Risk Factors Comparison 2024-03-06 to 2023-03-10 Form: 10-K

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

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10- K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations. Risk Factor SummaryBelow is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with all of the other information appearing in or incorporated by reference into this Annual Report on Form 10- K and our other public filings with the SEC before making an investment decision regarding our common stock. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition **,** and results of operations. ● We are a clinical- stage company, we have a very limited operating history, are not currently profitable, do not expect to become profitable in the near future and may never become profitable. ● We are dependent on the success of one or more of our current product candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized. ● If development of our product candidates does not produce favorable results, or encounters challenges, we and our collaborators, if any, may be unable to commercialize these products. ● We **may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. ● We** expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability. ● Our debt agreement contains restrictive and financial covenants that may limit our operating flexibility and the failure to comply with such covenants could cause our outstanding debt to become immediately payable. ● Given our lack of current cash flow, we ~~may~~ **will** need to raise additional capital; however, it may be unavailable to us or, even if capital is obtained, may cause dilution or place significant restrictions on our ability to operate our business. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates ~~,~~ or continue our development programs. ● Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition **,** and results of operations. ● Interim and preliminary results 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 additional audit, validation and verification procedures that could result in material changes in the final data. ● Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations ~~. ● The COVID- 19 pandemic, and any other pandemic, epidemic or outbreak of an infectious disease may materially and adversely affect our business and operations~~ . ● Results of earlier clinical trials may not be predictive of the results of later- stage clinical trials. ● We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed. ● Our product candidates are subject to extensive regulation under the U. S. Food and Drug Administration (" FDA "), the European Medicines Agency (the " EMA ") or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates. ● If our competitors have product candidates that are approved faster, marketed more effectively, are better tolerated, have a more favorable safety profile or are demonstrated to be more effective than ours, our commercial opportunity may be reduced or eliminated. ● We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product ~~,~~ or fail to do so at acceptable quality levels or prices. ● The commercial success of our product candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community. ● If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our product candidates. ● We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in- licenses. ~~22~~ **23** ● If we fail to comply with our obligations in the agreements under which we in- license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business. ● We may not be able to protect our proprietary or licensed technology in the marketplace. ● The market price of our common stock is expected to be volatile. Risk FactorsRisks Related to the CompanyWe are a clinical- stage company, we have a very limited operating history, are not currently profitable, do not expect to become profitable in the near future and may never become profitable. We are a clinical- stage biopharmaceutical company. Since our incorporation, we have focused primarily on the development and acquisition of clinical- stage therapeutic candidates. All of our therapeutic candidates are in the clinical development stage and none of our pipeline therapeutic candidates have been approved for marketing or are being marketed or commercialized. As a result, we have no meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to obtain marketing approval for any of our product candidates

or successfully overcome the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. We also have generated minimal revenues from collaboration and licensing agreements and no revenues from product sales to date and continue to incur significant research and development and other expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. We have incurred an accumulated deficit of $ ~~214~~ **252** . ~~7~~ **6** million from our inception through December 31, ~~2022~~ **2023** . For the foreseeable future, we expect to continue to incur losses, which will increase significantly from historical levels as we expand our drug development activities, seek partnering and / or regulatory approvals for our product candidates and begin to commercialize them if they are approved by the FDA, the EMA or comparable foreign authorities. Even if we succeed in developing and commercializing one or more product candidates, we may never become profitable. We are dependent on the success of one or more of our current product candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized. We have spent significant time, money and effort on the licensing and development of our core assets, SLS- 002 and SLS- 005, and our other earlier- stage assets, SLS- 004, SLS- 006, SLS- 007, SLS- 008 **, SLS- 009** , SLS- 010 and SLS- 012. To date, no pivotal clinical trials designed to provide clinically and statistically significant proof of efficacy, or to provide sufficient evidence of safety to justify approval, have been completed with any of our pipeline product candidates. All of our product candidates will require additional development, including clinical trials as well as further preclinical studies to evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation, and regulatory clearances before they can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory clearances will be obtained. Our drug development efforts may not lead to commercial drugs, either because our product candidates may fail to be safe and effective or because we have inadequate financial or other resources to advance our product candidates through the clinical development and approval processes. **See the risk factor titled " We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success " below.** If any of our product candidates fail to demonstrate safety or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon, development of the product candidate. We do not anticipate that any of our current product candidates will be eligible to receive regulatory approval from the FDA, the EMA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these product candidates, we **,** or our potential future partners, if any, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost- effectiveness, the cost of manufacturing the product on a commercial scale and competition with other drugs. The success of our product candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current ~~product~~ **24product** candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our financial condition and stock price may decline. ~~23If~~ **If** development of our product candidates does not produce favorable results, or encounters challenges, we **,** and our collaborators, if any, may be unable to commercialize these products. To receive regulatory approval for the commercialization of our core assets, SLS- 002 and SLS- 005, and our earlier- stage assets, SLS- 004, SLS- 006, SLS- 007, SLS- 008 **, SLS- 009** , SLS- 010 and SLS- 012, or any other product candidates that we may develop, adequate and well- controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA, the EMA and comparable foreign authorities. In order to support marketing approval, these agencies typically require successful results in one or more Phase III clinical trials, which our current product candidates have not yet reached and may never reach. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent commercialization of our current or future product candidates, including the following: ● clinical trials may produce negative or inconclusive results; ● preclinical studies conducted with product candidates during clinical development to, among other things, evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation may produce unfavorable results; ● we or our contract manufacturers may encounter manufacturing challenges **,** or the FDA may raise concerns regarding Chemistry, Manufacturing, and Controls (CMC) data or GMP compliance, or biocompatibility or drug- device interaction concerns for our combination product candidates; ● patient recruitment and enrollment in clinical trials may be slower than we anticipate; ● costs of development may be greater than we anticipate; ● our product candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved; ● collaborators who may be responsible for the development of our product candidates may not devote sufficient resources to these clinical trials or other preclinical studies of these candidates or conduct them in a timely manner; or ● we may face delays in obtaining regulatory approvals to commence one or more clinical trials. Success in early development does not mean that later development will be successful because, for example, product candidates in later- stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical trials. We have licensed or acquired all of the intellectual property related to our product candidates from third parties. All clinical trials, preclinical studies and other analyses performed to date with respect to our product candidates have been conducted by their original owners. Therefore, as a company, we have limited experience in conducting clinical trials for our product candidates. Since our experience with our product candidates is limited, we will need to train our existing personnel and hire additional personnel in order to successfully administer and manage our clinical trials and other studies as planned, which may result in delays in completing such planned clinical trials and preclinical studies. Moreover, to date our product candidates have been tested in less than the number of patients that will likely need to be studied to obtain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these product candidates. We currently do not have strategic collaborations in place for clinical development of any of our current product candidates, except for our collaborative agreement with Team Sanfilippo Foundation (" TSF "), which we

assumed in connection with the asset purchase agreement with Bioblast Pharma Ltd. for IV Trehalose, which is now known as SLS- 005. Therefore, in the future, we or any potential future collaborative partner will be responsible for establishing the targeted endpoints and goals for development of our product candidates. These targeted endpoints and goals may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected during the development of our product candidates are promising, such data may not be sufficient to support marketing approval by the FDA, the EMA or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA, the EMA or comparable foreign authorities may interpret such data in different ways than us or our collaborators. Our failure to adequately demonstrate the safety and efficacy of our product candidates would prevent our receipt of regulatory approval, and ultimately the potential commercialization of these product candidates. ~~24Since~~ **25Since** we do not currently possess the resources necessary to independently develop and commercialize our product candidates or any other product candidates that we may develop, we may seek to enter into collaborative agreements to assist in the development and potential future commercialization of some or all of these assets as a component of our strategic plan. However, our discussions with potential collaborators may not lead to the establishment of collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and potential commercialization delays, which would adversely affect our business, financial condition and results of operations **. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, on March 29, 2023, we announced that we plan to focus the majority of our resources on the Phase II study of SLS- 002 for the potential treatment of acute suicidal ideation and behavior (" ASIB ") in patients with major depressive disorder (" MDD ") and the fully enrolled Phase II / III study of SLS- 005 in Amyotrophic Lateral Sclerosis (" ALS "). We further announced that we have temporarily paused additional enrollment of patients in the SLS- 005- 302 study in Spinocerebellar Ataxia (" SCA "). Patients already enrolled will continue in the study and data will continue to be collected in order to make decisions for resuming enrollment in the future. We also announced that we are pausing all non- essential preclinical work. Our resource allocation decisions may cause us to fail to capitalize on viable commercial medicines or profitable market opportunities. Our projections of both the number of people who have these disorders, as well as the subset of people with these disorders who have the potential to benefit from treatment with our product candidates, are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects** . We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability. We expect to expend substantial funds in research and development, including preclinical studies and clinical trials of our product candidates, and to manufacture and market any product candidates in the event they are approved for commercial sale. We also may need additional funding to develop or acquire complementary companies, technologies **,** and assets, as well as for working capital requirements and other operating and general corporate purposes. Moreover, our planned increases in staffing will dramatically increase our costs in the near and long- term. However, our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Due to our limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. **For example, as of March 2023, in order to focus the majority of our resources on the Phase II study of SLS- 002 (intranasal racemic ketamine) for ASIB in patients with MDD and the fully enrolled Phase II / III study of SLS- 005 in ALS, we are temporarily pausing additional enrollment of patients in the SLS- 005- 302 study in SCA. Patients already enrolled will continue in the study and data will continue to be collected in order to make decisions for resuming enrollment in the future. This temporary pause has been implemented as a business decision due to financial considerations and is not based on any data related to safety or therapeutic effects. Our focus on these studies may cause us to fail to capitalize on other opportunities.** Because the successful development of our product candidates is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate sufficient revenue, even if we are able to commercialize any of our product candidates, to become profitable. ~~Our~~ **26Our** debt agreement contains restrictive and financial covenants that may limit our operating flexibility and the failure to comply with such covenants could cause our outstanding debt to become immediately payable. On November 23, 2021, we issued and sold to Lind Global Asset Management V, LLC (" Lind ") a convertible promissory note in an **initial** aggregate principal amount of $ 22. 0 million for an aggregate purchase price of $ 20. 0 million **, as amended** (the " Convertible Promissory Note "). The Convertible Promissory Note contains certain restrictive covenants and event of default provisions, including restrictions on certain sales or other dispositions of company assets, restrictions on entering into certain variable- rate transactions and a covenant requiring us to

maintain an aggregate minimum balance **equal to 50 %** of ~~$ 10. 0 million~~ **the then outstanding principal amount under the Convertible Promissory Note** or more in cash and cash equivalents ~~through June 30~~ **commencing on March 28** , ~~2023~~ **2024 . As** ~~and an aggregate minimum balance~~ of **February 21, 2024, the outstanding principal amount of the Convertible Promissory Note was approximately** $ 12. ~~5~~ **6** million ~~on or after July 1, 2023~~ . In the event we fail to meet the minimum cash balance as required under the Convertible Promissory Note, and if we are unable to cure such default within fifteen days from its occurrence or otherwise obtain a waiver from Lind or amend the terms of the Convertible Promissory Note, we would trigger a default under the Convertible Promissory Note. If we are not able to comply or regain compliance with any of the covenants in, or otherwise trigger a default under, the Convertible Promissory Note, Lind could declare the Convertible Promissory Note immediately due and payable, which would require us to pay 120 % of the outstanding principal amount of the Convertible Promissory Note and would have a material adverse effect on our liquidity, financial condition, operating results, business and prospects, and could cause the price of our common stock to decline. In addition, since the borrowings under the Convertible Promissory Note are secured by a first priority lien on our assets, Lind would be able to foreclose on our assets if we do not cure any default or pay any amounts due and payable under the Convertible Promissory Note. **In addition, upon an Event of Default (as defined in the Convertible Promissory Note), Lind shall have the right to convert the then- outstanding principal amount of the Convertible Promissory Note into shares of our common stock at the lower of (x) the then- current conversion price (which is currently $ 180. 00 per share, subject to adjustment in certain circumstances as described in the Convertible Promissory Note) and (y) 85 % of the average of the five lowest daily volume weighted- average price of our common stock during the 20 trading days prior to the delivery by Lind of a notice of conversion.** Given our lack of current cash flow, we ~~may~~ **will** need to raise additional capital; however, it may be unavailable to us or, even if capital is obtained, may cause dilution or place significant restrictions on our ability to operate our business. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates ~~,~~ or continue our development programs. As of December 31, ~~2022~~ **2023** , we had a cash balance of approximately $ ~~15~~ **3** . ~~5~~ **0** million. Since we will be unable to generate sufficient, if any, cash flow to fund our operations for the foreseeable future, we ~~may~~ **will** need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations. ~~25As~~ **As** a result of our recurring losses from operations **, in addition to the risk of noncompliance with the minimum cash balance requirements under the Convertible Promissory Note as discussed above under the heading " Our debt agreement contains restrictive and financial covenants that may limit our operating flexibility and the failure to comply with such covenants could cause our outstanding debt to become immediately payable "** , there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. If we are unsuccessful in our efforts to raise outside financing, we may be required to significantly reduce or cease operations. The report of our independent registered public accounting firm on our audited financial statements for the year ended December 31, ~~2022~~ **2023** included a " going concern " explanatory paragraph indicating that our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. We currently have an effective shelf registration statement on Form S- 3 filed with the SEC **(the " Shelf Registration Statement ")** . We may use the **" ~~shelf~~ Shelf** ~~registration~~ **Registration** ~~statement~~ **Statement** ~~on Form S- 3~~ to offer from time to time **up to $ 246. 0 million of** any combination of debt securities, common and preferred stock and warrants. ~~Moreover~~ **However , for so long as our public float remains less than $ 75 million, in no event will** we ~~have the ability to~~ sell ~~up~~ **securities pursuant** to ~~$ 50. 0 million~~ **shelf registration statements, including pursuant to the Shelf Registration Statement, with a value more than one- third** of ~~additional shares~~ **the aggregate market value** of our common stock ~~to the public through~~ **held by non- affiliates in** ~~an~~ **any** ~~" at the market " offering pursuant to the Sales~~ **12- month period. In addition, we agreed in a securities purchase** ~~Agreement~~ **agreement** ~~we~~ entered into **in connection** with **our March** ~~Jefferies, LLC on May 12, 2022~~ **2023** ~~. As of~~ **registered direct offering (** the **" March 2023 RDO ") that we would not, subject to certain exceptions, effect or enter into an agreement to effect any issuance of shares of common stock or common stock equivalents involving a variable** ~~date~~ **rate** ~~hereof~~ **transaction** , ~~a total~~ **which includes the Sale Agreement, until the earlier** of ~~$ 94. 6 million~~ **: (a) such time as no investor holds any warrants issued in the March 2023 RDO, and (b) September 21, 2026 (or, in the case** of **an at- the- market offering, September 21, 2024). Additionally, we agreed in a** securities ~~remains available~~ **purchase agreement entered into in connection with our 27September 2023 registered direct offering that, until March 25, 2024, we will not effect** ~~for~~ **or enter into an agreement to effect any** issuance ~~pursuant to the shelf registration statement (inclusive~~ of **shares of common stock or common stock equivalents involving an at-** the ~~$ 49~~ **- market offering or variable rate transaction** . ~~5 million~~ **We also agreed in a securities purchase agreement entered into in connection with our January 2024 registered direct offering** that ~~remained allocated~~ **, subject** to ~~sales~~ **certain exceptions, until March 15, 2024, we will not to enter into any agreement to issue or announce the issuance or proposed issuance of any common stock or common stock equivalents and that, until July 30, 2024, we will not, subject to certain exceptions, effect any issuance** of shares ~~pursuant to the Sales Agreement as~~ of ~~such~~ **common Stock or common stock equivalents involving an at- the- market offering or variable** ~~date~~ **rate** ~~)~~ **transaction** . There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all ~~. In addition, the impact of the COVID- 19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern~~ . If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit **,** or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations will be materially adversely affected. In addition, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our inability to fund our business could lead to the loss of your investment. Our future capital requirements will depend on many factors, including, but not limited to: ● the scope, rate of progress, results and cost of our clinical trials, preclinical studies and

other related activities; ● our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements; ● the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates; ● the number and characteristics of the product candidates we seek to develop or commercialize; ● the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates; ● the cost of commercialization activities if any of our current or future product candidates are approved for sale, including marketing, sales and distribution costs; ● the expenses needed to attract and retain skilled personnel; ● the costs associated with being a public company; ● the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and ● the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation. If we raise additional capital by issuing equity securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences **,** and privileges senior to those of our common stock. Given our need for cash and that equity issuances are the most common type of fundraising for similarly situated companies, the risk of dilution is particularly significant for our stockholders. In addition, debt financing may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures **,** or declaring dividends and may be secured by all or a portion of our assets. For example, we granted to Lind, as the holder of the Convertible Promissory Note, a first priority lien on our assets and properties and the Convertible Promissory Note includes restrictive covenants and event of default provisions, including restrictions on certain sales or other dispositions of company assets, restrictions on entering into certain variable- rate transactions and a covenant requiring us to maintain an aggregate minimum balance **equal to 50 %** of ~~$ 10. 0 million~~ **the then-outstanding principal amount under the Convertible Promissory Note** or more in cash and cash equivalents **commencing** ~~through June 30, 2023 and an aggregate minimum balance of $ 12. 5 million~~ on **March 28** ~~or after July 1~~ , ~~2023~~ **2024** . Our inability to raise capital when needed may harm our business, financial condition **,** and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether. ~~26Our~~ -- **Our** product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition **,** and results of operations. Undesirable side effects observed in clinical trials or in supportive preclinical studies with our product candidates could interrupt, delay or halt their development and could result in the denial of regulatory approval by the FDA, the EMA or comparable foreign ~~authorities~~ **28authorities** for any or all targeted indications or adversely affect the marketability of any such product candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our product candidates. Our product candidates may exhibit adverse effects in preclinical toxicology studies and adverse interactions with other drugs. There are also risks associated with additional requirements the FDA, the EMA or comparable foreign authorities may impose for marketing approval with regard to a particular disease. Our product candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post- marketing observational study, and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug ~~,~~ or could be limited to a more restricted patient population. Any risk management program required for approval of our product candidates could potentially have an adverse effect on our business, financial condition and results of operations. Undesirable side effects involving our product candidates may have other significant adverse implications on our business, financial condition and results of operations. For example: ● we may be unable to obtain additional financing on acceptable terms, if at all; ● our collaborators may terminate any development agreements covering these product candidates; ● if any development agreements are terminated, we may determine not to further develop the affected product candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all; ● if we were to later continue the development of these product candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization; ● we may be subject to product liability or stockholder litigation; and ● we may be unable to attract and retain key employees. In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product: ● regulatory authorities may withdraw their approval of the product, or we or our partners may decide to cease marketing and sale of the product voluntarily; ● we may be required to change the way the product is administered, conduct additional clinical trials or preclinical studies regarding the product, change the labeling of the product, or change the product' s manufacturing facilities; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product. ~~27Interim~~ **29Interim** and preliminary results 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 additional audit, validation and verification procedures that could result in material changes in the final data. From time to time, we may publish interim data, including interim top-line results or preliminary results from our clinical trials. Any interim data and other results from our clinical trials may materially change as more patient data become available. Preliminary or top- line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or considerations may qualify such results ~~,~~ once we have received and fully evaluated additional data. Differences between preliminary or interim data and final data could adversely affect our business. Our efforts to discover product candidates beyond our current product candidates may not succeed, and any product candidates we recommend for clinical development may not actually begin clinical trials. We intend to use our technology, including our licensed technology, knowledge **,** and expertise to develop novel drugs to address some of the

world' s most widespread and costly central nervous system, respiratory and other disorders, including orphan indications. We intend to expand our existing pipeline of core assets by advancing drug compounds from current ongoing discovery programs into clinical development. However, the process of researching and discovering drug compounds is expensive, time- consuming **,** and unpredictable. Data from our current preclinical programs may not support the clinical development of our lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds we recommend for clinical development may not demonstrate, through preclinical studies, indications of safety and potential efficacy that would support advancement into clinical trials. Such findings would potentially impede our ability to maintain or expand our clinical development pipeline. Our ability to identify new drug compounds and advance them into clinical development also depends upon our ability to fund our research and development operations, and we cannot be certain that additional funding will be available on acceptable terms, or at all. Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations. Delays in the commencement or completion of clinical trials could significantly impact our drug development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to: ● obtaining regulatory approval to commence one or more clinical trials; ● reaching agreement on acceptable terms with prospective third- party contract research organizations (" CROs ") and clinical trial sites; ● manufacturing sufficient quantities of a product candidate or other materials necessary to conduct clinical trials; ● obtaining institutional review board approval to conduct one or more clinical trials at a prospective site; ● recruiting and enrolling patients to participate in one or more clinical trials; and ● the failure of our collaborators to adequately resource our product candidates due to their focus on other programs or as a result of general market conditions. In addition, once a clinical trial has begun, it may be suspended or terminated by us, our collaborators, the institutional review boards or data safety monitoring boards charged with overseeing our clinical trials, the FDA, the EMA or comparable foreign authorities due to a number of factors, including: ● failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols; ● inspection of the clinical trial operations or clinical trial site by the FDA, the EMA or comparable foreign authorities resulting in the imposition of a clinical hold; ● unforeseen safety issues; or ● lack of adequate funding to continue the clinical trial. ~~28If~~ **30If** we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Delays in completing our clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates ~~. The COVID- 19 pandemic, and any other pandemic, epidemic or outbreak of an infectious disease, may materially and adversely affect our business and operations. The COVID- 19 pandemic is continuing to affect the United States and global economies and may affect our operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct of future clinical trials. Additionally, while the potential economic impact brought by, and the duration of the COVID- 19 pandemic, are difficult to assess or predict, the impact of the COVID- 19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short- term and long- term liquidity. In addition, the loss of any of our employees as a result of COVID- 19 or another pandemic may have a material adverse effect on our operations. Any continued and prolonged public health crisis such as the COVID- 19 pandemic could have a material negative impact on our business, financial condition, and operating results~~ . Results of earlier clinical trials may not be predictive of the results of later- stage clinical trials. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons. This product candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early to late **-** stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late **-** stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives. In addition, nonclinical studies may be requested or required even after clinical trials have been commenced or completed. Any of these changes could make the results of our planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates, and / or jeopardize our ability to commence product sales and generate revenues. If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in

relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. ~~29If~~ **If** we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Additionally, enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed. We intend to rely upon third- party CROs, medical institutions, clinical investigators **,** and contract laboratories to monitor and manage data for our ongoing preclinical and clinical programs. Nevertheless, we maintain responsibility for ensuring that each of our clinical ~~trials~~ **31trials** and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards **,** and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with current requirements on good manufacturing practices (" cGMP ") good clinical practices (" GCP ") and good laboratory practice (" GLP "), which are a collection of laws and regulations enforced by the FDA, the EMA and comparable foreign authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes. We may not be able to enter into arrangements with CROs on commercially reasonable terms, or at all. In addition, our CROs will not be our employees, and except for remedies available to us under our agreements with such CROs, we will not be able to control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our product candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed. Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition **,** or results of operations. ~~30Our~~ -- **Our** product candidates are subject to extensive regulation under the FDA, the EMA or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates. The clinical development, manufacturing, labeling, storage, record- keeping, advertising, promotion, export, marketing **,** and distribution of our product candidates are subject to extensive regulation by the FDA and other U. S. regulatory agencies, the EMA or comparable authorities in foreign markets. In the U. S., neither we nor our collaborators are permitted to market our product candidates until we or our collaborators receive approval of a new drug application (" NDA ") from the FDA or receive similar approvals abroad. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. Any guidance that may result from recent FDA advisory panel discussions may make it more expensive to develop and commercialize such product candidates. In addition, as a company, we have not previously filed NDAs with the FDA or filed similar applications with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our product candidates for which development and commercialization is our responsibility. Despite the time and expense invested, regulatory approval is never guaranteed. The FDA, the EMA or comparable foreign authorities can delay, limit or deny approval of a product candidate for many reasons, including: ● a product candidate may not be deemed safe or effective; ● agency officials of the FDA, the EMA or comparable foreign authorities may not find the data from non- clinical or preclinical studies and clinical trials generated during development to be sufficient; ● the FDA, the EMA or comparable foreign authorities may not approve our third- party manufacturers' processes or facilities; **32** ● the FDA, the EMA or a comparable foreign authority may change its approval policies or adopt new regulations; or ● our inability to obtain these approvals would prevent us from commercializing our product candidates. We are pursuing the FDA 505 (b) (2) NDA pathway for our lead product candidate, SLS- 002, which presents certain additional development and commercialization risks as compared to a conventional 505 (b) (1) NDA for an innovator product candidate. We may pursue this pathway for other product candidates as well. For our lead product candidate (SLS- 002) we are pursuing development in

order to seek potential FDA approval under an abbreviated regulatory pathway called a 505 (b) (2) NDA, which permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. We may also pursue this pathway for other of our product candidates. Section 505 (b) (2), if applicable to us for a particular product candidate, would allow an NDA we submit to the FDA to rely, in part, on data in the public domain or the FDA' s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for a product candidate by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. Even if the FDA allows us to rely on the 505 (b) (2) regulatory pathway, there is no assurance that such marketing approval will be obtained in a timely manner, or at all. The FDA may require us to perform additional nonclinical studies and clinical trials, and conduct other development work, to support any change from the reference listed drug (including with respect to the route of administration and drug delivery method and device), which presents uncertainty about the data that may ultimately be necessary and could be time- consuming and substantially delay our application for or potential receipt of marketing approval. Even if we are able to utilize the 505 (b) (2) regulatory pathway, a drug approved via this pathway may be subject to the same post- approval limitations, conditions and requirements as any other drug, including, for example a Risk Evaluation and Mitigation Strategy (" REMS "), which we anticipate will be required for our lead product candidate. Also, as has been the experience of others in our industry, our competitors may file citizens' petitions with the FDA to contest approval of our NDA, which may delay or even prevent the FDA from approving any NDA that we submit under the 505 (b) (2) regulatory pathway. If an FDA decision or action relative to our product candidate, or the FDA' s interpretation of Section 505 (b) (2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505 (b) (2) application for such product candidate. ~~31In~~ **In** addition, we may face Hatch- Waxman litigation in relation to our NDAs submitted under the 505 (b) (2) regulatory pathway, which may further delay or prevent the approval of our product candidate. The pharmaceutical industry is highly competitive, and 505 (b) (2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a 505 (b) (2) NDA. If the previously approved drugs referenced in an applicant' s 505 (b) (2) NDA are protected by patent (s) listed in the FDA' s Approved Drug Products with Therapeutic Equivalence Evaluations publication, or the Orange Book, the 505 (b) (2) applicant is required to make a claim after filing its NDA that each such patent is invalid, unenforceable or will not be infringed. The patent holder may thereafter bring suit for patent infringement, which will trigger a mandatory 30- month delay (or the shorter of dismissal of the lawsuit or expiration of the patent (s)) in approval of the 505 (b) (2) NDA application. If the FDA determines that our 505 (b) (2) regulatory pathway is not viable for SLS- 002 or any other applicable product candidate for any reason, we ~~would~~ **will** need to reconsider our plans and might not be able to commercialize any such product candidate in a cost- efficient manner, or at all. If we were to pursue approval under the 505 (b) (1) NDA pathway, we would be subject to more extensive requirements and risks such as conducting additional clinical trials, providing additional data and information **,** or meeting additional standards for marketing approval. As a result, the time and financial resources required to obtain marketing approval for our product candidates would likely increase substantially and further complications and risks associated with our product candidates may arise. Also, new competing products may reach the market faster than ours, which may materially and adversely affect our competitive position, business and prospects. Even if our product candidates receive regulatory approval in the U. S., we may never receive approval or commercialize our products outside of the U. S. In order to market any products outside of the U. S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing ~~and~~ **33and** additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U. S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to develop foreign markets for our product candidates. Even if any of our product candidates receive regulatory approval, our product candidates may still face future development and regulatory difficulties. If any of our product candidates receive regulatory approval, the FDA, the EMA or comparable foreign authorities may still impose significant restrictions on the indicated uses or marketing of the product candidates or impose ongoing requirements for potentially costly post- approval studies and trials. In addition, regulatory agencies subject a product, our manufacturer and the manufacturer' s facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our collaborators or us, including requiring withdrawal of the product from the market. Our product candidates will also be subject to ongoing FDA, EMA or comparable foreign authorities' requirements for the labeling, packaging, storage, advertising, promotion, record- keeping and submission of safety and other post- market information on the drug. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may: ● issue warning letters or other notices of possible violations; ● impose civil or criminal penalties or fines or seek disgorgement of revenue or profits; ● suspend any ongoing clinical trials; ● refuse to approve pending applications or supplements to approved applications filed by us or our collaborators; ● withdraw any regulatory approvals; ● impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations; or ● seize or detain products or require a product recall. ~~32The~~ -- **The** FDA, the EMA and comparable foreign authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses. The FDA, the EMA and comparable foreign authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, the EMA or comparable foreign authorities as

reflected in the product' s approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment that our products could be used in such manner. However, if we are found to have promoted our products for any off- label uses, the federal government could levy civil, criminal or administrative penalties, and seek fines against us. Such enforcement has become more common in the industry. The FDA, the EMA or comparable foreign authorities could also request that we enter into a consent decree or a corporate integrity agreement ~~,~~ or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition and results of operations. If our competitors have product candidates that are approved faster, marketed more effectively, are better tolerated, have a more favorable safety profile or are demonstrated to be more effective than ours, our commercial opportunity may be reduced or eliminated. The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including commercial biopharmaceutical enterprises, academic institutions, government agencies and private and public research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. ~~Many~~ **34Many** of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than any which we are developing, or that would render our product candidates obsolete and noncompetitive. Even if we obtain regulatory approval for any of our product candidates, our competitors may succeed in obtaining regulatory approvals for their products earlier than we do. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in- licensing technologies and products complementary to our programs or advantageous to our business. The key competitive factors affecting the success of each of our product candidates, if approved, are likely to be its efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition and the availability of coverage and reimbursement from government and other third- party payors. The pharmaceutical market for the treatment of major depressive disorder includes selective serotonin reuptake inhibitors (" SSRIs "), serotonin and norepinephrine reuptake inhibitors (" SNRIs ") and atypical antipsychotics. A number of these marketed antidepressants will be generic ~~,~~ and would be key competitors to SLS- 002. These products include Forest Laboratory' s Lexapro / Cipralex (escitalopram) and Viibryd (vilazodone), Pfizer, Inc.' s Zoloft (sertraline), Effexor (venlafaxine) and Pristiq (desvenlafaxine), GlaxoSmithKline plc' s Paxil / Seroxat (paroxetine), Eli Lilly and Company' s Prozac (fluoxetine) and Cymbalta (duloxetine), AstraZeneca plc' s Seroquel (quetiapine) and Bristol- Myers Squibb Company' s Abilify (aripiprazole), among others. Patients with treatment- resistant depression often require treatment with several antidepressants, such as an SSRI or SNRI, combined with an " adjunct " therapy such as an antipsychotic compound, such as AstraZeneca plc' s Seroquel (quetiapine) and Bristol- Myers Squibb Company' s Abilify (aripiprazole), or mood stabilizers, such as Janssen Pharmaceutica' s Topamax (topiramate). In addition, Janssen' s Spravato (intranasal esketamine), which has been approved for treatment- resistant depression and for depressive systems in adults with major depressive disorder with suicidal thoughts or actions, targets the NMDA receptor and is expected to have a faster onset of therapeutic effect as compared to currently available therapies. ~~33Current~~ -- **Current** treatments for Parkinson' s Disease (" PD ") are intended to improve the symptoms of patients. The cornerstone of PD therapy is levodopa, as it is the most effective therapy for reducing symptoms of PD. There are other drug therapies in development that will target the disease, such as gene and stem cell therapy and A2A receptor agonists. Further, despite the great need for an effective disease- modifying treatment for ALS and significant research efforts by the pharmaceutical industry to meet this need, there have been limited clinical successes and no curative therapies approved to date. In May 2022, the FDA approved an orally administered version of edaravone, which has been available since 2017 as an intravenous infusion for the treatment of ALS. In July 2022, the FDA accepted an NDA for tofersen, an investigational drug from Biogen Inc., for the treatment of superoxide dismutase 1 ALS. ~~The NDA has been~~ **In April 2023, the FDA** granted **accelerated approval to tofersen** ~~priority review with a Prescription Drug User Fee Act goal date of April 25~~ , ~~2023~~ **branded as QALSODY, for the treatment of superoxide dismutase 1 ALS** . Additionally, in September 2022, the FDA approved AMX0035, now branded as Relyvrio, a drug from Amylyx Pharmaceuticals, Inc., for the treatment of ALS. AMX0035 previously received a conditional approval by Health Canada in June 2022 **. In October 2023, the EMA Committee for Medicinal Products for Human Use confirmed a June 2023 recommendation to refuse a marketing authorization for AMX0035 in the European Union, with the final decision expected from the European Commission by the end of 2023** . We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States. In the United States and Europe, obtaining orphan drug approval may allow us to obtain financial incentives, such as an extended period of exclusivity during which only we are allowed to market the orphan drug. While we have received orphan drug designation for SLS- 005 in Sanfilippo Syndrome and in spinocerebellar ataxia type 3 and in oculopharyngeal muscular dystrophy and we plan to seek orphan drug designation from the FDA for SLS- 008 for the treatment of a pediatric indication, we, or any future

collaborators, may not be granted orphan drug designations for our product candidates in the U. S. or in other jurisdictions. ~~Even~~ **35Even** if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because FDA has taken the position that, under certain circumstances, another drug with the same active chemical and pharmacological characteristics, or moiety, can be approved for the same condition. Specifically, the FDA' s regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. The active ingredient of our lead product candidate, SLS- 002, ketamine hydrochloride, is recognized as having the potential for abuse, misuse and diversion and, as a result, is and will be subject to extensive federal and state laws and regulations governing controlled substances and the entities involved in their research, manufacturing, sale and distribution, and possession. In addition, we anticipate that if we obtain marketing approval for SLS- 002 it will be the subject of an FDA Risk Evaluation and Mitigation Strategy (REMS). Ketamine is listed by the Drug Enforcement Administration (" DEA ") as a Schedule III controlled substance under the Controlled Substances Act. The DEA classifies substances as Schedule I, II, III, IV or V controlled substances, with Schedule I controlled substances considered to present the highest risk of substance abuse and Schedule V controlled substances the lowest risk. Scheduled controlled substances are subject to DEA regulations relating to supply, procurement, manufacturing, storage, distribution and physician prescription procedures. In addition to federal scheduling, some drugs may be subject to state- level controlled substance laws and regulations and in some cases more broadly applicable or more extensive requirements than those determined by the DEA and FDA. Federal and state- level controlled substance laws impose a broad range of registration and licensure requirements along with requirements for systems and controls intended to provide security and reduce the risk of diversion and misuse, and to identify suspicious activities. ~~34Compliance~~ -- **Compliance** with these laws can be expensive and time consuming. Failure to follow these requirements can lead to significant civil and / or criminal penalties and possibly even lead to a revocation of a DEA registration and state- level licenses. If SLS- 002 receives marketing approval from the FDA or other regulatory authority, we may be required to implement REMS to address the potential for abuse and misuse of our product candidate. As a result, our product candidate may only be available through a restricted or limited distribution system to which only certain prescribing healthcare professionals may have access for their patients or healthcare professionals may be limited in their prescribing. Furthermore, product candidates containing controlled substances may generate public controversy. As a result, these products may be at risk of having their sale and distribution and marketing approvals further restricted or in extreme cases withdrawn in the event that regulators were to assess that the benefits of a product no longer outweigh emerging risks. Political pressures or adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the commercialization of our product or product candidates. We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates. The process of manufacturing our product candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our product candidates are made could be adversely ~~affected~~ **36affected** by equipment failures, labor shortages, natural disasters, public health crises, pandemics and epidemics, power failures and numerous other factors. In addition, any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our product candidates. We also may need to take inventory write- offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives. We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product ~~,~~ or fail to do so at acceptable quality levels or prices. We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on our manufacturers to purchase from third- party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete such clinical trial, any significant delay or discontinuity in the supply of a product

candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third- party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates, which could harm our business, financial condition and results of operations. ~~35Product~~ -- **Product** candidates that are considered combination products for FDA purposes, such as the SLS- 002 drug- device combination product consisting of ketamine hydrocholoride and a USP aqueous spray solution in a bi- dose nasal delivery device, may face additional challenges, risks and delays in the product development and regulatory approval process. SLS- 002 is delivered by an intranasal delivery device and considered a drug- device combination product (the device having been developed by a third party is subject to a license agreement). When evaluating products that utilize a specific drug delivery system or device, the FDA will evaluate the characteristics of that delivery system and its functionality, as well as the potential for undesirable interactions between the drug and the delivery system, including the potential to negatively impact the safety or effectiveness of the drug. The FDA review process can be more complicated for combination products, and may result in delays, particularly if novel delivery systems are involved. Additionally, quality or design concerns with the delivery system could delay or prevent regulatory approval and commercialization of our product candidates. We and our contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements. All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late- stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or marketing authorization application (“ MAA ”) on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA, the EMA or comparable foreign authorities through their facilities inspection program. Some of our contract manufacturers may not have produced a commercially approved pharmaceutical product and therefore may not have obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third- party contractors must pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or any of our other potential products or the associated quality systems for compliance with the regulations ~~applicable~~ **37applicable** to the activities being conducted. Although we plan to oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre- approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third- party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition and results of operations. If we or any of our third- party manufacturers fail to maintain regulatory compliance, the FDA, the EMA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a product candidate, withdrawal of an approval or suspension of production. As a result, our business, financial condition and results of operations may be materially and adversely affected. Additionally, if supply from one manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. ~~36These~~ -- **These** factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed **,** or we could lose potential revenue. Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future product candidates. We may seek collaboration arrangements with biopharmaceutical companies for the development or commercialization of our current and potential future product candidates. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement can lead to delays in

developing or commercializing the applicable product candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with biopharmaceutical companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect our business, financial condition and results of operations. If we are unable to develop our own commercial organization or enter into agreements with third parties to sell and market our product candidates, we may be unable to generate significant revenues. We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. If any of our product candidates are approved for commercialization, we may be required to develop our sales, marketing and distribution capabilities, or make arrangements with a third party to perform sales and marketing services. Developing a sales force for any resulting product or any product resulting from any of our other product candidates is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or ~~cost~~ **38cost** - effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our product candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we marketed and sold our product candidates independently. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable. The commercial success of our product candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community. Even if our product candidates obtain regulatory approval, our products, if any, may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including: ● the effectiveness of our approved product candidates as compared to currently available products; ● patient willingness to adopt our approved product candidates in place of current therapies; ● our ability to provide acceptable evidence of safety and efficacy; ● relative convenience and ease of administration; ● the prevalence and severity of any adverse side effects; ● restrictions on use in combination with other products; ● availability of alternative treatments; ● pricing and cost- effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our product candidates and target markets; ~~37~~ ● effectiveness of us or our partners' sales and marketing strategy; ● our ability to obtain sufficient third- party coverage or reimbursement; and ● potential product liability claims. In addition, the potential market opportunity for our product candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions based on our industry knowledge, industry publications, third- party research reports and other surveys. Independent sources have not verified all of our assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for our product candidates is smaller than we expect, our product revenue may be limited, it may be harder than expected to raise funds and it may be more difficult for us to achieve or maintain profitability. If we fail to achieve market acceptance of our product candidates in the U. S. and abroad, our revenue will be limited and it will be more difficult to achieve profitability. If we fail to obtain and sustain an adequate level of reimbursement for our potential products by third- party payors, potential future sales would be materially adversely affected. There will be no viable commercial market for our product candidates, if approved, without reimbursement from third- party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our current product candidates or any other product candidate we may develop. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected. Third- party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U. S. healthcare industry toward cost containment. Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many ~~third~~ **39third** - party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third- party payors may limit the covered indications. Cost- control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistent with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to provide reimbursement for our drugs, which would significantly reduce the likelihood of our products gaining market acceptance. We expect that private insurers will consider the efficacy, cost- effectiveness, safety and tolerability of our potential products in determining whether to approve reimbursement for such products and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our potential products from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our product candidates or other potential products. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country- by- country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical

pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our products to other available therapies. ~~38If~~ **If** the prices for our potential products are reduced or if governmental and other third- party payors do not provide adequate coverage and reimbursement of our drugs, our future revenue, cash flows and prospects for profitability will suffer. Current and future legislation may increase the difficulty and cost of commercializing our product candidates and may affect the prices we may obtain if our product candidates are approved for commercialization. In the U. S. and some foreign jurisdictions, there have been a number of adopted and proposed legislative and regulatory changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post- marketing activities and affect our ability to profitably sell any of our product candidates for which we obtain regulatory approval. In the U. S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“ MMA ”) changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit the coverage and reimbursement rate that we receive for any of our approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the “ PPACA ”), was enacted. The PPACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA increased manufacturers’ rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of “ average manufacturer price ”, which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services, which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U. S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a 50 % discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the “ donut hole. ” Legislative and regulatory proposals have ~~been~~ **40been** introduced at both the state and federal level to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. There have been public announcements by members of the U. S. Congress regarding plans to repeal and replace or amend and expand the PPACA and Medicare. For example, on December 22, 2017 the Tax Cuts and Jobs Act of 2017 was signed into law, which, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U. S. Congress of the FDA’ s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing approval testing and other requirements. In addition to the PPACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third- party payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third- party payers. While in general it is difficult to predict specifically what effects the PPACA or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition. In Europe, the United Kingdom withdrew from the European Union on January 31, 2020 and began a transition period that ended on December 31, 2020. Although the ultimate effects of Brexit have yet to be seen, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for companies and increased restrictions on imports and exports throughout Europe, which could adversely affect our ability to conduct and expand our operations in Europe and which may have an adverse effect on our business, financial condition and results of operations. Additionally, Brexit may increase the possibility that other countries may decide to leave the EU in the future. ~~39In~~ **In** addition, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which **took** ~~shall take~~ effect in 2023. Under the Inflation Reduction Act, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single- source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The new law also caps Medicare out- of- pocket drug costs at an estimated $ 4, 000 a year in 2024 and, thereafter beginning in 2025, at $ 2, 000 a year. Changes in government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, properly administer drug innovation, or prevent our product candidates from being developed or commercialized, which could negatively impact our business, financial condition and results of operations. The ability of the FDA to review and approve new products

can be affected by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, 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 agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. In December 2016, the 21st Century Cures Act was signed into law. This new legislation is designed to advance medical innovation and empower the FDA with the authority to directly hire positions related to drug and device development and review. However, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may result in a reduced ability by the FDA to perform their respective roles; including the related impact to academic institutions and research laboratories whose funding is fully or partially dependent on both the level and timing of funding from government sources. Disruptions at the FDA and other agencies may also slow the time necessary for our product candidates to be reviewed or approved by necessary government agencies, which could adversely affect our business, financial condition and results of operations. ~~We~~ **41We** are subject to " fraud and abuse " and similar laws and regulations, and a failure to comply with such regulations or prevail in any litigation related to noncompliance could harm our business, financial condition and results of operations. In the U. S., we are subject to various federal and state healthcare " fraud and abuse " laws, including anti- kickback laws, false claims laws and other laws intended, among other things, to reduce fraud and abuse in federal and state healthcare programs. The federal Anti- Kickback Statute makes it illegal for any person, including a prescription drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug, or other good or service for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti- Kickback Statute. The federal False Claims Act prohibits anyone from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services to obtain money or property of any healthcare benefit program. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including penalties, fines or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U. S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states. ~~40Many~~ -- **Many** states have adopted laws similar to the federal Anti- Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers or the Pharmaceutical Research and Manufacturers of America' s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found in violation of one of these laws, we could be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from governmental funded federal or state healthcare programs and the curtailment or restructuring of our operations. If this occurs, our business, financial condition and results of operations may be materially adversely affected. If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and any of our product candidates that are ultimately approved for commercialization could be subject to restrictions or withdrawal from the market. Any government investigation of alleged violations of law could require us to expend significant time and resources in response ~~,~~ and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from any of our product candidates that are ultimately approved for commercialization. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business, financial condition and results of operations will be adversely affected. Additionally, if we are unable to generate revenues from product sales, our potential for achieving profitability will be diminished and our need to raise capital to fund our operations will increase. ~~If~~ **42If** we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our product candidates. Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. As of February ~~24~~ **21** , ~~2023~~ **2024** , we have 16 employees. Our organization will rely primarily on outsourcing research, development and clinical trial activities, and manufacturing operations, as well as other functions critical to our business. We believe this approach enhances our ability to focus on our core product opportunities, allocate resources efficiently to different projects and allocate internal resources more effectively. We have filled several key open positions and are currently recruiting for a few remaining positions. However, competition for qualified personnel is intense. In addition, regulation or legislation impacting the workforce, such as the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent

employers from entering into non- compete agreements with employees and require employers to rescind existing non- compete agreements, may lead to increased uncertainty in hiring and competition for talent. We may not be successful in attracting qualified personnel to fulfill our current or future needs and there is no guarantee that any of these individuals will join us on a full- time employment basis, or at all. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of our product candidates, and may have difficulty in meeting our obligations as a public company. ~~In addition, we may experience employee turnover as a result of the ongoing " great resignation " occurring throughout the U. S. economy, which has impacted job market dynamics. New hires require training and take time before they achieve full productivity.~~ New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of our product candidates, and may have difficulty in meeting our obligations as a public company. We do not maintain " key person " insurance on any of our employees. ~~41In~~ **In** addition, competitors and others are likely in the future to attempt to recruit our employees. The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management and other technical personnel, could materially and adversely affect our business, financial condition and results of operations. Moreover, regulation or legislation impacting the workforce, such as the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent employers from entering into non- compete with employees and require employers to rescind existing non- competes, may lead to increased uncertainty in hiring and competition for talent. In addition, the replacement of key personnel likely would involve significant time and costs ~~,~~ and may significantly delay or prevent the achievement of our business objectives. From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with us. We will need to increase the size of our organization and may not successfully manage our growth. We are a clinical- stage biopharmaceutical company with a small number of planned employees, and our management system currently in place is not likely to be adequate to support our future growth plans. Our ability to grow and to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, it could have a material adverse effect on our business, financial condition and results of operations. Our management' s limited public company experience could put us at greater risk of incurring fines or regulatory actions for failure to comply with federal securities laws and could put us at a competitive disadvantage ~~,~~ and could require our management to devote additional time and resources to ensure compliance with applicable corporate governance requirements. Our executive officers have limited prior experience as executive officers in managing and operating a public company, which could have an adverse effect on their ability to quickly respond to problems or adequately address issues and matters applicable to public companies. Any failure to comply with federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, financial condition and results of operations. Further, since our executive officers ~~have~~ **43have** limited prior experience as executive officers managing and operating a public company, we may need to dedicate additional time and resources to comply with legally mandated corporate governance policies relative to our competitors whose management teams have more public company experience. We are exposed to product liability, non- clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us. Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. In addition, the use in our clinical trials of pharmaceutical products and the subsequent sale of these products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations. We currently carry product liability insurance for our clinical development activities. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. ~~42Our~~ -- **Our** research and development activities involve the use of hazardous materials, which subject us to regulation, related costs and delays and potential liabilities. Our research and development activities involve the controlled use of hazardous materials and chemicals, and we will need to develop additional safety procedures for the handling and disposing of hazardous materials. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood- borne pathogens and the handling of biohazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations. We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber- attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security

breaches could cause interruptions in our operations ~~,~~ and could result in a material disruption of our drug development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of drug development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs **,** and the development of our product candidates could be delayed. Our employees and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended 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 commissions, customer incentive programs and other business arrangements. Employee and consultant misconduct also could 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 such 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~~ **44lawsuits** stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us. Business disruptions such as natural disasters could seriously harm our future revenues and financial condition and increase our costs and expenses. We and our suppliers may experience a disruption in our and their business as a result of natural disasters. A significant natural or man-made disaster, such as an earthquake, power outages, hurricane, flood or fire, droughts and other extreme weather events and changing weather patterns, which are increasing in frequency due to the impacts of climate change, could severely damage or destroy our headquarters or facilities or the facilities of our manufacturers or suppliers, which could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts or acts of war targeted at the U. S., and specifically the greater New York, New York region, **as well as the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia and the Israel- Hamas war,** could cause damage or disruption to us, our employees, facilities, partners and suppliers, which could have a material adverse effect on our business, financial condition and results of operations. ~~43We~~ **We** may engage in strategic transactions that could impact our liquidity, increase our expenses **,** and present significant distractions to our management. From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out- licensing or in- licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non- recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our business, financial condition and results of operations. For example, these transactions may entail numerous operational and financial risks, including: ● exposure to unknown liabilities; ● disruption of our business and diversion of our management' s time and attention in order to develop acquired products, product candidates or technologies; ● incurrence of substantial debt or dilutive issuances of equity securities to pay for any of these transactions; ● higher- than- expected transaction and integration costs; ● write- downs of assets or goodwill or impairment charges; ● increased amortization expenses; ● difficulty and cost in combining the operations and personnel of any acquired businesses or product lines with our operations and personnel; ● impairment of relationships with key suppliers or customers of any acquired businesses or product lines due to changes in management and ownership; and ● inability to retain key employees of any acquired businesses. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks ~~,~~ and could have a material adverse effect on our business, financial condition and results of operations. Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations. The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation (the " GDPR "), which took effect across all member states of the European ~~Economic~~ **45Economic** Area (the " EEA ") in May 2018. The GDPR is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third- party processors. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are

considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and / or impose substantial fines for violations of the GDPR, which can be up to 4 % of global revenues or € 20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. ~~44Similar~~ -- **Similar** actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act (the " CCPA "), which went into effect on January 1, 2020, and ~~was amended by~~ the California Privacy Rights Act (the " CPRA "), effective January 1, 2023, secure new privacy rights for consumers and impose new obligations on us. Many other states have implemented or are considering similar legislation which will change the privacy law landscape in the United States. For example, Virginia, Colorado, Utah and Connecticut have all adopted privacy laws, which take effect in 2023. **Additionally, Delaware, Indiana, Iowa, Montana, Oregon, Tennessee and Texas also adopted privacy laws, which take effect from July 1, 2024 through 2026. Further, Washington' s My Health My Data Act, taking effect July 1, 2024, imposes similar requirements specific to consumer health data.** A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. **This is particularly true with respect to** ~~Given the breadth and depth of changes in~~ data ~~protection obligations~~ **security incidents** , ~~preparing for~~ and ~~complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third- party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of~~ sensitive ~~data, such as healthcare data or other~~ personal information ~~from our clinical trials~~ , **including health** ~~could require us to change our business practices~~ and **biometric data** ~~put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws~~ . Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and **business. Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third- party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and** our business. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. If we fail to comply with these laws, we could be subject to civil or criminal liabilities, other remedial measures and legal expenses, be precluded from developing, manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition. Our operations are subject to anti- corruption laws, including the U. S. Foreign Corrupt Practices Act (the " FCPA "), the U. K. Bribery Act 2010 (the " Bribery Act ") and other anti- corruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from ~~bribing~~ **46bribing** , being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act or local anti- corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which

existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. ~~45We~~ **We** are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, the United Kingdom and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations (collectively referred to as " Trade Control Laws "). In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti- corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act and other anti- corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Any investigation of any potential violations of the FCPA, the Bribery Act, other anti- corruption laws or Trade Control Laws by U. S., United Kingdom or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any. In some countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries, we, or our future collaborators, may be required to conduct a clinical trial or other studies that compare the cost- effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed. Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks. There is an increasing focus from certain investors, employees, regulators **,** and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our ~~policies~~ **47policies** relating to corporate responsibility are inadequate. Third- party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. ~~46We~~ **We** may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third- party rating services. A low ESG or sustainability rating by a third- party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time. In addition, the SEC has announced proposed rules that, among other matters, will establish a framework for reporting of climate- related risks. To the extent the proposed rules impose additional reporting obligations, we could face increased costs. Separately, the SEC has also announced that it is scrutinizing existing climate- change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient. Risks Related to Our Intellectual PropertyWe may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in- licenses. Because several of our programs require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain and exploit these proprietary rights. In addition, we may need to acquire or in- license additional intellectual property in the future. We may be unable to acquire or in- license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our product candidates. We face competition with regard to acquiring

and in- licensing third- party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash 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 intellectual property rights to us. We also may be unable to acquire or in- license third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment. We may enter into collaboration agreements with U. S. and foreign academic institutions to accelerate development of our current or future preclinical product candidates. Typically, these agreements include an option for the company to negotiate a license to the institution' s intellectual property rights resulting from the collaboration. Even with such an option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to license rights from a collaborating institution, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our desired program. If we are unable to successfully obtain required third- party intellectual property rights or maintain our existing intellectual property rights, including if our patent applications do not result in the issuance of patents, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected. ~~If~~ **48If** we fail to comply with our obligations in the agreements under which we in- license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business. Our license agreement with Ligand Pharmaceuticals Incorporated, Neurogen Corporation and CyDex Pharmaceuticals, Inc. (the " Ligand License Agreement "), our license agreement with the Regents of the University of California (the " UC Regents License Agreement "), our license agreement with Duke University (the " Duke License Agreement ") and our license agreement with iX Biopharma Ltd. (the " iX License Agreement ", together with the Ligand License Agreement, the UC Regents License Agreement, and the Duke License Agreement, the " License Agreements ") are important to our business and we expect to enter into additional license agreements in the future. The License Agreements impose, and we expect that future license agreements will impose, various milestone payments, royalties and other obligations on us. If we fail to comply with our obligations under these agreements, or if we file for bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses could materially and adversely affect our business, financial condition and results of operations. ~~47Pursuant~~ -- **Pursuant** to the terms of the Ligand License Agreement, the licensors each have the right to terminate the Ligand License Agreement with respect to the programs licensed by such licensor under certain circumstances, including, but not limited to: (i) if we do not pay an amount that is not disputed in good faith, (ii) if we willfully breach the Ligand License Agreement in a manner for which legal remedies would not be expected to make such licensor whole, or (iii) if we file or have filed against us a petition in bankruptcy or make an assignment for the benefit of creditors. In the event the Ligand License Agreement is terminated by a licensor, all licenses granted to us by such licensor will terminate immediately. Further, pursuant to the terms of the UC Regents License Agreement, the licensor has the right to terminate the UC Regents License Agreement or reduce our license to a nonexclusive license if we fail to achieve certain milestones within a specified timeframe. Similarly, pursuant to the terms of the Duke License Agreement and the iX License Agreement, each licensor has the right to terminate the Duke License Agreement or the iX License Agreement, as applicable, if we fail to achieve certain milestones within a specified timeframe. In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we in- license, then we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to: ● the scope of rights granted under the license 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 licensing agreement; ● the sublicensing of patent and other rights; ● our diligence obligations under the license agreement and what activities satisfy those diligence obligations; ● the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by us, our licensors and our collaborators; and ● the priority of invention of patented technology. If disputes over intellectual property and other rights that we have in- licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with any such obligations to our licensor, such licensor may terminate its licenses to us, in which case we would not be able to market products covered by these licenses. The loss of our licenses would have a material adverse effect on our business. ~~We~~ **49We** are required to make certain cash payments and may be required to pay milestones and royalties pursuant to certain commercial agreements, which could adversely affect the overall profitability for us of any products that we may seek to commercialize. Under the terms of the Ligand License Agreement, we may be obligated to pay the licensor under the Ligand License Agreement up to an aggregate of approximately $ 126. 7 million in development, regulatory and sales milestones. Similarly, under the terms of the iX License Agreement, we may be obligated to pay the licensor under the iX License Agreement up to an aggregate of approximately $ 239 million in development, regulatory and sales milestones. We will also be required to pay royalties on future worldwide net product sales. We will also be required to pay up to an aggregate of approximately $ 17 million in development and regulatory milestones and royalties on any net sales of SLS- 005 pursuant to our asset purchase agreement with Bioblast Pharma Ltd. These cash, milestone and royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize. ~~48We~~ **We** may not be able to protect our proprietary or licensed technology in the

marketplace. We depend on our ability to protect our proprietary or licensed technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any licensor' s or licensee' s ability to obtain and maintain patent protection in the U. S. and other countries with respect to our proprietary or licensed technology and products. We currently in- license some of our intellectual property rights to develop our product candidates and may in- license additional intellectual property rights in the future. We cannot be certain that patent enforcement activities by our current or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We also cannot be certain that our current or future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents. Even if we are not a party to these legal actions, an adverse outcome could prevent us from continuing to license intellectual property that we may need to operate our business, which would have a material adverse effect on our business, financial condition and results of operations. Although we believe we will be able to obtain, through prosecution of patent applications covering our owned technology and technology licensed from others, adequate patent protection for our proprietary drug technology, including those related to our in- licensed intellectual property, if we are compelled to spend significant time and money protecting or enforcing our licensed patents and future patents we may own, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business, financial condition and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or in- license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our products. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection for licensed patents, pending patent applications and potential future patent applications and patents could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or patent applications will be due to be paid to the U. S. Patent and Trademark Office (" USPTO ") and various governmental patent agencies outside of the U. S. in several stages over the lifetime of the applicable patent and / or patent application. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs with respect to our in- licensed patents or patent applications we may file in the future, our competitors might be able to use our technologies, which would have a material adverse effect on our business, financial condition and results of operations. ~~The~~ **50The** patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the U. S. and many jurisdictions outside of the U. S. is not consistent. For example, in many jurisdictions, the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the U. S. and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our current product candidates and potential products may prevent us from obtaining or enforcing patents relating to these product candidates and potential products, including without limitation composition- of- matter patents, which are generally believed to offer the strongest patent protection. Patents that we currently license and patents that we may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including, without limitation, the following: ● the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our product candidates; ~~49~~ ● there can be no assurance that the term of a patent can be extended under the provisions of patent term extensions afforded by U. S. law or similar provisions in foreign countries, where available; ● the issued patents and patents that we may obtain or license in the future may not prevent generic entry into the market for our product candidates; ● we, or third parties from whom we in- license or may license patents, may be required to disclaim part of the term of one or more patents; ● there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim; ● there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim; ● there may be other patents issued to others that will affect our freedom to operate; ● if the patents are challenged, a court could determine that they are invalid or unenforceable; ● there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents we may own that adversely affects the scope of our patent rights; ● a court could determine that a competitor' s technology or product does not infringe our licensed patents or any future patents we may own; and ● the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing. If we encounter delays in our development or clinical trials, the period of time during which we could market our potential products under patent protection would be reduced. Our competitors may be able to circumvent our licensed patents or future patents we may own by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our licensed patents or any

future patents we may own, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensed patents or any future patents we may own invalid or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we own or in- license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In this regard, third parties may challenge our licensed patents or any future patents we may own in the courts or patent offices in the U. S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. ~~We~~ **51We** may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing or increase the costs of commercializing our products. Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our product candidates or potential products infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our product candidates or potential products infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation- in- part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates. ~~50Third~~ -- **Third** parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U. S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. 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 have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third- party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we acquire or obtain a license under the applicable patents or until the patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, 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 product candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. Any claims or lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely affect our business, financial condition and results of operations. We may be required to initiate litigation to enforce or defend our licensed and owned intellectual property. Lawsuits to protect our intellectual property rights can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the biopharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities. In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. 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. 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 resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or ~~proceedings~~ **52proceedings** more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. In addition, our licensed patents and patent applications, and patents and patent applications that we may apply for, own or license in the future, could

face other challenges, such as interference proceedings, opposition proceedings, re- examination proceedings and other forms of post- grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our licensed patents and patent applications and patents and patent applications that we may apply for, own or license in the future subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel' s time and attention. ~~51Changes~~ **Changes** in U. S. patent law **or the patent law of other countries or jurisdictions** could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time- consuming **,** and inherently uncertain. For example, the U. S. previously enacted and is currently implementing wide- ranging patent reform legislation. Specifically, on September 16, 2011, the Leahy- Smith America Invents Act (the " Leahy- Smith Act ") was signed into law and included a number of significant changes to U. S. patent law, and many of the provisions became effective in March 2013. However, it may take the courts years to interpret the provisions of the Leahy- Smith Act, and the implementation of the statute could increase the uncertainties and costs surrounding the prosecution of our licensed and future patent applications and the enforcement or defense of our licensed and future patents, all of which could have a material adverse effect on our business, financial condition and results of operations. In addition, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. **Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary Effect (a " Unitary Patent "). Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court (" UPC "). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of the new unitary patent system.** We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the U. S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents ~~and~~ **53and** other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our licensed patents and future patents we may own, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U. S. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the U. S. and abroad. For example, China currently affords less protection to a company' s intellectual property than some other jurisdictions. As such, the lack of strong patent and other intellectual property protection in China may significantly increase our vulnerability regarding unauthorized disclosure or use of our intellectual property and undermine our competitive position. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. We may be unable to adequately prevent disclosure of trade secrets and other proprietary information. In order to protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position. ~~52If~~ **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. We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest, and it may be difficult and costly to register,

maintain and / or protect our rights to these trademarks and trade names in jurisdictions in and outside of the United States. At times, competitors 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. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We expect to employ individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. To date, none of our employees have been subject to such claims. We may be subject to claims challenging the inventorship of our licensed patents, any future patents we may own and other intellectual property. Although we are not currently experiencing any claims challenging the inventorship of our licensed patents or our licensed or owned intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our licensed patents or other licensed or owned intellectual property as an inventor or co- inventor. For example, we may have inventorship disputes arising from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership ~~of~~ **54of** , or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. If we do not obtain additional protection under the Hatch- Waxman Amendments and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected. Depending upon the timing, duration and specifics of FDA regulatory approval for our product candidates, one or more of our licensed U. S. patents or future U. S. patents that we may license or own may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one- half the time between the effective date of an investigational new drug application (" IND ") (falling after issuance of the patent), and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA. ~~53The~~ -- **The** application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected. Risks Related to Owning Our Common StockThe market price of our common stock has been and will likely continue to be volatile. The trading price of our common stock has been and is likely to continue to be volatile. For example, in ~~2022~~ **2023** our closing stock price ranged from $ ~~0~~ **1** . ~~51~~ **25** to $ ~~1~~ **49** . ~~71~~ **20** per share **(such prices reflect the Reverse Stock Split (as defined below))** . Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following: ● results from, and any delays in, planned clinical trials for our product candidates, or any other future product candidates, and the results of trials of competitors or those of other companies in our market sector; ● any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA' s review of that NDA; ● significant lawsuits, including patent or stockholder litigation; ● inability to obtain additional funding; ● failure to successfully develop and commercialize our product candidates; ● changes in laws or regulations applicable to our product candidates; ● inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices; ● unanticipated serious safety concerns related to any of our product candidates; ● adverse regulatory decisions; ● introduction of new products or technologies by our competitors; ● failure to meet or exceed drug development or financial projections we provide to the public; ● failure to meet or exceed the estimates and projections of the investment community; ● the perception of the biopharmaceutical industry by the public, legislatures, regulators and the investment community; ● announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; ● disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our licensed and owned technologies; ● additions or departures of key scientific or management personnel; **55** ● changes in the market valuations of similar companies; ● general economic and market conditions and overall fluctuations in the U. S. equity market, including any potential recession or economic downturn; ● public health crises, pandemics and epidemics, such as the COVID- 19 pandemic; ● sales of our common stock by us or our stockholders in the future; and ● the trading volume of

our common stock. In addition, the stock market in general, and small biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond our control may cause our stock price to decline rapidly and unexpectedly. ~~54If~~ **Moreover, in the past, stockholders have initiated class action and other lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock or periods of decreased stock price. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management' s attention and resources from our business. We are not currently party to any such litigation. However, on October 10, 2023, Empery Asset Management, LP (" Empery ") issued a press release disclosing that it transmitted a letter to our management and board of directors claiming that our Chief Executive Officer allegedly made material misrepresentations regarding the Phase II study of SLS- 002 (intranasal racemic ketamine) for ASIB in patients with MDD. We disagree with the statements and allegations in the press release and believe that we have good and substantial defenses to the claims alleged by Empery, but there is no guarantee that Empery will not bring a lawsuit against us or that we will prevail in any such litigation, if initiated. If** we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. We must continue to satisfy the Nasdaq Capital Market' s continued listing requirements, including, among other things, a minimum closing bid price requirement of $ 1. 00 per share for 30 consecutive business days. If a company fails for 30 consecutive business days to meet the $ 1. 00 minimum closing bid price requirement, The Nasdaq Stock Market LLC (~~"~~Nasdaq ") will send a deficiency notice to the company, advising that it has been afforded a " compliance period " of 180 calendar days to regain compliance with the applicable requirements. A delisting of our common stock from the Nasdaq Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors and employees. On ~~April 22~~ **November 1** , ~~2022~~ **2023** , we received written notice **(the " First Notice ")** from Nasdaq indicating that, for the last ~~thirty~~ **30** consecutive business days, the bid price for our common stock had closed below the minimum $ 1. 00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing **Rule 5550 (a) (2) (" Rule 5550 (a) (2) "). On January 12, 2024, we received a letter from Nasdaq notifying us that we regained full compliance with Nasdaq Listing Rule 5550 (a) (2) as of December 13, 2023, after the closing bid price of our common stock had been at $ 1. 00 per share or greater for 11 consecutive business days from November 28, 2023 through December 12, 2023. On November 1, 2023, we received an additional written notice from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $ 1. 00 per share requirement for continued listing on the Nasdaq Capital Market under** Rule 5550 (a) (2). In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we were provided an initial period of 180 calendar days, or until ~~October 19~~ **April 29** , ~~2022~~ **2024** , to regain compliance ~~.~~ On ~~September 1~~ **January 12** , ~~2022~~ **2024** , we received a letter from Nasdaq notifying us that we regained full compliance with ~~Nasdaq Listing~~ Rule 5550 (a) (2) **as of December 13, 2023,** after the closing bid price of our common stock had been at $ 1. 00 per share or greater for ~~ten~~ **11** consecutive business days ~~,~~ from ~~August 18~~ **November 28** , ~~2022~~ **2023** through ~~August 31~~ **December 12** , ~~2022~~ **2023** . ~~On~~ **In addition, on** November ~~21~~ **2** , ~~2022~~ **2023** , we received an additional written notice from Nasdaq indicating that, for the last thirty **- two** consecutive business days, the ~~bid price for~~ **market value of** our ~~common stock had closed~~ **listed securities has been** below the minimum **requirement of** $ **35 million** ~~1. 00 per share requirement~~ for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550 (~~a~~ **b**) (2 **) (" Rule 5550 (b) (2) "**). In accordance with Nasdaq Listing Rule 5810 (c) (3) (~~A~~ **C**), we ~~were~~ **have been** provided **a** ~~an initial~~ period of 180 calendar days, or until ~~May 22~~ **April 30** , ~~2023~~ **2024** , to regain ~~compliance~~ **56compliance** . The Nasdaq staff will provide written ~~confirmation~~ **notification** that we have achieved compliance with Rule 5550 (~~a~~ **b**) (2) if at any time before ~~May 22~~ **April 30** , ~~2023~~ **2024** , the ~~bid price~~ **market value** of our common stock closes at $ **35 million** ~~1. 00 per share~~ or more for a minimum of ten consecutive business days. We ~~intend~~ **will continue** to monitor the bid price **and market value** of our common stock and consider available options if our common stock does not trade at a level likely to result in our regaining compliance with **the minimum market value of listed securities rule by April 30, 2024.** ~~The~~ **There can be no assurances that we will be able to regain compliance with Nasdaq' s minimum market value of listed securities rule or that we will otherwise be in compliance with the other listing standards for the** Nasdaq Capital Market ~~' s minimum bid price rule by May 22, 2023, which may include, among other options, effectuating a reverse stock split. There is no guarantee that we will regain compliance by May 22, 2023~~ . If we do not regain compliance with Rule 5550 (~~a~~ **b**) (2) by ~~May 22~~ **April 30** , ~~2023~~ **2024** , we **will receive written notification that our securities are subject to delisting. In the event we receive any such notification, we** may **appeal the Nasdaq staff' s determination to delist our securities, but there can** be **no assurances that the Nasdaq staff** ~~afforded a second 180 calendar day period to regain compliance. To qualify, we~~ would **grant any request** ~~be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intent to cure the deficiency during the second compliance period, which may include, if necessary, implementing a reverse stock split. In addition, we have previously received similar notices from Nasdaq that our bid price of our common stock had closed below the minimum $ 1. 00 per share requirement~~ for continued listing ~~on the Nasdaq Capital Market under Nasdaq Listing Rule 5550 (a) (2)~~ . Even though we previously regained compliance with the Nasdaq Capital Market' s minimum ~~market value of listed securities requirement and minimum~~ closing bid price **requirement, and minimum market value of listed securities** requirement, there is no guarantee that we will remain in compliance with such listing requirements or other listing requirements in the future. Any failure to maintain compliance with continued listing

requirements of the Nasdaq Capital Market could result in delisting of our common stock from the Nasdaq Capital Market and negatively impact our company and holders of our common stock, including by reducing the willingness of investors to hold our common stock because of the resulting decreased price, liquidity and trading of our common stock, limited availability of price quotations and reduced news and analyst coverage. Delisting may adversely impact the perception of our financial condition, cause reputational harm with investors, our employees and parties conducting business with us and limit our access to debt and equity financing. ~~55We~~ **We** will incur significant costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010 (the " Dodd- Frank Act ") as well as rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act that require the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such insurance coverage. As a publicly traded company, we will incur legal, accounting **,** and other expenses associated with the SEC reporting requirements applicable to a company whose securities are registered under the Exchange Act, as well as corporate governance requirements, including those under the Sarbanes- Oxley Act, the Dodd- Frank Act and other rules implemented by the SEC and Nasdaq. The expenses incurred by public companies generally to meet SEC reporting, finance and accounting and corporate governance requirements have been increasing in recent years as a result of changes in rules and regulations and the adoption of new rules and regulations applicable to public companies. Sales of a substantial number of shares of our common stock in the public market by our existing stockholders, future issuances of our common stock or rights to purchase our common stock, could cause our stock price to fall. Sales of a substantial number of shares of our common stock by our existing stockholders in the public market, or the perception that these sales might occur, could depress the market price of our common stock **,** and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, ~~2022~~ **2023** , we have outstanding warrants to purchase an aggregate of approximately ~~2.~~5 **. 3** million shares of our common stock, which, if exercised, would further increase the number of shares of our common stock outstanding and the number of shares eligible for resale in the public market. As of December 31, ~~2022~~ **2023** , ~~18~~ **818** , **843** ~~873, 072~~ shares of our common stock were reserved for issuance under our equity incentive plans, of which ~~10~~ **511** , **429** ~~399, 170~~ shares of our common stock were subject to options outstanding at such date at a weighted- average exercise price of $ ~~2~~ **48** . ~~26~~ **13** per share, ~~5~~ **174** , **888** ~~418, 648~~ shares of our common stock were reserved for future issuance pursuant to our Amended and Restated 2012 Stock Long Term Incentive Plan, ~~646~~ **21** , ~~465~~ **756** shares of our common stock ~~were~~ **57were** reserved for future issuance pursuant to our 2019 Inducement Plan and ~~2~~ **110** , **770** ~~408, 789~~ shares of our common stock were reserved for issuance pursuant to our 2020 Employee Stock Purchase Plan. To the extent outstanding options are exercised, our existing stockholders may incur dilution. Furthermore, from time to time and before the maturity date of the Convertible Promissory Note, Lind currently has the option to convert any portion of the then- outstanding principal amount of the Convertible Promissory Note into shares of our common stock at a price per share of $ ~~6~~ **180** . 00, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions. We may also elect to make amortization and interest payments on the Convertible Promissory Note in the form of shares of our common stock, with the number of shares issuable calculated based on ninety percent (90 %) of the average of the five (5) lowest daily volume weighted average price of shares of our common stock during the twenty (20) trading days ending on the last trading day prior to such payment date. Any issuances of shares of our common stock pursuant to the Convertible Promissory Note will result in dilution to our then- existing stockholders and increase the number of shares eligible for resale in the public market ~~. Sales of substantial numbers of such shares in the public market could depress the market price of our common stock. The Financing Warrants contain price- based adjustment provisions which, if triggered, may cause substantial additional dilution to our stockholders. On October 16, 2018, we entered into a Securities Purchase Agreement with the investors listed on the Schedule of Buyers attached thereto, as amended, pursuant to which, among other things, we issued warrants to purchase shares of our common stock (the " Financing Warrants "). The outstanding Financing Warrants contain price- based adjustment provisions, pursuant to which the exercise price of the Financing Warrants may be adjusted downward in the event of certain dilutive issuances by us. 56If the Financing Warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to our then- existing stockholders and increase the number of shares eligible for resale in the public market. As of December 31, 2022, the Financing Warrants were exercisable for approximately 0. 3 million shares of our common stock at an exercise price of $ 0. 2957 per share of common stock~~ . Sales of substantial numbers of such shares in the public market could depress the market price of our common stock. Anti- takeover provisions in our governing documents and under Nevada law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management. Provisions in our articles of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors and the ability of the board of directors to issue preferred stock without stockholder approval. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of

the board of directors, which is responsible for appointing the members of management. Certain provisions of Nevada corporate law deter hostile takeovers. Specifically, Nevada Revised Statutes (" NRS ") 78. 411 through 78. 444 prohibit a publicly held Nevada corporation from engaging in a " combination " with an " interested stockholder " for a period of two years following the date the person first became an interested stockholder, unless (with certain exceptions) the " combination " or the transaction by which the person became an interested stockholder is approved in a prescribed manner. Generally, a " combination " includes a merger, asset or stock sale, or certain other transactions resulting in a financial benefit to the interested stockholder. Generally, an " interested stockholder " is a person who, together with affiliates and associates, beneficially owns or within two years prior to becoming an " interested stockholder " did own, 10 % or more of a corporation' s voting power. While these statutes permit a corporation to opt out of these protective provisions in its articles of incorporation, our articles of incorporation do not include any such opt- out provision. Nevada' s " acquisition of controlling interest " statutes, NRS 78. 378 through 78. 3793, contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. These " control share " laws provide generally that any person that acquires a " controlling interest " in certain Nevada corporations may be denied voting rights, unless a majority of the disinterested stockholders of the corporation elects to restore such voting rights. These statutes provide that a person acquires a " controlling interest " whenever a person acquires shares of a subject corporation that, but for the application of these provisions of the NRS, would enable that person to exercise (1) one- fifth or more, but less than one- third, (2) one- third or more, but less than a majority or (3) a majority or more, of all of the voting power of the corporation in the election of directors. Once an acquirer crosses one of these thresholds, shares that it acquired in the transaction taking it over the threshold and within the 90 days immediately preceding the date when the acquiring person acquired or offered to acquire a controlling interest become " control shares " to which the voting restrictions described above apply. While these statutes permit a corporation to opt out of these protective provisions in its articles of incorporation or bylaws, our articles of incorporation and bylaws do not include any such opt- out provision. Further, NRS 78. 139 also provides that directors may resist a change or potential change in control of the corporation if the board of directors determines that the change or potential change is opposed to or not in the best interest of the corporation upon consideration of any relevant facts, circumstances, contingencies **,** or constituencies pursuant to NRS 78. 138 (4). ~~57Our~~ **58Our** net operating loss carryforwards and certain other tax attributes may be subject to limitations. The net operating loss carryforwards and certain other tax attributes of us may also be subject to limitations as a result of certain prior ownership changes. In general, a corporation that undergoes an " ownership change " as defined in Section 382 of the United States Internal Revenue Code of 1986, as amended, is subject to limitations on its ability to utilize its pre- change net operating loss carryforwards to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders, generally stockholders beneficially owning five percent or more of a corporation' s common stock, applying certain look- through and aggregation rules, increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period, generally three years. We may have experienced ownership changes in the past and may experience ownership changes in the future. It is possible that our net operating loss carryforwards and certain other tax attributes may also be subject to limitation as a result of ownership changes in the past. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations. We are a " smaller reporting company " and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are a smaller reporting company, as defined in Rule 12b- 2 under the Exchange Act, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non- voting common stock held by non- affiliates is more than $ 250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than $ 100 million during the most recently completed fiscal year and our voting and non- voting common stock held by non- affiliates is more than $ 700 million measured on the last business day of our second fiscal quarter. Smaller reporting companies are permitted to rely on exemptions from certain disclosure requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting, reduced disclosure obligations regarding executive compensation and not being required to provide disclosures regarding quantitative and qualitative disclosures about market risk in our Annual Reports on Form 10- K. We have elected to take advantage of certain of these exemptions in the past and may continue to choose to take advantage of some, but not all, of them in the future. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, which may result in additional stock price volatility. We may never pay dividends on our common stock so any returns would be limited to the appreciation of our stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate we will declare or pay any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. General Risk FactorsAn active trading market for our common stock may not be sustained, and you may not be able to resell your common stock at a desired market price. If no active trading market for our common stock is sustained, you may be unable to sell your shares when you wish to sell them or at a price that you consider attractive or satisfactory. The lack of an active market may also adversely affect our ability to raise capital by selling securities in the future or impair our ability to acquire or in- license other product candidates, businesses or technologies using our shares as consideration. ~~58~~ **59Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes- Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act, could have a material adverse effect on our business and share price. Our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and**

possible remediation. In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies or material weaknesses that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes- Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and, when required, receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm. Failure to achieve and maintain an effective internal control environment could have a material adverse effect on our business, financial condition and results of operations and could limit our ability to report our financial results accurately and in a timely manner. If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline. The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline. The impact of the Russian invasion of Ukraine and the Israel- Hamas war on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations. The short and long- term implications of Russia' s invasion of Ukraine and the Israel- Hamas war are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine, the subsequent institution of sanctions against Russia by the United States and several European and Asian countries and the Israel- Hamas war may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, a prolonged conflict in Ukraine or Israel may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the wars in Ukraine or Israel may adversely affect our business as discussed herein, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our technology infrastructure, including through cyberattack, ransom attack, or cyber- intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition. Unstable market and economic conditions may have serious adverse consequences on our business and financial condition. Our business, financial condition and results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, service providers, manufacturers or other partners and there is a risk that one or more would not survive or be able to meet their commitments to us under such circumstances. As widely reported, global credit and financial markets have experienced volatility and disruptions in the past several years and especially in 2020, 2021 and 2022 due to the impacts of the COVID- 19 pandemic, and, more recently, the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Moreover, the global impacts of the Israel- Hamas war are still unknown. There can be no assurances that further deterioration in credit and financial markets and confidence in economic conditions will not occur. For example, U. S. debt ceiling and budget deficit concerns have increased the 60possibility of additional credit- rating downgrades and economic slowdowns, or a recession in the United States. Although U. S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, including a suspension of the federal debt ceiling in June 2023, ratings agencies have lowered or threatened to lower the long- term sovereign credit rating on the United States. The impact of this or any further downgrades to the U. S. government' s sovereign credit rating or its perceived creditworthiness could adversely affect the U. S. and global financial markets and economic conditions. Absent further quantitative easing by the Federal Reserve, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our results of operations or financial condition. Moreover, disagreement over the federal budget has caused the U. S. federal government to shut down for periods of time. 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 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 its financial condition and results of operations. Actual 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. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC stated all depositors of SVB would have access to all of their money after only one business day of closure, including

funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008- 2010 financial crisis. Although 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 institutions with which we have credit agreements or arrangements directly, or 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 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. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following: ● delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; ● loss of access to revolving existing credit facilities or other working capital sources and / or the ● inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources; ● potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements; ● potential or actual breach of financial covenants in our credit agreements or credit arrangements; ● potential or actual cross- defaults in other credit agreements, credit arrangements or operating or financing agreements; or ● termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. 61