates. A key component of our strategy includes the use of biomarkers to inform patient selection for and / or to confirm responses to our drug candidates. In some cases, third parties provide this technology. It is not always the case, however, that the biomarker we have identified is on a standard panel offered by testing providers. If not already commercially available, we may collaborate with testing providers for the development of biomarker tests associated with our drug candidates. We may have difficulty in establishing or maintaining such development relationships, and we will face competition from other companies in establishing these collaborations. There are also several risks associated with biomarker identification and validation. We, in collaboration with any testing providers, may not be able to identify predictive biomarkers or pharmacodynamic biomarkers for one or more of our programs. We may not be able to validate potential biomarkers or their functional relevance preclinically in relevant in vitro or in vivo models. Data analytics and information from databases that we rely on for identifying or validating some of our biomarker- target relationships may not accurately reflect potential patient populations. Potential biomarkers, even if validated preclinically, may not be functionally effective or validated in human clinical trials. If testing providers experience any delays including the biomarkers we have identified for patient selection and / or drug response monitoring on their panels or tests, or if they do not include those biomarkers on their panels or tests, our clinical trials may be delayed or may not identify sufficient patients to complete the trial, and our drug candidates may not advance to approval or realize their full commercial potential. ~~68The~~ **71The** regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate' s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any drug candidate, and it is possible that any drug candidates we may seek to develop in the future will never obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our drug candidates in the United States until we receive regulatory approval of an NDA from the FDA. The FDA and other regulatory authorities may delay, limit or deny approval of our drug candidates for many reasons, including: ● we may not be able to demonstrate to the satisfaction of the FDA or other regulatory authorities that denifanstat or any of our other future drug candidates are safe and effective for any indication; ● the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA or other regulatory authorities for approval; ● the FDA or other regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials; ● the FDA or other regulatory authorities may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the benefits of denifanstat or any of our other future drug candidates outweigh their safety risks; ● the FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials, or may not accept data generated at our clinical trial sites; ● the data collected from preclinical studies and clinical trials of denifanstat or any of our other future drug candidates may not be sufficient to support the submission of an NDA or other application for regulatory approval; ● the FDA may have difficulties scheduling an advisory committee meeting in a timely manner, or the advisory

committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions; ● the FDA or other regulatory authorities may require development of a risk evaluation and mitigation strategy (REMS), or risk management plan (RMP), as a condition of approval; ● the FDA or other regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third- party manufacturers with which we enter into agreements for clinical and commercial supplies; ● the FDA or other regulatory authorities may change their approval policies or adopt new regulations; and ● the FDA or other regulatory authorities may require simultaneous approval for both adults and for children and adolescents, which may delay approval, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa. In addition, any of these regulatory authorities may change requirements for the approval of a drug candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA or other regulatory authorities may require that we conduct additional clinical, preclinical, manufacturing validation or drug product quality studies and submit those data before considering or reconsidering the application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or other regulatory authorities for obtaining approval. ~~69In~~ **72In** addition, the FDA or other regulatory authorities may approve a drug candidate for fewer or more limited indications than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications or may grant approval contingent on the performance of costly post- marketing clinical trials or risk mitigation requirements, such as the implementation of a REMS or comparable foreign risk management approaches. The FDA or other regulatory authorities may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our drug candidates. Obtaining and maintaining regulatory approval for a drug candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that drug candidate in other jurisdictions. Obtaining and maintaining regulatory approval for a drug candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval for a drug candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the drug candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical 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, a drug candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for denifanstat or any of our other future drug candidates is also subject to approval. Regulatory authorities in jurisdictions outside of the United States and the European Union also have requirements for approval for drug candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of denifanstat or any of our other future drug candidates in certain countries. If we fail to comply with the regulatory requirements in international markets and / or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of denifanstat or any of our other future drug candidates will be harmed, which would adversely affect our business, prospects, financial condition, and results of operations. We may not be able to file INDs or IND amendments, or comparable foreign applications, to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or comparable foreign regulatory authorities may not permit us to proceed. We may not be able to file Investigational New Drug applications (INDs), or comparable foreign applications, for our drug candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND- enabling studies. Moreover, we cannot be sure that submission of an IND, or comparable foreign applications, will result in the FDA or other regulatory authorities allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, or comparable foreign applications, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND or comparable foreign applications. Any failure to file INDs, or comparable foreign applications, or submit our clinical trial protocols to regulatory authorities for review on the timelines we expect may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. Use of denifanstat or any future drug candidates could be associated with side effects, adverse events or other properties that could delay or prevent regulatory approval or result in significant negative consequences following marketing approval, if any. As is the case with pharmaceuticals generally, it is likely that there may be side effects and ~~adverse events (~~ AEs ~~)~~ associated with the use of denifanstat or any future drug candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. For example, in our oncology Phase 1 clinical trial, six episodes of serious pneumonitis were experienced by five patients, one of which was fatal, assessed by the investigator as at least possibly related to both denifanstat and paclitaxel. No ~~serious adverse events (~~ SAEs ~~)~~ assessed as drug- related have been reported in our MASH trials to date. Undesirable side effects caused by denifanstat and any future drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. If drug- related SAEs are observed, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval for denifanstat or any of our other future drug candidates for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability ~~70of~~ **of** enrolled patients to complete the trial ~~or~~ **73or** result in potential

product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly. Furthermore, over ~~700~~ **740** subjects have been treated with denifanstat in our clinical trials to date. It is possible that as we test our drug candidates in larger, longer and more extensive clinical trials, illnesses, injuries, discomforts and other AEs that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. In many cases, side effects are only detectable after investigational products are tested in large- scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval. Additionally, if denifanstat and any future drug candidates receive marketing approval, and we or others later identify undesirable side effects caused by such drug candidate, a number of potentially significant negative consequences could result, including: ● we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace; ● regulatory authorities may withdraw approvals or change their approvals of such product, or seek an injunction against its manufacture or distribution; ● regulatory authorities may require additional warnings on the label, including boxed warnings, issue safety alerts or press releases, or limit access to that product; ● we may be required to create a REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients and other elements to assure safe use, or comparable foreign risk management approaches; ● we may be required to change the way the product is administered; ● we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and ● the product may become less competitive, and our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of denifanstat or any future drug candidates, if approved, and could significantly harm our business, results of operations, and prospects. **Although we have received Breakthrough Therapy designation for denifanstat, this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood of receiving marketing approval in the United States. In October 2024, the FDA granted Breakthrough Therapy designation to denifanstat for the treatment of non- cirrhotic MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. The Breakthrough Therapy designation we have obtained for denifanstat may not result in faster development processes, reviews or approvals compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that our denifanstat development program no longer meets the criteria for the designation and may rescind the designation.** We have received ~~fast~~ **Fast** ~~track~~ **Track** designation for denifanstat for MASH and may seek such designation for our other drug candidates or for other indications, but we might not receive such designations, and even if we do, such designations may not actually lead to a faster development or regulatory review or approval process. If a drug candidate is intended for the treatment of a serious condition and preclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA ~~fast~~ **Fast** ~~track~~ **Track** designation. The sponsor of a fast track ~~drug~~ **74drug** candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the drug candidate may be eligible for priority review if the relevant criteria are met. A fast track drug candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. In March 2021, we received ~~fast~~ **Fast** ~~track~~ **Track** designation for denifanstat for the treatment of MASH and we may seek ~~fast~~ **Fast** ~~track~~ **Track** designation for certain other indications for denifanstat or any future drug candidates we may develop, but we might not receive such designations from the FDA. However, even if we receive ~~fast~~ **Fast** ~~track~~ **Track** designation, ~~fast~~ **Fast** ~~track~~ **Track** designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with ~~fast~~ **Fast** ~~track~~ **Track** designation compared to conventional FDA procedures. In addition, the FDA may withdraw ~~fast~~ **Fast** ~~track~~ **Track** designation if it believes that the designation is no longer supported by data from our clinical development program. Fast ~~track~~ **Track** designation alone does not guarantee qualification for the FDA' s priority review procedures. The European Medicines Agency (EMA) has a similar program called PRIority MEdicine (PRIME) designation. The purpose of this program is to enhance support for the development of medicinal products that target an unmet medical need. PRIME provides enhanced interaction and early dialogue between the EMA and developers of promising medicinal products to optimize generation of robust data on the benefits and risks of a medicinal product and enable accelerated assessment of medicines applications. Participation in PRIME does not, however, limit the obligations that must be fulfilled for grant of a related marketing authorization. We ~~71may~~ -- **may** seek PRIME designation for one or more of our drug candidates, but might not receive such designations. Even if we receive PRIME designation, there is no guarantee of grant of marketing authorization at all or within any specific timeframe. Our drug candidates will remain subject to ongoing regulatory review even if they receive marketing approval, and if we fail to comply with continuing regulations, we could lose these approvals and the sale of any approved commercial products could be suspended. Any regulatory approvals that we may receive for our drug candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the drug candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or

contraindications, and may include burdensome post- approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our drug candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our drug candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as on- going compliance with GCP for any clinical trials that we conduct post- approval. Further, the FDA closely regulates the post- approval marketing and promotion of drugs to ensure drugs are marketed only for their approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on companies' communications regarding off- label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off- label marketing. Violations of the FDCA relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other domestic and foreign regulatory authorities for compliance with current good manufacturing practice (cGMP), regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we fail to comply with the regulatory requirements of the FDA and other applicable domestic and foreign regulatory authorities, or if previously unknown problems with any approved product, manufacturer, or manufacturing process are discovered, we could be subject to administrative or judicially imposed sanctions, including: ● restrictions on the marketing or manufacturing of our products; ● revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings; **75** ● imposition of a REMS, or comparable foreign risk management approaches, which may include distribution or use restrictions; ● requirements to conduct additional post- marketing clinical trials to assess the safety of the product; ● civil or criminal penalties; ● fines, warning letters or holds on clinical trials; ● injunctions; ● product seizures or detentions; ● voluntary or mandatory product recalls; ~~72~~ ● suspension, modification or withdrawal of regulatory approvals; and ● refusal by the FDA or other domestic or foreign regulatory authorities to approve pending applications for marketing approval of new products or supplements to approved applications. The occurrence of any event or penalty described above may inhibit our ability to commercialize our drug candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, and compliance with such regulation may be expensive and consume substantial financial and management resources. If we or any future marketing collaborators or CMOs are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies or are not able to maintain regulatory compliance, it could delay or prevent the promotion, marketing or sale of our products, which would adversely affect our business and results of operations. Changes in the manufacturing process or formulation may result in additional costs or delay. As drug candidates progress through preclinical studies 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 drug 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 our drug candidates and jeopardize our ability to commercialize our drug candidates, if approved, and generate revenue. If we or our CMOs are not able to successfully manufacture our drug candidates in sufficient quality and quantity, clinical development and timelines for our drug candidates and subsequent approval could be adversely impacted. Changes in funding for the FDA and other domestic and foreign government authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business. The ability of the FDA and other domestic and foreign government authorities 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, accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government authorities that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other domestic and foreign authorities may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government authorities, which would adversely affect our business. For example, over the last several years, ~~including for 35 days beginning on December 22, 2018,~~ the U. S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Our business depends upon the ability of the FDA to accept and review our potential regulatory filings. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and ~~process~~ **76process** our regulatory submissions, which could have a material adverse effect on our ability to advance clinical development of our drug candidates. Further, future shutdowns of other government authorities, such as the U. S. Securities and Exchange Commission (SEC), may also impact our business through review of our public filings and our ability to access the public markets. Our industry is highly competitive, and our drug candidates may become obsolete. We are

engaged in a rapidly evolving field. Competition from other pharmaceutical companies, biotechnology companies and research and academic institutions is intense and likely to increase. Many of those companies and institutions have substantially greater financial, technical and human resources than we have. Those companies and institutions also have substantially greater experience in developing products, conducting clinical trials, obtaining regulatory approval and in manufacturing and marketing pharmaceutical products. Our competitors may succeed in obtaining regulatory approval for their products more rapidly than we do. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these competitive products may have an entirely different approach or means of accomplishing the desired therapeutic effect than ~~73products~~ -- **products** being developed by us. Our competitors may succeed in developing products that are more effective and / or cost competitive than those we are developing, or that would render our drug candidates less competitive or even obsolete. In addition, one or more of our competitors may achieve product commercialization or patent protection earlier than us, which could materially adversely affect our business **. For example, in March 2024, Madrigal Pharmaceuticals, Inc. (Madrigal) announced that the FDA approved Rezdiffra ™ (resmetirom) for the treatment of MASH in patients with moderate to advanced liver fibrosis** . If denifanstat is approved for the treatment of MASH, future competition could also arise from products currently in development with multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions, including 89bio, Inc., Akero Therapeutics, Inc., Altimmune, Inc., ~~Bristol- Myers Squibb Company~~ **AstraZeneca, Boston Pharmaceuticals, Boehringer Ingelheim and Zealand Pharma** , Eli Lilly and Company, Galmed Pharmaceuticals Ltd., Gilead Sciences, Inc., **GSK plc** ~~Intercept Pharmaceuticals, Inc.~~ , Inventiva S. A., Madrigal Pharmaceuticals, Inc., ~~NGM Biopharmaceuticals~~ **Merck & Co.** , Inc. ~~, NorthSea Therapeutics B. V., Novartis AG~~ , Novo Nordisk A / S, Pfizer Inc., Terns Pharmaceuticals, Inc., Viking Therapeutics, Inc., and Zydus Therapeutics Inc. Smaller or earlier- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. It is also probable that the number of companies seeking to develop drugs and therapies for the treatment of serious metabolic diseases, such as MASH, will increase. Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize denifanstat and any future drug candidates and may affect the prices we may set. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost- containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of legislative and executive initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. The Inflation Reduction Act of 2022 (IRA), for example, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out- of- pocket cap for Medicare Part D beneficiaries to $ 2, 000 starting in 2025; impose ~~new~~ manufacturer financial liability on certain drugs under Medicare Part D; allow the U. S. government to negotiate Medicare Part B and Part D price caps for certain high- cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than the rate of inflation; and delay until January 1, 2032 the implementation of the Department of Health and Human Services (HHS) rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA' s Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known. ~~President~~ **Presidential** ~~Biden has~~ **administrations have** also **previously** issued multiple executive orders that have sought to reduce prescription drug costs. ~~In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA' s accelerated approval pathway. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the potential use of march- in rights under the Bayh- Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights that would be voluntary for federal government agencies to follow when deciding whether to exercise march- in rights and which for the first time includes the price of a product as a factor a federal government agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain whether the federal government will actually exercise such march- in rights in connection with pharmaceutical products or whether any such exercise will be subject to judicial review or challenge.~~ Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the ~~Biden~~ **presidential** administration may reverse or otherwise change these measures, both the ~~Biden~~ **incoming Trump** administration and Congress have indicated that they will continue to seek new measures to control drug costs. ~~At~~ **77At** the state level, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, regional ~~74healthcare~~ -- **healthcare** authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for denifanstat, if approved, or put pressure on our product pricing, which

could negatively affect our business, results of operations, financial condition, and prospects. For more information regarding these and other healthcare reform initiatives, see " Business — Government regulation and product approval. " We cannot predict the likelihood, nature, or extent of healthcare reform initiatives that may arise from future legislation or administrative action. We expect that healthcare reform measures, including those that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from third- party payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize denifanstat or our other drug candidates, if approved. We may attempt to seek approval from the FDA for one or more of our drug candidates through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained. We may in the future seek an accelerated approval for our one or more of our drug candidates. Under the accelerated approval pathway, the FDA may grant accelerated approval to a drug candidate designed to treat a serious or life- threatening condition that provides meaningful therapeutic benefit over available therapies, upon a determination that the drug candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor' s agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verify and describe the drug' s clinical benefit and, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is permitted to require, ~~as appropriate,~~ that such studies be underway prior to approval or within a specified time period after the date accelerated approval is granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. In addition, FDORA gives the FDA increased authority to withdraw accelerated approval on an expedited basis if, for example, the sponsor fails to conduct such studies in a timely manner, such studies fail to confirm the drug' s clinical benefit, or the sponsor fails to send the necessary updates to the FDA. The FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post- approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA generally requires, unless otherwise informed by the agency, pre- approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Prior to seeking accelerated approval for any of our drug candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA seeking accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e. g., ~~fast~~ **Fast** ~~track~~ **Track** designation) for our drug candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities ~~could~~ **78could** also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our drug candidates would result in a longer time period to commercialization of such drug candidate, if any, could increase the cost of development of such drug candidate and could harm our competitive position in the marketplace. ~~75In~~ **In** addition, the policies of the FDA ~~, the competent authorities of the EU Member States, the EMA, the European Commission~~ and other comparable regulatory authorities with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union recently evolved. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and ~~repeals~~ **repealed** the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission **through** ~~to both~~ the ~~competent authority and an ethics committee~~ **centralized EU portal (the Clinical Trials Information System) to apply for authorization of the clinical trial** in ~~each~~ **all applicable** EU Member ~~State~~ **States** ~~, leading to a single decision for each EU Member State~~ . The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State' s decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial has been approved, clinical study development may proceed. ~~The~~ **All new applications for clinical trial authorization in the EU must now be made under the** CTR **and, on January 31, 2025, all** ~~foresees a three- year transition period. The extent to which~~ ongoing ~~and new clinical~~ trials **previously authorized under** ~~will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of~~ the EU Clinical Trials

Directive ~~before January 31, 2022, the EU Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors could choose to submit a clinical trial application under either the EU Clinical Trials Directive or the CTR until January 31, 2023, and, if authorized, those trials will be governed by the EU Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become~~ **became** subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third- party service providers, such as CROs, may impact our development plans. ~~It is currently unclear to what extent the United Kingdom will seek to align its regulations with the European Union in the future.~~ The **existing** UK regulatory framework in relation to clinical trials is derived from the EU Clinical Trials Directive. However, **on December 12, 2024,** the ~~Retained EU Law~~ **UK government introduced a legislative proposal- the Medicines for Human Use** (**Clinical Trials** ~~Revocation and Reform~~) ~~Bill published in late~~ **(Amendment) Regulations** ~~2022~~ **2024** ~~which is intended to remove all EU~~ - **that** ~~derived legislation from the UK statute book by the end of 2023~~ , **if implemented** ~~may result in a divergence of approach between the European Union and the United Kingdom. In January 2022~~ , **will replace** the **current** ~~UK Medicines and Healthcare products Regulatory~~ **regulatory framework** ~~Agency (MHRA), launched an eight- week consultation on reframing the UK legislation~~ for clinical trials **in the UK** . The **legislative proposal** ~~consultation closed in March 2022 and~~ aims to ~~streamline~~ **provide a more flexible regime to make it easier to conduct** clinical trials ~~approvals, enable innovation, enhance~~ **in the UK and increase the transparency of** clinical trials ~~transparency,~~ **conducted in the UK. This includes a notification scheme to** enable ~~greater~~ **lower-** risk ~~proportionality, and promote patient and public involvement in~~ clinical trials ~~. The outcome of the consultation will be closely watched and will determine whether the United Kingdom chooses~~ to ~~align~~ **be automatically approved by the MHRA, where the risk is similar to that of standard medical care (although such trials would still require ethics committee approval). Such Regulations are expected to come into force in early 2026. Compliance** with **new** ~~the CTR or diverge from it to maintain regulatory flexibility. A decision by the United Kingdom not to closely align its~~ regulations ~~with the CTR~~ **for clinical trials** in the ~~EU may~~ **UK could impact our development plans or** have an effect on the cost of **any** ~~conducting clinical~~ trials **we intend** ~~in the United Kingdom as opposed~~ to ~~other countries and / or make it harder to seek a marketing authorization in the European Union for our drug candidates on the basis of clinical trials conducted~~ -- **conduct** in the **UK** ~~United Kingdom~~ . If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. If any product liability lawsuits are brought against us or any of our collaborative partners, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates. We face an inherent risk of product liability lawsuits related to the testing of our drug candidates in seriously ill patients and will face an even greater risk if drug candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling any of our future approved products. If we cannot successfully defend against any such claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for any of our future approved products; ● injury to our reputation; ● withdrawal of clinical trial participants; ● termination of clinical trial sites or entire trial programs; ● significant litigation costs; ● substantial monetary awards to or costly settlements with patients or other claimants; ● product recalls or a change in the indications for which products may be used; ~~76~~ ● loss of revenue; ● diversion of management and scientific resources from our business operations; ~~and~~ **and79** ● the inability to commercialize our drug candidates. If any of our drug candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of our company and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. In addition, because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our results of operations. We do not currently hold **commercial** product liability insurance coverage. Prior to commercialization of our drug candidates, we will need to purchase insurance coverage. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our product development and commercialization efforts. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our available insurance coverage, could decrease our cash resources and adversely affect our business, financial condition and results of operations. Our employees, contractors and partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of fraud or other misconduct by our employees, contractors or partners. Misconduct by these parties could include failures to comply with FDA regulations or comparable foreign regulations, to provide accurate information to the FDA or comparable foreign authorities, to comply with federal, state or foreign healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to disclose unauthorized activities to us, or failure to comply with comparable foreign requirements. In particular, sales, marketing and business arrangements in the healthcare 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. Third-party misconduct 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, 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 resulting from this misconduct 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, exclusion from government funded healthcare programs, such as Medicare and Medicaid or comparable foreign equivalents, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations. In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our potential sublicensees' exercise of rights under the agreement. With respect to our commercial agreements, we indemnify our vendors from any third- party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable ~~77insurance~~ **insurance** coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected. ~~If~~ **80If** we fail to develop and commercialize other drug candidates, we may be unable to grow our business. Although the development and commercialization of denifanstat is our primary focus, as part of our longer- term growth strategy, we plan to evaluate the development and commercialization of other therapies related to MASH, FASN inhibition, and other diseases mediated by overproduction of palmitate, including acne and some forms of cancer. We will evaluate internal opportunities from our compound libraries, and also may choose to in- license or acquire other drug candidates as well as commercial products to treat patients suffering from MASH or other disorders with high unmet medical needs and limited treatment options. These other drug candidates may require additional, time- consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and / or applicable foreign regulatory authorities. All drug candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the drug candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot be certain that any such products that are approved will be manufactured or produced economically, be successfully commercialized, be widely accepted in the marketplace, or be more effective than other commercially available alternatives. If we are unable to successfully validate, develop and obtain regulatory approval for diagnostic tests for certain **of** our drug candidates that would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates. In connection with the clinical development of certain of our drug candidates for certain indications, we may engage third parties to develop or otherwise obtain access to in vitro complementary diagnostic tests to identify patients within a disease category who may derive meaningful benefit from our drug candidates. Such complementary diagnostics may be used during our clinical trials as well as in connection with the commercialization of our products that receive regulatory approval. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable foreign regulatory authorities regulate in vitro complementary diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we or third parties may develop, which we expect will require separate regulatory clearance or approval prior to commercialization of such diagnostics. We intend to rely on third parties for the design, development and manufacture of such complementary diagnostic tests for our drug candidates. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these complementary diagnostics. It may be necessary to resolve issues such as selectivity / specificity, analytical validation, reproducibility, or clinical validation of complementary diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a complementary diagnostic for a drug candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the complementary diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory clearance or approval for, manufacturing and commercializing complementary diagnostics similar to those we face with respect to our drug candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop complementary diagnostics for these drug candidates, or experience delays in doing so, the development and commercialization of these drug candidates may be adversely affected, these drug candidates may not obtain regulatory approval, and we may not realize the full commercial potential of any of these products that obtain regulatory approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the complementary diagnostic test that we anticipate using in connection with development and commercialization of our drug candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our drug candidates or do so on commercially reasonable terms. We may engage in strategic transactions that could increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, subject us to other risks, adversely affect our liquidity, increase our expenses and present significant distractions to our management. ~~Although we currently have no agreements or commitments to complete any such transactions and are not involved in negotiations to do so, from~~ **From** time to time, we may consider strategic transactions, such as **mergers,** acquisitions

~~of companies~~ , asset purchases and out- licensing or in- licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future ~~78include~~ -- **include** a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. Any future transactions could increase our near and long- term expenditures, result in potentially dilutive issuances of our equity securities, including our Series A common stock, or the incurrence of debt, contingent ~~liabilities~~ **81liabilities** , amortization expenses or acquired in- process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Furthermore, we may experience losses related to investments in other companies, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects. Any pandemic, epidemic, or outbreak of an infectious disease may materially and adversely affect our business and our financial results and could cause a disruption to the development of our drug candidates. Public health crises, such as pandemics or similar outbreaks, could adversely impact our business. For example, the impact of the COVID- 19 pandemic resulted in disruptions to the global economy, as well as businesses and capital markets around the world. We experienced modest delays in our development activities as a result of the COVID- 19 pandemic, primarily due to temporary closures of certain clinical sites that delayed patient enrollment in our FASCINATE- 2 trial. Any future pandemic, epidemic or outbreak of an infectious disease could have similar effects. Furthermore, economic recessions, increased inflation and / or interest rates, and any disruptions to our operations or workforce availability may have a negative effect on our operating results. The foregoing and other disruptions to our business as a result of a public health crisis could result in an adverse effect on our business, results of operations, financial condition and cash flows. Risks related to intellectual propertyIf we are unable to obtain, maintain and enforce sufficient patent protection for our drug candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our drug candidates successfully may be adversely affected. Our success depends in large part on our ability to protect our proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the composition of matter of our drug candidates, including denifanstat, their methods of use, related technologies and other inventions that are important to our business. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technologies and drug candidates that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our proprietary platform of selective FASN inhibitors. If we do not adequately obtain, maintain, protect or enforce our intellectual property, third parties, including our competitors, may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The patent application and approval process is expensive, time- consuming and complex. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. The standards applied by the United States Patent and Trademark Office (the USPTO) and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and drug candidates. ~~79Our~~ **82Our** pending patent applications may not result in issued patents if other parties invented or filed patent applications on the same technology prior to our invention or filing of patent applications on our technology. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our drug candidates. Further, in cases where a particular compound of interest is in the public domain, third parties may be able to obtain patents on improvements or other inventions relating to such compound if they were to discover the same patentable inventions relating to such compounds after us but manage to file a patent application before we do. In addition, we may enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, including any polymorphs and variants, such as our employees, collaborators, consultants, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. Furthermore, if third parties have filed patent applications related to our drug candidates or technology, an interference proceeding in the United States can be initiated by the USPTO or a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Therefore, we cannot be certain that we were

the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue, or that our issued patents or patents that issue in the future will not be challenged and rendered invalid and / or unenforceable. 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 drug candidates by obtaining and defending patents. We have pending and issued U. S. and foreign patents and patent applications in our portfolio; however, we cannot predict: ● if and when patents may issue based on our patent applications; ● the scope of protection of any patent issuing based on our patent applications; ● whether the claims of any issued patent will provide protection against competitors; ● whether or not third parties will find ways to invalidate or circumvent our patent rights; ● whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; ● whether we will need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; and / or ● whether the patent applications will result in issued patents with claims that cover each of our drug candidates or uses thereof in the United States or in other foreign countries. We may be subject to a third- party pre- issuance submission of prior art to the USPTO or become involved in post- grant review procedures, oppositions, derivations, revocation, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenge may result in loss of exclusivity or in our 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. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. We may rely on more than one patent to provide multiple layers of patent protection for our drug candidates. If the latest- expiring patent is invalidated or held unenforceable, in whole or in part, the overall protection for the drug candidate may be adversely affected. For example, if the latest- expiring patent is invalidated, the overall patent term for our drug candidate could be adversely affected. ~~80Our~~ **83Our** pending and future patent applications may not result in patents being issued that protect our drug candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Given the amount of time required for the development, testing and regulatory review of new drug candidates, our patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical ours. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic or biosimilar versions of any approved products and in so doing, claim that patents owned by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or may find that our competitors are competing in a non- infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Moreover, some of our patents may in the future be co- owned with third parties. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Our patents may be subject to a reservation of rights by one or more third parties. If any of our technologies are developed in the future with government funding, the government may obtain certain rights in any resulting patents, including a non- exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. If the U. S. government then decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may also permit the government to disclose our confidential information to third parties and to exercise march- in rights to use or allow third parties to use our licensed technology. The government may also exercise its march- in rights if it determines that action is necessary because we failed to achieve practical application of the government- funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U. S. industry. In addition, our rights in such government- funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of aforementioned proprietary rights could harm our competitive position, business, financial condition, results of operations, and prospects. Changes to the patent law in the United States and other 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 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. Recent patent reform legislation in the United States and other countries, including the Leahy- Smith America Invents Act (Leahy- Smith Act), signed into law in September 2011, could increase those uncertainties and costs and it is not yet clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy-

Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners' patent applications and the enforcement or defense of our or our collaboration partners' issued patents, all of which could harm our business, results of operations, financial condition and prospects. The U. S. Supreme Court and the Court of Appeals for the Federal Circuit (the Federal Circuit) have 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. For example, with respect to patent term adjustment, the Federal Circuit' s recent holding in In re Cellect, LLC, 81 F. 4th 1216 (Fed. Cir. 2023), that obviousness- type double patenting analysis for a patent that has received patent term adjustment must be based on the expiration date of the patent after the patent term adjustment has been added, which may negatively impact the term of certain U. S. patents. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing ~~81patents~~ **84patents** could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For a description of the intellectual property regulatory framework, see " Business — Intellectual property. " We may become involved in lawsuits or administrative disputes to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe our patents, trademarks, copyrights, trade secrets or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or their intellectual property, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from manufacturing and selling the competing product 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 patent claims do not cover said product. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our 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 business position, business prospects and financial condition. 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. 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 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 a material adverse effect on the price of shares of our Series A common stock. Moreover, there can be no assurance 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. Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the United States or comparable foreign authorities, even outside the context of litigation. Such mechanisms include re- examination, inter partes review, post- grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. If a third party 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 one or more of our drug candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects. We may not be able to enforce our intellectual property rights throughout the world. Filing, prosecuting and defending patents with respect to our drug candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. Consequently, competitors and other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us. ~~82Moreover~~ **85Moreover** , our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and several developing countries, do not favor the

enforcement of patents and other intellectual property rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. In addition, many countries limit the enforceability of patents against government authorities or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are 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. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. 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. 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 drug candidates in any jurisdiction. 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. For example, we may incorrectly determine that our products 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. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation or disputes could be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates. Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our drug candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. If any third- party patents or patent applications are found to cover our drug candidates or their methods of use or manufacturing, we may be required to pay damages, which could be substantial, and we would not be free to manufacture or market our drug candidates without obtaining a license, which may not be available on commercially reasonable terms, or at all. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our drug candidates. Third parties may assert infringement, misappropriation or other claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation and other disputes is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of using or manufacturing products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our drug candidates, products or methods of use, manufacturing or other applicable activities either do not infringe the patent claims of the asserted patent or that the patent claims are invalid or unenforceable, and we may not be successful in doing so. Proving invalidity is difficult. For example, in the United States, ~~83proving~~ **86proving** invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity that applies to all issued patents. Even if we believe third- party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, or enforceability. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If we are found to infringe, misappropriate or otherwise violate a third party' s intellectual property rights and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing drug candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing drug candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties, particularly from our competitors currently developing products for the treatment of MASH, could have a similar negative impact on our business, financial condition, results of operations and prospects. We may be subject to claims by third parties asserting that our employees or consultants or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property, or we may need to bring similar claims against third

parties. Some of our employees and consultants are currently or have been previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non- disclosure and non- competition agreements, or similar agreements, in connection with such other current or previous employment. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. In addition, such agreements may not be self- executing such that the intellectual property subject to such agreements may not be assigned to us without additional assignments being executed, and we may fail to obtain such assignments. In addition, such agreements may be breached. Accordingly, we may be forced to bring claims against third parties, or defend claims that they may bring against us, related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel, which would have a material adverse effect on our business, financial condition, results of operations and prospects. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co- inventor. For example, we or our collaborators may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our patents, trade secrets or other intellectual property. If we or our licensors 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, intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs ~~84and~~ **87and** be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. The term of our patents may be inadequate to protect our competitive position on our products. 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. 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 United States patent may also be shortened if the patent is terminally disclaimed over an earlier- filed patent. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and other factors relating to any FDA marketing approval we receive for any of our drug candidates, one or more of our U. S. patents may be eligible for limited patent term extension (PTE), under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch- Waxman Amendments). We plan to seek PTE in the United States, however, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. We also plan to see analogous forms of PTE in other countries where we are prosecuting patents. However, the laws governing analogous PTEs 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. If we are unable to obtain PTE or the term of any such extension is less than we request, our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects. For more information about obtaining extensions, see " Business — Intellectual property. " Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. While an inadvertent lapse can 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 a patent or patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and

submit formal documents. In such an event, our competitors and other third parties might be able to enter the market with similar or identical products of technology, which would 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 and proprietary know- how, the value of our technology could be materially adversely affected, and our business would be harmed. While we have obtained composition of matter patents with respect to certain of our drug candidates, including denifanstat, we also rely on proprietary know- how and trade secret protection and confidentiality agreements to protect proprietary know- how or trade secrets that are not patentable or that we elect not to patent. For example, we may elect to not patent some composition matter from our proprietary library of selective FASN inhibitors and therefore rely on protecting the proprietary aspects of our platform as a trade secret. We seek to protect our trade secrets and proprietary know- how in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, CMOs, suppliers, collaborators and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary know- how. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third- party infringement or misappropriation. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. Courts outside ~~85the~~ **88the** United States are sometimes less willing to protect proprietary information, technology and know- how. Further, we may need to share our trade secrets and confidential know- how with current or future business 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. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets, including with respect to our proprietary platform of selective FASN inhibitors, were to be disclosed to or independently developed by a competitor or other third party, our business, financial condition, results of operations and prospects our business and competitive position could be materially harmed. If we fail to comply with our obligations under any license, collaboration or other agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our drug candidates. We rely, in part, on license, collaboration and other agreements, including our license agreement with Ascletis. We may need to obtain additional licenses from others to advance our research or allow commercialization of our drug candidates and it is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third- party 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. 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. In addition, our present and future licenses, collaborations and other intellectual property related agreements, currently impose, and are likely to further impose development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any of these obligations, or use any future intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If any future license or other intellectual property related agreements are terminated, we may be required to cease developing and commercializing drug candidates that are covered by the licensed intellectual property. Disputes may arise regarding intellectual property subject to a licensing, collaboration or other agreement, including: ● the scope of rights granted under the agreement and other interpretation related issues; ● the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement; ● the sublicensing of patent and other rights under our collaborative development relationships; ● our diligence obligations under the agreement and what activities satisfy those diligence obligations; ● the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and ● the priority of invention of patented technology. In addition, the agreements under which we license intellectual property or technology to third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering the technology that we have licensed or assigned to third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our licensees or assignees fail to obtain or maintain such intellectual property, or lose rights to such intellectual property, our right to develop and commercialize any of our products that are subject to such licensed rights could be adversely affected. ~~86If~~ **89If** we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate and our business, financial condition, results of operations and prospects could suffer. Intellectual property rights do not necessarily address all potential threats. 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. For example: ● others may be able to make products similar to any drug candidates we may develop or utilize similarly related technologies that are not covered by the claims of the patents that we license or may own in the future; ● we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future; ● we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions; ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating any of our owned or licensed intellectual property rights; ● it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents; ● issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; ● our competitors or other third parties might conduct research and development activities 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; ● the patents of others may harm our business; ● we may choose not to file a patent in order to maintain certain trade secrets or proprietary know- how, and a third party may subsequently file a patent covering such intellectual property; and ● our trade secrets or proprietary know-how may be unlawfully disclosed, thereby losing their trade secret or proprietary status. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects. If our 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. Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable authorities 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, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, 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. Although these license agreements may provide guidelines for how ~~87our~~ **90our** 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. Moreover, any proprietary name we have proposed to use with our drug 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. Similar requirements exist in Europe. The FDA typically conducts a review of proposed proprietary product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute 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. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. 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. Risks related to third partiesWe have licensed rights to denifanstat to Ascletis ~~, a significant stockholder,~~ for Greater China. Under the license agreement, Ascletis controls certain product development efforts in its territory, including conduct of clinical trials, which could have an impact on our clinical development programs. Under our license agreement with Ascletis, Ascletis is responsible for the design and conduct of certain clinical trials for the licensed drug candidate, denifanstat, which is referred to as ASC40 in the People' s Republic of China, Hong Kong, Macau and Taiwan (referred to collectively as Greater China). As a result, these clinical trials may not be conducted in the manner or on the timeline we desire or may not be designed in a manner that will demonstrate a statistically significant result, any of which may negatively impact our development efforts outside of Greater China. We do not have any right to control those trial designs nor control their interactions with respect to obtaining and maintaining regulatory approvals in Greater China. In addition, if Ascletis elects not to continue development of ASC40 or abandons clinical trials, it could have a negative effect on our business and our drug candidate development efforts outside of Greater China. Our lack of control over aspects of drug candidate development in our agreement with Ascletis, or any other future license partner, could cause delays or other difficulties in the development and commercialization of our drug candidates, which could harm our business and prospects. We may be exposed to reputational risk as a result of certain allegations against our license partners, which may require the attention of their management. For example, Ascletis, its affiliate Gannex, and certain of its other affiliates ~~, and the chief executive officer of Ascletis and Gannex, Jinzi J. Wu (who is also a member of our board of directors)~~ , are the subject of legal complaints filed by another biopharmaceutical company in the U. S. District Court in the Southern District of California and the U. S. International Trade Commission with respect to intellectual property matters. We are not the subject of or party to such complaints, nor are they directed at the intellectual property under our license agreement with

Ascletis. We do not believe that Ascletis' legal proceedings will have a material impact on our business, operations or financial condition. We rely on third parties to conduct our clinical trials of our drug candidates and expect to rely on third parties to conduct future clinical trials, as well as investigator- sponsored clinical trials of our drug candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed. We currently rely on, and intend to continue relying on third parties, including independent clinical investigators and third- party CROs, to conduct certain aspects of our preclinical studies and clinical trials for denifanstat and any other future drug candidates. We control or will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with applicable protocol, legal, regulatory, and scientific standards, and our reliance on our CROs does not relieve us of our regulatory responsibilities. We, our investigators and CROs are required to comply with GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for drug candidates in clinical development. Regulatory authorities enforce GCP through ~~88periodic~~ -- **periodic** inspections of trial sponsors, principal investigators and trial sites. If we or any of these CROs fail to comply with applicable ~~GCP~~ **91GCP** regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing products. Upon inspection, such regulatory authorities may determine that our clinical trials do not comply with the GCP regulations. In addition, our clinical trials must be conducted with drug product produced under cGMP regulations and will require a large number of test subjects. Our failure or any failure by our investigators or CROs to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our investigators or CROs violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws and foreign equivalents. Our investigators and CROs are not our employees, and, except for remedies available to us under our agreements with such investigators and CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These investigators and CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If our investigators and 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 or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory approval for or successfully commercialize denifanstat or any other future drug candidates. As a result, our financial results and the commercial prospects for denifanstat and any future drug candidates could be harmed, our costs could increase and our ability to generate revenues could be delayed. Our investigators and CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our investigators and 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 terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding investigators or CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new investigator or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with our investigators and CROs, we may encounter challenges or delays in the future and these delays or challenges may have a material adverse impact on our business, prospects, financial condition, and results of operations. We may also rely on individual investigators or academic and non- academic institutions to conduct investigator- sponsored clinical trials relating to our drug candidates. We will not control the design or conduct of these investigator- sponsored trials, and it is possible that the FDA or comparable foreign regulatory authorities will not view these investigator- sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. Such arrangements will likely provide us certain information rights with respect to the investigator- sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator- sponsored trials. However, we would not have control over the timing and reporting of the data from investigator- sponsored trials, nor would we own the data from the investigator- sponsored trials. If we are unable to confirm or replicate the results from the investigator- sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our drug candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our drug candidates, or if the data proves to be inadequate compared to the first- hand knowledge we might have gained had the investigator- sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. We have relied on, and we expect to continue to rely on, third- party manufacturers to produce our drug candidates. Our manufacturers may experience manufacturing difficulties due to the ongoing effects of inflationary pressures, resource constraints, labor disputes or unstable political environments, which could delay the completion of our clinical trials, increase the costs associated with maintaining clinical trial programs and, significantly impact our ability to develop, obtain regulatory approval for, or market denifanstat and any future drug candidates. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our drug candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely, and expect to rely for the foreseeable future, on ~~89third~~ **92third** - party manufacturers to supply our drug candidates. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured our drug candidates ourselves, including: ● the failure of the third- party to manufacture our drug

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 drug candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them; ● the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms; ● the breach by the third- party contractors of our agreements with them; ● the failure of third- party contractors to comply with applicable regulatory requirements; ● the failure of the third- party to manufacture our drug candidates according to our specifications; ● the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study 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; ● the misappropriation of our proprietary information, including our trade secrets and know- how; and ● the possible termination or non- renewal of manufacturing agreements by third parties, at a time that is costly or inconvenient to us. If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our drug candidates and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us. In some cases, the technical skills required to manufacture our drug candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate manufacturer, or we may be unable to transfer such skills at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and all applicable regulations, and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities. We will also need to verify, such as through a comparability study, that any new manufacturer or new manufacturing process will produce our drug candidate according to the specifications previously submitted to the FDA or another domestic or foreign regulatory authority. The delays associated with the verification of a new manufacturer and demonstrating comparability of clinical trial drug product could negatively affect our ability to develop drug candidates or commercialize our products in a timely manner or within budget. To date, we have relied on three CMOs based in the United States and China to produce denifanstat drug substance and two CMOs in the United States and China to produce denifanstat drug product. We will need to manufacture additional material to support late stage studies such as Phase 3 trials. Under the terms of our license agreement with Ascletis, we can source drug substance from and manufacture Product in Taiwan, but not from or in any other country in the territory of Greater China unless from Ascletis itself. There are no restrictions upon our manufacturing rights other than within Greater China (excluding Taiwan). We currently rely on several manufacturers for the production of raw materials, APIs, and the finished products of denifanstat. Our reliance on third- party suppliers and CMOs could harm our ability to develop denifanstat and any future drug candidates or to commercialize any drug candidates that are approved. Further, any delay in identifying and qualifying a manufacturer for commercial production could delay the potential commercialization of denifanstat and any future drug candidates, and, in the event that we do not have sufficient product to complete our clinical trials, it could delay such trials. The FDA and other foreign regulatory authorities require manufacturers to register their manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMP and other applicable laws. We, our CMOs, any future collaborators and their CMOs could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. CMOs may face manufacturing or quality control problems causing production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable ~~90cGMP~~ **93cGMP** requirements. Despite our efforts to audit and verify regulatory compliance, one or more of our CMOs or third- party vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Any failure to comply with cGMP requirements or other FDA and foreign regulatory authority requirements may result in shutdown of the CMO or third- party vendor or invalidation of drug product lots or processes and could adversely affect our clinical research activities and our ability to develop our drug candidates and market our products following approval, if obtained. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products, if approved. We currently do not control the manufacturing process of denifanstat and are completely dependent on our CMOs for complying with the FDA' s cGMP requirements for manufacture of both the active drug substances and finished drug product. If our CMOs cannot successfully manufacture material that conforms to our specifications and the FDA and comparable foreign regulatory authorities' strict regulatory requirements, we will not be able to secure or maintain FDA or comparable foreign regulatory approval for our drug candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authority does not approve these facilities for the manufacture of denifanstat or any future drug candidates, or if it withdraws any such approval in the future, or if our suppliers or CMOs decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop, obtain regulatory approval for, or market denifanstat and any future drug candidates. **The** ~~In addition, the~~ manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. Furthermore, if contaminants are discovered in our supply of denifanstat or any future drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the

contamination. Any stability or other issues relating to the manufacture of denifanstat or any future drug candidates may occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to inflationary pressures, resource constraints, labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely **. In addition, legislative proposals are pending that, if enacted, could negatively impact U. S. funding for certain biotechnology providers having relationships with foreign adversaries or which pose a threat to national security. The potential downstream adverse impacts on entities having commercial relationships with any impacted biotechnology providers is unknown but may include supply chain disruptions or delays** . Our current and anticipated future dependence upon others for the manufacture of our drug candidates may adversely affect our future profit margins and our ability to develop our drug candidates and commercialize any products that receive regulatory approval on a timely basis. Disputes under key agreements or conflicts of interest with our scientific advisors or clinical investigators could delay or prevent development or commercialization of our drug candidates. Any agreements we have or may enter into with third parties, such as collaboration, license, formulation supplier, manufacturing, clinical research organization or clinical trial agreements, including our license agreement with Ascletis, may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of research and development, rights to receive milestones, royalties or other payments, the approach for regulatory approvals or commercialization strategy. Any disputes, delays or commercial conflicts could lead to the termination of agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly litigation. ~~91We~~ **94We** currently have no marketing and sales organization and have no organizational experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell denifanstat and any future drug candidates, we may not be able to generate product revenues. We currently do not have a commercial organization for the marketing, sales, and distribution of pharmaceutical products. To commercialize denifanstat and any future drug candidates, we must build our marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services. The establishment and development of our own sales force or the establishment of a contract sales force to market denifanstat and any future drug candidates, if approved, will be expensive and time- consuming and could delay any commercial launch. Moreover, we may not be able to successfully develop this capability. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of denifanstat or any of our other future drug candidates. To the extent we rely on third parties to commercialize denifanstat or any of our other future drug candidates, if approved, we may have little or no control over the marketing and sales efforts of such third parties and our revenues from product sales may be lower than if we had commercialized denifanstat or any future drug candidates ourselves. In the event we are unable to develop our own marketing and sales force or collaborate with a third- party marketing and sales organization, we would not be able to commercialize denifanstat or any future drug candidates. Risks related to our industry and the regulatory environment in which we operateA drug candidate may not achieve adequate market acceptance among physicians, patients, third- party payors and others in the medical community necessary for commercial success. Even if a drug candidate receives regulatory approval, it may not gain adequate market acceptance among physicians, patients, third- party payors, pharmaceutical companies and others in the medical community. Demonstrating the safety and efficacy of a drug candidate and obtaining regulatory approvals will not guarantee future revenue. Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government authorities or private third- party payors will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any drug candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that drug candidate and may not become or remain profitable. Our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Our commercial success depends on obtaining and maintaining coverage and adequate reimbursement of a drug candidate by third- party payors, including government payors, which may be difficult or time- consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third- party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Government authorities and other third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. 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. We cannot be sure that coverage and reimbursement will be available for any product that we or our partners commercialize or, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of,

any drug candidate for which we or our partners obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our partners may not be able to successfully commercialize any drug candidate for which marketing approval is obtained. ~~92There~~ **95There** may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or third- party payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Additionally, we may develop complementary diagnostic tests for use with our drug candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our drug candidates, once approved. While we have not yet developed any complementary diagnostic tests for our drug candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our drug candidates. Third- party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. 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 drug candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. In many regions, including Europe, Japan and Canada, where we may market a product, either directly or with a collaborator, the pricing of prescription drugs is controlled by the government or regulatory authorities. Regulatory authorities in these countries could determine that the pricing for a product should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market a drug at a premium as new drugs. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval. Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and / or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. Health Technology Assessment (HTA), of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021 / 2282 on HTA, amending Directive 2011 / 24 / EU, was adopted in the European Union. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU ~~93Member~~ **96Member** States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at European Union level for joint clinical assessments in these areas. The Regulation foresees a three- year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for drug candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the European Union could be negatively affected. Legislators, policymakers and healthcare insurance funds in the European Union may continue to propose and implement cost- containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for drug

candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third- party payors. Further, an increasing number of European Union and other foreign countries use prices for medicinal products established in other countries as " reference prices " to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. Our relationships with customers, healthcare providers, and third- party payors may be subject, directly or indirectly, to federal, state and foreign healthcare fraud and abuse laws, transparency laws, and other healthcare laws and regulations, including analogous foreign laws. If we or our employees, independent contractors, consultants, commercial partners, or vendors violate these laws, we could face substantial penalties. Our relationships with customers, healthcare providers, and third- party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws with respect to drug pricing and payments and other transfers of value made to physicians and other healthcare providers, and other healthcare laws and regulations. These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed to prevent fraud, 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, and other business arrangements. In addition, we may be subject to federal or comparable foreign consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers. We may also be subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. For example, we may be subject to the following: state anti- kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental, third-party payors, including private insurers, or that apply regardless of payor; 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; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; and state and local laws requiring the registration of pharmaceutical sales and medical representatives. Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti- bribery laws of European countries, national sunshine rules, regulations, industry self- regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. For a description of the U. S. healthcare laws and regulations that may affect our ability to operate, see " Business — Government regulation and product approval. " Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, some of whom have been granted stock options, could be subject to challenge under one or more of such laws. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct 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 be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our ~~94business~~ **97business** practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and / or significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar foreign programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and / or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of denifanstat or any of our future drug candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer ~~security~~ **cybersecurity incidents or** breaches and we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, loss of customers or sales, and other adverse consequences. We and the third parties upon which we rely face a variety of evolving threats, which could cause ~~security~~ **cybersecurity** incidents **or breaches** , such as cyber- attacks, malicious internet- based activity, online and offline fraud, and other similar activities. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources. Despite the implementation of security and back- up measures designed to protect against ~~security~~ **cybersecurity** incidents **and breaches** , our internal computer, server, and other information technology systems as well as those of our third- party collaborators, consultants, contractors, suppliers, and service providers upon which we rely, may be vulnerable to various threats including, but not limited to, damage from physical or electronic break- ins, computer viruses, malware, ransomware, personnel misconduct or error, supply chain attacks, natural disasters, terrorism, war, telecommunication and electrical failure, denial of service, attacks enhanced or facilitated by artificial intelligence (AI), and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and / or proprietary data, including personal data, and health- related information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. In particular, severe

ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Such theft could also lead to loss of intellectual property rights through disclosure of our proprietary business information, and such loss may not be capable of remedying. In addition, our reliance on third- party partners could introduce new cybersecurity risks and vulnerabilities. If we or our third- party collaborators, consultants, contractors, suppliers, or service providers upon which we rely were to suffer ~~an~~ **a cyber-** attack **, cybersecurity incident** or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal data, we may have to notify consumers, partners, collaborators, government authorities, other stakeholders and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Any such disclosures may involve inconsistent requirements and are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Likewise, we rely on third parties to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. While we may be entitled to damages if these providers fail to satisfy their data privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. Our reliance on internet technology and the number of our employees, and those of our CROs, who continue to work remotely may create additional opportunities for cybercriminals to exploit vulnerabilities, as this has caused an increased usage of computers operated on home networks, while in transit, or in public locations. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience ~~security~~ **cybersecurity incidents or** breaches that may remain undetected for an extended period. ~~95We~~ **98We** take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. **Un-** ~~Unremediated~~ -- **remediated** high risk or critical vulnerabilities pose material risks to our business. **Like other companies in our industry, we have experienced threats and cybersecurity incidents relating to our information technology systems and infrastructure, and we expect to continue to experience them.** To the extent that any disruption or ~~security~~ **cybersecurity incident or** breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, and / or sensitive data, we could incur liability and suffer reputational harm, and the development and commercialization of denifanstat, or future drug candidates could be delayed. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that any insurance coverage that we do or will obtain will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a ~~security~~ **cybersecurity** incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Furthermore, our sensitive information could be leaked, disclosed or revealed as a result of or in connection with our employees', personnel' s or vendors' use of generative AI technologies. Failure to comply with data privacy and security laws, regulations and other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, negative publicity, and / or other adverse consequences that could negatively affect our operating results and business. We and our partners may be subject to federal, state, and foreign data protection laws and regulations (i. e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health- related and other personal data could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Depending on the facts and circumstances, we could be subject to penalties if we violate HIPAA. Even when HIPAA does not apply, according to the Federal Trade Commission (FTC), failing to take appropriate steps to keep consumers' personal data secure may constitute unfair acts or practices in or affecting commerce in violation of the Federal Trade Commission Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. In addition, certain state laws govern the privacy and security of health- related and other personal data in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, thus, complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and / or criminal penalties and private litigation. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the CCPA), grants individual privacy rights for California consumers, business representatives, and employees who are California residents, including the right to access, correct, or delete certain personal data, and opt- out of certain data processing

activities, such as targeted advertising, profiling, and automated decision- making. The CCPA provides for administrative fines of up to $ 7, 500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. The CCPA also created a new California data protection agency authorized to implement and enforce the law. Additional compliance investment and potential business process changes may be required. The CCPA marked the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. For example, ~~new~~ consumer privacy laws ~~were~~ **similar to the CCPA have been** passed **or proposed** in ~~several~~ **numerous** other states **,** including Connecticut, Colorado, Virginia and Utah ~~. In addition~~ , **and** ~~a number of~~ other states **, such as Washington,** have **99enacted** ~~proposed and / or passed new~~ privacy laws **specifically regulating health information. Additionally, a small number of states have implemented privacy laws which regulate other specific types of information, such as biometric data** . Such legislation may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in ~~96increased~~ -- **increased** compliance costs and / or changes in business practices and policies **. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time** . The existence of comprehensive privacy laws in different states in the country could **also** make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. **In addition, such requirements may require us to modify our data processing practices and policies, utilize management' s time and / or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. For additional information, see " Business — Government regulation and product approval — Data privacy and security laws. " The use of new and evolving technologies, such as AI, in our business may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential and / or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability. We have used and may continue to use and integrate AI into our business processes, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. For example, we have used, and intend to continue to use AI- based digital pathology to evaluate denifanstat in our clinical trials.** Additionally, our employees and personnel may use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. **The use of certain AI technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement.** Governments have **also** passed and are likely to pass additional laws regulating generative AI. **For example, the EU' s Artificial Intelligence Act (the AI Act) — the world' s first comprehensive AI law — was entered into force on August 1, 2024 and most provisions will become effective on August 2, 2026. This legislation imposes significant obligations on providers and deployers of high risk AI systems, and encourages providers and deployers of AI systems to account for EU ethical principles in their development and use of these systems. The rapid evolution of AI intelligence will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts.** Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we **enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. Our vendors may also incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business. If we** are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. ~~For additional information, see " Business — Government regulation and product approval — Data privacy and security laws. "~~ Foreign data protection laws, including the European Union' s General Data Protection Regulation (the EU GDPR), and the UK equivalent of the same (the UK GDPR, together with the EU GDPR, the GDPR) may also apply to our processing of health- related and other personal data regardless of where the processing in question is carried out. The GDPR imposes stringent requirements for controllers and processors of personal data of individuals within the ~~European Economic Area (~~ EEA ~~)~~, or the United Kingdom. The GDPR applies to any company established in the EEA or United Kingdom as well as to those outside the EEA or United Kingdom if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or United Kingdom or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA Member States and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In ~~particular~~ **100particular** ,

these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million (£ 17. 5 million) or 4 % of the annual global revenues of the noncompliant company, whichever is greater. The EU GDPR also confers a private right of action on data subjects to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the EU GDPR. The UK Government ~~has also now~~ introduced a Data Protection and Digital Information **Bill which failed in the UK legislative process. A new Data (Use and Access)** Bill (UK Bill) **has now been introduced** into **parliament** ~~the UK legislative process~~. ~~The aim~~ **If passed, the final version** of the UK Bill ~~is to reform~~ **may have the effect of further altering the similarities between** the UK ~~'s~~ **and EEA** data protection regime ~~following Brexit~~. ~~If passed, the final version of the UK Bill may have the effect of further~~ **Further ,** ~~altering the similarities between the UK and EU data protection regime. This~~ **this** may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU' s and UK' s GDPR may further diverge in the future and create additional regulatory challenges and uncertainties. In addition, EU Member States have adopted implementing national laws to implement the GDPR which may partially deviate from the GDPR and the competent authorities in the EU Member States may interpret GDPR obligations slightly differently from country to country, so that we do not expect to operate in a uniform legal landscape in the EU. The EU GDPR prohibits the transfer of personal data from the EEA to third countries that are not considered to provide adequate protections for personal data, including the U. S. With regard to transfers of personal data from the EEA, transfers to third countries that have not been approved as " adequate " are prohibited unless an appropriate safeguard specified by the EU GDPR is implemented, such as the Standard Contractual Clauses (SCCs) approved by the European Commission, certification to the EU- U. S. Data Privacy Framework (which allows for transfers for relevant U. S.- based organizations who self- certify compliance and participate in the framework), binding corporate rules, or a derogation applies. Where relying on the SCCs for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The Information Commissioner' s Office has ~~recently~~ introduced ~~new~~ mechanisms for international transfers of personal data originating from the UK (an International Data Transfer Agreement along with a separate addendum to the EU SCCs). The UK and U. S. have also agreed an extension to the EU- US Data Privacy Framework to cover transfers of personal data from the UK to the U. S. These mechanisms are subject to legal challenges, and therefore the circumstances where we can rely on these measures may change with time, such that there is no assurance that we can continue to satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the United Kingdom, or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, ~~97the~~ -- **the** inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR' s cross- border data transfer rules. Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA Member States and the United Kingdom may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, and orders to cease / change our use of data or enforcement notices. While we have taken steps to comply with the GDPR where applicable, our efforts to achieve and remain in compliance may not be fully successful. Compliance with U. S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Failure (or perceived failure) to comply with U. S. and foreign data protection laws and regulations could result in government investigations and enforcement actions which could include civil or criminal penalties (e. g., fines, penalties, audits, additional reporting requirements and / or oversight, bans on processing personal data, and orders to destroy or not use personal data), private litigation (including class- action claims) and mass arbitration demands, and / or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, ~~even~~ **101even** if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for significant statutory damages, depending on the volume of data and the number of violations. Any of these events could have a

material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions (including in relation to clinical trials); limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. For additional information, see " Business — Government regulation and product approval — Data privacy and security laws. " Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited. We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Our ability to use our U. S. federal and state net operating loss carryforwards (NOLs) and other tax attributes to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs, or other tax attributes. Unused U. S. federal NOLs arising in taxable years beginning before January 1, 2018, may be carried forward to the earlier of the next subsequent twenty tax years to offset future taxable income, if any. Under current federal tax law, U. S. federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the ability to use such U. S. federal NOLs to offset taxable income in taxable years beginning after December 31, 2020, is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to current U. S. federal tax law. As of December 31, ~~2023~~ **2024**, we had U. S. federal NOLs of approximately $ ~~139~~ **158**. ~~6~~ **4** million which may be available to offset future U. S. federal income. Our U. S. federal NOLs incurred in taxable years beginning prior to January 1, 2018 of approximately $ 91. 0 million expire beginning in 2029 while U. S. federal NOLs incurred in taxable years beginning after December 31, 2017 of approximately $ ~~48~~ **67**. ~~6~~ **4** million will have an indefinite carryforward period, subject to annual limitations. As of December 31, ~~2023~~ **2024**, we also had state NOL carryforwards of approximately $ 25. ~~5~~ **7** million which may be available to offset future state income and expire at various years beginning with 2028. Our NOL carryforwards are subject to review and possible adjustment by the U. S. federal and state tax authorities. ~~98As~~ **As** of December 31, ~~2023~~ **2024**, we had U. S. federal research and development tax credit carryforwards of approximately $ ~~5~~ **8**. ~~5~~ **1** million available to reduce future tax liabilities which expire at various years beginning with 2028. As of December 31, ~~2023~~ **2024**, we had state credit carryforwards of approximately $ 2. ~~6~~ **9** million available to reduce future tax liabilities which do not expire. Our NOL carryforwards and research and development (R & D) credits are subject to review and possible adjustment by the U. S. federal and state tax authorities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (Code), and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by " 5 % shareholders " over a rolling three- year period, the corporation' s ability to use its pre- change NOLs, R & D credits and certain other tax attributes to offset its post- change income or taxes may be limited. This could limit the amount of NOLs, R & D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U. S. tax rules in respect of the utilization of NOLs, R & D credits and other applicable tax attributes carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows. Changes in tax law may adversely affect us or our investors. The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (IRS) and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our Series A common stock. For example, under Section 174 ~~of~~ **102of** the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the United States are capitalized and amortized, which may have an adverse effect on our cash flow. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. We have incurred, and will continue to incur, significant increased costs as a result of operating as a public company, and our management is devoting substantial time and resources to ~~new~~ compliance initiatives. As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes- Oxley Act of 2002 (Sarbanes- Oxley Act), the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations. Complying with these rules and regulations has increased, and will continue to increase, our legal and financial compliance costs and may make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management' s attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We have a very small team with only ~~10~~ **14 full- time** employees as of December 31, **2024In** ~~2023, two of which work on a part- time basis. We may need to hire additional financial reporting, internal controls and other finance personnel or consultants in order to develop and implement appropriate internal controls and reporting procedures, which will increase our costs and expenses. In~~ addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal

and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by ~~99regulatory~~ ~~-~~ **regulatory** or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be significantly harmed. As a ~~result of becoming a~~ public company, we are obligated to ~~develop and~~ maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our **Series A** common ~~shares~~ **stock** . We are required, pursuant to Section 404 of the Sarbanes- Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting ~~for the fiscal year ending December 31, 2024~~ . This assessment ~~will need to include~~ **includes** disclosure of any material weaknesses identified by our management in our internal controls over financial reporting ~~and will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts~~ . We **are also** ~~have never been~~ required to ~~test~~ **disclose changes made to** our internal controls ~~within a specified period,~~ and **procedures** ~~, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements~~ on a ~~timely~~ **quarterly** basis ~~, could increase our operating costs and harm our business~~ . ~~We may discover weaknesses in~~ **However, we expect that** our **independent registered public** ~~system of internal financial and~~ accounting ~~controls and procedures that could result in a material misstatement~~ **firm will not be required to report on the effectiveness** of our ~~financial statements. Our~~ internal control over financial reporting **pursuant** ~~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 **until the date we are no longer an " emerging growth company " as defined in the JOBS Act, if we take advantage of the exemptions contained in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse if it is not satisfied with the level at which our controls are documented, designed, or operating. Additionally, the existence of any material weakness or significant deficiency would require management to devote significant time and incur significant expense to remediate any such material weaknesses or significant deficiencies and management may not be able to remediate any such material weaknesses or significant deficiencies** in a timely manner ~~,~~ **. The existence of any material weakness in** ~~or~~ **our** ~~if we are unable to maintain proper and effective~~ internal ~~controls~~ ~~-~~ **control over financial reporting could also result in errors in our** ~~, we may not be able to produce timely and accurate~~ financial statements ~~. If~~ that ~~were to happen, our investors~~ could **require us to restate our financial statements, cause us to fail to meet our reporting obligations, and cause stockholders to** lose confidence in our reported financial information, **all of which could materially and adversely affect our business and** the ~~market~~ price of our **Series A common** stock ~~could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities~~ . ~~Our~~ **103Our** future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business. We are highly dependent on the management, research and development, clinical, financial, and business development expertise of David Happel, our Chief Executive Officer, **Thierry Chauche, our Chief Financial Officer,** Dr. Eduardo Martins, our Chief Medical Officer and Elizabeth Rozek, our General Counsel and Chief Compliance Officer ~~. On January 31, 2024, Anthony Rimac resigned from his position of Chief Financial Officer and on February 1, 2024, Joseph Oriti, a director at Stout, a global advisory firm specializing in corporate finance, accounting and transaction advisory services, began serving as our Interim Principal Financial Officer and Principal Accounting Officer. We have undertaken a search for a permanent replacement for our former Chief Financial Officer. Each of our other executive officers may currently terminate their employment with us at any time~~ . We do not currently maintain " key person " insurance for any of our executives or employees. Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. If we fail to manage these transitions successfully, we could experience significant delays or difficulty in the achievement of our product development and our business, financial condition and results of operations could be materially and adversely affected. We also experience competition for the hiring of scientific and clinical personnel from

universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. ~~100Risks~~ --- **Risks** related to our Series A common stockOur quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, many of which are beyond our control, including without limitation: ● variations in the level of expense related to the ongoing development of our drug candidates or future development programs; ● results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners; ● our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements; ● any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved; ● additions and departures of key personnel; ● strategic decisions by us or our competitors, such as acquisitions, divestitures, spin- offs, joint ventures, strategic investments or changes in business strategy; ● if any of our drug candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such drug candidates; ● regulatory developments affecting our drug candidates or those of our competitors; and ● changes in general market and economic conditions. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our Series A common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our ~~stock~~ **104stock** to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. Our stock price has been and may continue to be volatile, and purchasers of our Series A common stock could incur substantial losses. Our stock price has been and is likely to continue to be volatile. The market price for our Series A common stock may be influenced by various factors, many of which are beyond our control, including the other risks described in this " Risk Factors " section and many others, such as but not limited to: ● our ability to advance denifanstat or potential future drug candidates; ● results of preclinical studies and clinical trials of denifanstat or potential future drug candidates, or those of our competitors or potential collaborative partners; ● regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our drug candidates; ● the success of competitive products; ● introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements; ~~101~~ ● actions taken by regulatory authorities with respect to our drug candidates, potential products, clinical trials, manufacturing process or sales and marketing terms; ● actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us; ● the success of our efforts to acquire or in- license additional technologies, products or drug candidates; ● developments concerning any future collaborations, including, but not limited to, those with our sources of manufacturing supply and our commercialization partners; ● market conditions in the biopharmaceutical and biotechnology sectors; ● manufacturing, supply or distribution delays or shortages; ● announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, financing efforts or capital commitments; ● developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products; ● our ability or inability to raise additional capital and the terms on which we raise it; ● the recruitment or departure of key personnel; ● changes in the structure of healthcare payment systems; ● actual or anticipated changes in earnings estimates or changes in securities analyst recommendations regarding our Series A common stock, other comparable companies or our industry generally; ● our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; **105** ● fluctuations in the valuation of companies perceived by investors to be comparable to us; ● speculation in the press or investment community; ● trading volume of our Series A common stock; ● sales of our Series A common stock by us or our stockholders; ● the concentrated ownership of our common stock; ● changes in accounting principles; ● macroeconomic conditions, including volatility in the credit and financial markets and inflationary pressures; ● terrorist acts, acts of war or periods of widespread civil unrest, including Russia' s invasion of Ukraine and the ~~recent~~ conflict in Israel; ● natural disasters, including earthquakes, and other calamities; and ● general economic, industry and market conditions. ~~102In~~ **In** addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our Series A common stock, regardless of our operating performance. The dual series structure of our common stock may limit our Series A common stockholders' ability to influence corporate matters and may limit visibility with respect to certain transactions. The dual series structure of our common stock may limit our Series A common stockholders' ability to influence corporate matters. Holders of our Series A common stock are entitled to one vote per share, while our Series B common stock is non- voting. Nonetheless, each share of our Series B common stock may be converted at any time into one share of our Series A common stock at the option of the holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Consequently, if the holder of our Series B common stock exercises its option to make this conversion, this will have the effect of increasing the relative voting power of the holder of our Series B common stock, and correspondingly decreasing the voting power of the holders of our Series A common stock, which may limit our stockholders' ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10 % of our Series A common stock and Series B common stock, but 10 % or less of our Series A common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to transactions in our Series B common stock pursuant to Section 16 (a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16 (b) of the Exchange Act. Future sales and issuances of our Series A common stock, or rights to purchase our Series A common stock, could result in dilution of the percentage ownership of our stockholders and

could cause our stock price to fall. We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To the extent that additional capital is raised through the issuance of shares of Series A common stock or other securities convertible into shares of Series A common stock, our stockholders will be diluted. Future issuances of our Series A common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our Series A common stock and impair our ability to raise capital through future offerings of shares or equity securities **. In August 2024, we entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. (Cantor) to establish an at- the- market offering (ATM Offering) through which we may offer and sell, from time to time at our sole discretion, up to $ 75. 0 million of shares of our Series A common stock through Cantor acting as our sales agent. There were no sales under the ATM Offering during the year ended December 31, 2024** . No prediction can be made as to the effect, if any, that future sales of Series A common stock or other equity securities or the availability of Series A common stock for future sales will have on the trading price of our Series A common stock. **106We** ~~Our principal stockholders and management own a significant percentage of our common stock and have the ability to exercise significant control over matters subject to stockholder approval. Our executive officers and directors, principal stockholders and their respective affiliates, beneficially own a significant amount of our Series A common stock. As a result, these stockholders, if acting together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as, and may even conflict with, the interests of our other Series A stockholders. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our stockholders, which could deprive such stockholders of an opportunity to receive a premium for their Series A common stock as part of a sale of our company or our assets and might affect the prevailing market price of our Series A common stock. The significant concentration of stock ownership may adversely affect the trading price of our Series A common stock due to investors' perception that conflicts of interest may exist or arise. We~~ are an " emerging growth company " and a " smaller reporting company " and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our Series A common stock less attractive to ~~investors~~ **investorsWe** ~~. We~~ are an " emerging growth company " as defined in the Jumpstart Our Business Startups Act (JOBS Act). 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 (Section 404), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory ~~103vote~~ **vote** on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements. We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $ 1. 235 billion in annual revenue; (ii) the date we qualify as a " large accelerated filer, " with at least $ 700. 0 million of equity securities held by non- affiliates; (iii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt securities during the prior three- year period; and (iv) December 31, 2028. Even after we no longer qualify as an emerging growth company, we could 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 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our Series A common stock less attractive because we may rely on these exemptions. In addition, the JOBS Act provides that an emerging growth company can also take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies. We are also a " smaller reporting company " as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non- voting common stock held by non- affiliates is less than $ 250. 0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and our voting and non- voting common stock held by non- affiliates is less than $ 700. 0 million measured on the last business day of our second fiscal quarter. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders. We have never declared or paid **any** cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our Series A common stock will be the sole source of gain for our stockholders in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee our Series A common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares. We may incur significant costs from class action litigation due to our expected stock volatility. Our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of our development efforts for our discovery platform and our drug candidates, the development efforts of future partners or competitors, the addition or departure of our key personnel, variations in our quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies. This risk is especially relevant to us because biopharmaceutical and

biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management. ~~Anti~~ **107Anti** - takeover provisions in our charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of our company or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include: ● a prohibition on actions by our stockholders by written consent; ~~104~~ ● a requirement that special meetings of stockholders be called only by our board of directors; ● advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings; ● division of our board of directors into three classes, serving staggered terms of three years each; and ● the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums for substantially all disputes 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, or employees. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: ● any derivative claim or cause of action brought on our behalf; ● any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; ● any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time); ● any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); ● any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and ● any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal- affairs doctrine. ~~However~~ **108However** , Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U. S. federal courts have exclusive jurisdiction. Moreover, Section 22 of the Securities Act of 1933, as amended (the Securities Act), creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. In addition, our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose ~~105profession~~ --- **profession** gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying such offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Additionally, our amended and restated bylaws provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. General risk factorsOur operations are vulnerable to interruption by earthquake, fire, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could harm our business. Our facility is located in a seismically active region. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a complete recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline. The trading market for our Series A common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property rights or our Series A common stock performance, or if our target studies and operating results fail to meet the expectations of the analysts,

our stock price could decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Unfavorable global political or economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global credit and financial markets have experienced severe volatility and disruptions in the past several years. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A weak or declining economy could also result in supply chain disruptions. In addition, the ongoing military conflict between Russia and Ukraine and in Israel could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions have been or may in the future be initiated by nations including the United States, the European Union or Russia, which could adversely affect our business and / or our supply chain, our CROs, CMOs and other third parties with whom we conduct business. 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. ~~Adverse~~ **109Adverse** developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non- performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and financial condition and results of operations. Events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. Even though we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or ~~106liquidity~~ --- **liquidity** agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. ~~107Item~~ **110Item** 1B. Unresolved Staff ~~Comments~~ **CommentsNone** ~~. None~~. Item 1C. ~~Cybersecurity~~ **CybersecurityCyber** ~~. Cyber~~ Risk Management and StrategyWe **have developed** ~~recognize the importance of assessing, identifying,~~ and **implemented a** ~~managing risks from cybersecurity threats. Our approach to~~ cybersecurity risk management **program designed to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program** is ~~aligned~~ **integrated into our broader information security policy, which is informed by industry standards such as the National Institute of Standards and Technology (NIST) Cybersecurity Framework and Center for Internet Security (CIS) benchmarks. Our approach to cybersecurity risk management includes, but is not limited to, the following elements: ● Security incident management processes designed to oversee, identify and manage security events and incidents, including a cybersecurity incident response plan and a managed 24 / 7 security operation center, which monitors all security events from endpoints and cloud services. ● System lifecycle and management processes designed to oversee and manage systems and services used by Sagimet, including system assessments and the management of vulnerabilities. ● System protections including firewalls, endpoint protection, access controls and cloud- based security systems. ● Annual cloud system assessments**

designed to help identify material cybersecurity risks to our critical systems, information and our broader enterprise Information Technology (IT) environment. ● Cybersecurity awareness training for all users with **access to** our ~~risk profile~~ **systems including employees, consultants** and ~~business~~ **senior management, with timely relevant security topics, which include social engineering, phishing, password protection, protecting personal data and appropriate use of assets** . We have leveraged the support of **a** third- party **data privacy organization** ~~information technology and security providers, including~~ to perform a risk assessment designed to identify, assess, and manage ~~cybersecurity~~ **data privacy** risks. Further, we follow a formal, documented process to assess the data protection practices of certain third- party vendors that handle sensitive information on our behalf. ~~Although~~ **This process includes a risk assessment process which is designed to oversee, identify and manage material cybersecurity and data privacy** risks ~~from~~ **associated with systems, services and third parties. To date, we have not experienced any** cybersecurity **incidents or** threats **that** have ~~to date not~~ materially affected **us or** ~~, and we do not believe they~~ are reasonably likely to materially affect ~~,~~ us ~~or~~ **, including** our business strategy, results of operations or financial condition **; however** , **like other companies in our industry,** we ~~could~~ **have** , from time to time, ~~experience~~ **experienced** threats and security incidents relating to our and our third- party vendors' information **technology** systems **and infrastructure** . For more information, please see the section entitled " Risk Factors " in this Annual Report on Form 10- K. Governance Related to Cybersecurity Risks Our Senior Director of ~~Information Technology (IT)~~ is responsible for the strategic leadership and direction of our cybersecurity program. The Senior Director of IT has ~~nearly~~ **over** 15 years of experience as an information technology professional **. Our Board of Directors has delegated oversight of our cybersecurity risk management program to our audit committee, per the audit committee charter** . Our audit committee has oversight over cybersecurity risks. Our management provides periodic presentations to the audit committee on our cybersecurity program, including updates on cybersecurity risks and related cybersecurity strategy, as applicable. **In addition, management alerts the audit committee of any material cybersecurity incidents.** The audit committee provides updates regarding our cybersecurity program to the board of directors when material. **111** ~~Item 2. Properties. Our headquarters is currently located in San Mateo, California and consists of approximately 3, 000 square feet of office space under a lease that expires in June 2024. We believe that our facilities are adequate to meet our current needs. We plan to reassess our facilities needs on a quarterly basis. Item 3. Legal Proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows. Item 4. Mine safety disclosures. Not applicable. 108~~