Risk Factors Comparison 2025-03-27 to 2024-03-12 Form: 10-K

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You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Annual Report on Form 10- K. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business. Risks Related to Our Financial Position and Capital Needs We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability. We incurred a net loss of $ **34. 4 million and $** 32. 5 million ~~and $ 32. 9 million~~ , respectively, in **2024 and** 2023 ~~and 2022~~ . We expect to incur significant expenses and operating losses over the next several years. Our financial results may fluctuate significantly from quarter to quarter and year to year. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We anticipate that our expenses will increase substantially as we: • conduct and complete our ongoing and planned clinical trials; • seek to discover, research and develop additional product candidates; • seek regulatory approvals for any product candidates that successfully complete clinical trials; • establish additional partnerships for the development and commercialization of our assets; • maintain, expand and protect our intellectual property portfolio; and • hire additional clinical, manufacturing and scientific personnel. To become and remain profitable, we must succeed in developing drugs that can generate significant revenue once commercialized. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, manufacturing, obtaining regulatory approval and potentially entering into agreements for the commercialization of any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate sufficient revenue to achieve profitability. Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations. A decline in our value could also cause you to lose all or part of your investment. We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our drug development programs or commercialization efforts. We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the ~~third~~ **fourth** quarter of 2025. However, we will need to obtain substantial additional funding in connection with our continuing operations beyond the ~~third~~ **fourth** quarter of 2025, including additional funding to ~~complete clinical development~~ **initiate the Phase 3 trials** of CLS- AX. Our future capital requirements will depend on many factors, including: • the progress and results of our ongoing, planned and future clinical trial programs; • the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates; • the number and development requirements of other product candidates that we may pursue; • the costs, timing and outcome of regulatory review of our product candidates; • the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval and intend to commercialize ourselves; • the amount of revenue, if any, received pursuant to our license and collaboration agreements; • the amount of revenue, if any, received from commercial sales of any of our product candidates for which we receive marketing approval; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims; and • the extent to which we acquire or in- license other product candidates and technologies. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval of our product candidates and achieve product sales. In addition, XIPERE and our other product candidates, if approved, may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenue **to fund our operations** , we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license and development agreements. For example, in February 2024, we completed a registered direct offering of 11, 111, 111 shares of common stock and accompanying warrants to purchase 11, 111, 111 shares of common stock for gross proceeds of approximately $ 15. 0 million, before deducting placement agent fees and estimated offering expenses. We do not currently have any committed external

source of funds, although as described in this report we have also entered into an at- the- market sales facility that allows us to sell shares of our common stock at prevailing market prices and on specified terms, depending on market conditions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, 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. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to grant licenses on terms that may not be favorable to or relinquish valuable rights to our technologies, research programs, product candidates or future revenue streams. For example, we, through our wholly- owned subsidiary, sold our rights to receive certain royalty and milestone payments under the Arctic Vision License Agreement, Bausch License Agreement, the Aura License Agreement, the REGENXBIO Option and License Agreement and any out- license agreements for, or related to, XIPERE or our SCS Microinjector technology to be used in connection with compounds or products of any third parties in exchange for up to $ 65 million. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development efforts or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. **We do not currently have sufficient working capital to fund our planned operations for the next twelve months and substantial doubt exists as to our ability to continue as a going concern. Our historical financial statements have been prepared under the assumption that we will continue as a going concern. As of December 31, 2024, we had an accumulated deficit of $ 355. 3 million and had cash and cash equivalents of $ 20. 0 million. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued. Based on our current plans and forecasted expenses, we expect that our cash, cash equivalents and short- term investments as of the filing date, March 27, 2025, will enable us to fund our planned operating expenses and capital expenditure requirements into the fourth quarter of 2025. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than expected. Until we can generate sufficient revenue, if ever, to fund our operations, we will need to finance future cash needs through public or private equity offerings, license agreements, debt financings or restructurings, collaborations, strategic alliances and marketing or distribution arrangements. The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors and employees. Additional financing may not be available to us when needed or, if available, it may not be obtained on commercially reasonable terms. If we are not able to obtain the necessary additional financing on a timely or commercially reasonable basis, we will be forced to delay or scale down some or all of our development activities (or perhaps even cease the operation of our business). If we are unable to continue as a going concern, our stockholders may lose some or all of their investment in the Company.** Our agreements with HCR contain various covenants and other provisions, which, if violated, could materially adversely affect our financial condition. In August 2022, we, through Royalty Sub, entered into the Purchase and Sale Agreement ~~,~~ with HCR pursuant to which we sold our rights to royalty and milestone payments due to us from XIPERE and certain license agreements related to our SCS Microinjector, or the Royalties, subject to a cap of ~~2~~ **3** . ~~5~~ **4** times the total purchase price paid by HCR under the Purchase and Sale Agreement ~~, which cap can be increased to 3. 4 times under certain circumstances~~ . Under the terms of the Purchase and Sale Agreement, Royalty Sub received an initial payment of $ 32. 5 million, less certain expenses ~~. The terms of the Purchase and Sale Agreement also provide for an additional $ 20 million milestone payment to Royalty Sub upon attainment of a second pre- specified sales milestone related to 2024 XIPERE sales~~ . In connection with the Purchase and Sale Agreement, we entered into a Contribution and Servicing Agreement with Royalty Sub, pursuant to which we assigned the Arctic Vision License Agreement, Bausch License Agreement, Aura License Agreement, REGENXBIO Option and License Agreement, our license agreement with Emory University and The Georgia Tech Research Corporation and related intellectual property rights, or collectively the Contributed Assets, to Royalty Sub. The Contribution and Servicing Agreement contains various representations and warranties, covenants, indemnification obligations and other provisions related to the contribution of the Contributed Assets and our maintenance and servicing obligations with respect to the same. In connection with the Purchase and Sale Agreement, we also entered into a Pledge and Security Agreement with HCR. The Pledge and Security Agreement contains various representations, warranties and covenants, and includes a limited recourse guaranty of Royalty Sub' s obligations under the Purchase and Sale Agreement which is secured by the pledge in favor of HCR all of the capital stock of Royalty Sub. HCR is entitled to foreclose on the capital stock of Royalty Sub following the occurrence of certain remedies events, including, without limitation, a bankruptcy of us, our failure of to perform our obligations under the Contribution and Servicing Agreement or in the event of a change of control of us, any failure to make the payment required under Section 2. 3 of the Purchase and Sale Agreement within the time period required thereunder. Such foreclosure, if it were to occur, could have a material adverse effect on our financial condition as HCR, by virtue of owning Royalty Sub, would own the Royalties and the Contributed Assets. Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, such as the conflicts in Ukraine and the Middle East, or other macroeconomic conditions. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability. In 2023, the Federal Reserve raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military hostilities in Russia, Ukraine and the

Middle East have created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our or our partners' business. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly or more dilutive or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including clinical trials costs and labor and employee benefit costs ~~. Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non- performance, could adversely affect our operations and liquidity. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market- wide liquidity problems. Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity~~ . Risks Related to the Development of Our Product Candidates Our efforts are focused on the development of product candidates for treatment of eye disease through suprachoroidal injection and partnering with companies who can leverage our SCS Microinjector to deliver their ophthalmic product candidates to the SCS. Suprachoroidal injection is a novel approach and may fail to achieve and sustain market acceptance. Injecting drugs into the SCS is a novel approach for ophthalmic therapies, and there is no guarantee this approach will provide adequate patient benefit or be accepted by physicians, patients or third- party payors. We have also licensed our SCS Microinjector technology to third parties to deliver their proprietary drug candidates into the SCS for the potential treatment of certain ocular indications. Although the FDA approved XIPERE for suprachoroidal use for the treatment of macular edema associated with uveitis, we cannot guarantee that suprachoroidal injection of other drugs will prove in ongoing and future clinical trials to be a safe or effective approach for treating eye diseases in humans, nor can we ensure that such other drugs will achieve regulatory approval, even if the clinical trials are successful. In addition, the novelty of suprachoroidal injection may make it difficult to demonstrate to physicians and third- party payors that suprachoroidal injection of drugs is an appropriate approach for treating eye diseases and provides advantages compared to the current standards of care. Further, if we or our commercialization and collaboration partners are not successful in conveying to physicians, patients and third- party payors that the suprachoroidal administration of drugs with our proprietary SCS Microinjector provides useful patient outcomes, we or our commercialization and collaboration partners may experience reluctance, or refusal, on the part of physicians to order and use, and third- party payors to cover and provide adequate reimbursement for, such drugs. Additionally, in some cases, drugs delivered using our SCS Microinjector will complement the current standard of care, rather than serve as a replacement for the current standard of care. Therefore, we or our commercialization and collaboration partners may encounter significant difficulty in gaining broad market acceptance by physicians, third- party payors and potential patients. Our licensing partners may require that we modify our SCS Microinjector to deliver their product candidates, and we may be unable to do so. We are currently partnering with companies who can leverage our SCS Microinjector to deliver their ophthalmic product candidates to the SCS. Our current and future licensing partners may request modifications to the design of our SCS Microinjector to accommodate the delivery of their respective product candidates. If we are unable to make such modifications, we may not receive regulatory and development milestone payments that we otherwise would be eligible to receive after we have satisfied our obligations under the Purchase and Sale Agreement, which could significantly harm our financial position. If we are unable to obtain regulatory approval for, and commercialize either on our own or with a third party, CLS- AX or our other product candidates, or if we experience significant delays in doing so, our business may be harmed. Given our experience with our clinical programs, the successful development of any of our product candidates is extremely uncertain, and we cannot guarantee that we will be successful in developing any of our product candidates. Further, the FDA may conclude that our clinical trials are not sufficient to support approval of our product candidates. We have invested substantially all of our efforts and financial resources in the development of our proprietary SCS Microinjector for suprachoroidal injection of drugs and the identification of potential drug candidates using that technology. Our ability to generate revenue from our product candidates will depend heavily on their successful development and eventual commercialization, either by us or third parties. The success of those product candidates will depend on several factors, including the following: • successful completion of preclinical studies and requisite clinical trials; • performing preclinical studies and clinical trials in compliance with FDA requirements; • receipt of marketing approvals from applicable regulatory authorities; • ability to import sufficient quantity of product for trials or potential commercialization; • obtaining marketing approvals with labeling for sufficiently broad patient populations and indications, without unduly restrictive distribution limitations or safety warnings, such as black box warnings or a risk evaluation and mitigation strategy, or REMS, program; • obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates; • making arrangements with third- party manufacturers for, or establishing, commercial manufacturing capabilities; • launching commercial sales of products, if and when approved, whether alone or in collaboration with others; • successful training of physicians in the proper use of our SCS Microinjector; • the ability to market our products for use with our SCS Microinjector without a requirement from the FDA that we obtain a separate medical device authorization; • acceptance of the therapies and of the concept of suprachoroidal injection of drugs, if and when approved, by physicians, patients and third- party

payors; • competing effectively with other therapies; • obtaining and maintaining healthcare coverage and adequate reimbursement from third- party payors; • protecting our rights in our intellectual property portfolio; and • maintaining a continued acceptable safety profile of the drugs and our SCS Microinjector following approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. Data from our clinical trials that we announce or publish from time to time may change as more patient data become available, and such data are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish data from our clinical trials. Data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our prospects for obtaining regulatory approval of our product candidates. We may not be successful in our efforts to build a pipeline of product candidates. A key element of our strategy is to build a pipeline of product candidates for the treatment of a variety of diseases of the back of the eye via suprachoroidal injection and to progress these product candidates through developmental efforts. We may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have significant side effects or other characteristics that indicate that they are unlikely to receive marketing approval or achieve market acceptance. If we do not successfully develop product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect our stock price. Clinical drug development involves a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of our product candidates. The risk of failure for our product candidates is high. It is impossible to predict when or if CLS- AX or any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval for our product candidates, including: • regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • ~~we may experience~~ delays in reaching, or ~~fail~~ **failure** to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; • clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; • the cost of clinical trials of our product candidates may be greater than we anticipate; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and • our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials. For example, our ODYSSEY trial was delayed due to the issuance by FDA of draft guidance, requiring us to reassess our original protocol design and we subsequently decided to amend the protocol to have aflibercept as the comparator drug. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • be delayed in obtaining marketing approval for our product candidates; • not obtain marketing approval at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, such as black box warnings or a REMS program; • be subject to additional post- marketing testing requirements; or • have the product removed from the market after obtaining marketing approval. Our drug development costs may also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our or our potential collaborators' ability to successfully commercialize our product candidates. If we experience delays or difficulties in the enrollment of patients in 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 similar regulatory authorities outside the United States. We cannot predict how successful we will be at enrolling patients in future clinical trials. In addition, if we are not successful at enrolling patients in one clinical trial, it may affect when we are able to initiate our next clinical trial, which could result in significant delays in our efforts to pursue regulatory approval of and commercialize our product candidates. In addition, some of our competitors have ongoing clinical trials to treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors. Patient enrollment is affected by other factors including: • the severity of the disease under investigation; • the eligibility criteria for the study in question; • the perceived risks and benefits of the product candidate under study; • the availability of drugs approved to treat the diseases under study; • the efforts to facilitate timely enrollment in clinical trials; • the patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; and • the proximity and availability of clinical trial sites for prospective patients. Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which could cause our value to decline and limit our ability to obtain additional financing. If serious adverse or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates. If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many product candidates that initially showed promise in early- stage testing have later been found to cause side effects that prevented further development of the product candidate. In addition, in some cases, the FDA could issue a clinical hold to stop the study. 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 management resources, we focus on research programs and product candidates that we identify for specific indications. 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. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. 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. Risks Related to Our Dependence on Third Parties We have granted an exclusive license to Bausch for the commercialization and development of XIPERE in the United States and Canada. After we have satisfied our obligations under the Purchase and Sale Agreement, if we are unable to maintain our partnership with Bausch, or if Bausch fails to successfully commercialize XIPERE, our business and prospects will be materially harmed. We have granted an exclusive license to Bausch for the commercialization and development of XIPERE in the United States and Canada. Pursuant to our agreement with Bausch, we are entitled to receive payments based on the achievement of specified sales and regulatory milestones and tiered royalties based on annual net sales of XIPERE. We will not retain these royalties and milestone payments until our obligations under the Purchase and Sale Agreement described above in " Business — Royalty Purchase and Sale Agreement " are satisfied. The successful or timely achievement of many of these milestones is outside of our control because the relevant activities will be conducted by Bausch or third parties engaged by Bausch, including manufacturers and suppliers. We expect to depend to a large degree on the payments from Bausch after we have satisfied our obligations under the Purchase and Sale Agreement as well as payments from future potential commercialization partners in order to fund our operations, and a failure to receive such payments may cause us to: • delay, reduce or terminate certain research and development programs; • reduce headcount; • pursue the raising of additional funds through equity or convertible debt financings that could be dilutive to our stockholders; • seek funds by entering into agreements that require us to assign rights to technologies or products that we would have otherwise retained; • enter into new arrangements that may be less favorable than those we would have obtained under different circumstances; or • consider strategic transactions or engaging in a joint venture with a third party. We have entered into, and intend to continue to enter into, collaborations with third parties for the development and commercialization of XIPERE. In addition, we may seek commercialization partners for our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of XIPERE and our product candidates. We have entered into, and intend to continue to enter into, agreements with third- party collaborators for the development and commercialization of XIPERE and our product candidates. Our likely collaborators for any collaboration arrangements include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and smaller biotechnology companies. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaborations involving XIPERE and our product candidates would pose the following risks to us: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected; • collaborators may refuse to perform clinical trials or other obligations required for approval in a particular jurisdiction outside the United States; • our collaborators' regulatory submissions may be denied by the applicable regulatory authorities; • collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; •

collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized on terms that are more economically attractive than ours; • product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; • a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; • collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and • collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated. We rely on third parties to conduct our clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements. We have engaged contract research organizations, or CROs, for our ongoing and planned clinical trials. We also expect to engage CROs for any of our other product candidates that may progress to clinical development. We expect to rely on CROs, as well as other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our drug development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as Good Clinical Practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within specified timeframes. Failure to do so by us or third parties can result in FDA refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our or our potential collaborators' efforts to, successfully commercialize our product candidates. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent the commercialization of our current or future product candidates. We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure or regulatory noncompliance on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue. We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of our current product candidates and our SCS Microinjector. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug products and our SCS Microinjector, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not have any manufacturing facilities or personnel. We currently procure the active pharmaceutical ingredient of our product candidates on a purchase order basis from a third- party manufacturer, but we do not have a commercial supply agreement in place with that manufacturer. In addition, we have entered into a supply agreement with Gerresheimer, our SCS Microinjector supplier. Some of our current suppliers are based outside of the United States. In addition, some of the facilities of our third- party manufacturers have only undergone a limited number of FDA inspections or no inspections. We expect to continue to rely on third parties as we proceed with preclinical and clinical studies using our SCS Microinjector, as well as for commercial manufacture, for any of our product candidates that receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug products including our SCS Microinjector or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts. In addition, we may be unable to establish any agreements with third- party manufacturers or collaborators or to do so on acceptable terms. Reliance on third- party manufacturers or collaborators entails additional risks, including: • reliance on the third party for regulatory compliance and

quality assurance; • the possible breach of the manufacturing agreement by the third party; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; and • the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. Our product candidates, including our proprietary drug formulations packaged together with our SCS Microinjector, are subject to the drug regulations of the FDCA. Third- party manufacturers may not be able to comply with current Good Manufacturing Practices, or cGMP, regulations, regulations applicable to drug / device combination products, including applicable provisions of the FDA' s drug cGMP regulations, device cGMP requirements embodied in the Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, a refusal to file determination by the FDA, receipt of a CRL, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect our ability to achieve regulatory approval of our product candidates. Our product candidates that we may develop may compete with other drugs and devices for access to manufacturing facilities. There are a limited number of manufacturers that operate under the drug and device cGMP regulations applicable to our product candidates and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance or our SCS Microinjector. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our drugs and the components of our SCS Microinjector, we may incur added costs and delays in identifying and qualifying any such replacement. For example, the FDA could require supplemental data if a new supplier is relied upon for the supply of our products. Any interruption or delay in the supply of components and materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders. Our current and anticipated future dependence upon others for the manufacture of our product candidates may compromise our future profit margins and / or our commercialization partner' s ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis. If we are not able to establish additional collaborations, we may have to alter some of our future development and commercialization plans. Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the future development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. Risks Related to the Commercialization of Our Product Candidates If we are unable to establish sales and distribution capabilities for our product candidates for which we do not out- license commercialization rights, we may not be successful in commercializing those product candidates, if and when they are approved. We do not have a sales infrastructure. To achieve commercial success for any product candidate for which we may obtain marketing approval in the United States and have not licensed the commercialization rights to a third party, we will need to establish a sales organization. There are risks involved with establishing our own sales and distribution capabilities. For example, recruiting and training a sales force is expensive and time- consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our drugs on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our product candidates; • the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we are unable to establish our

own sales and distribution capabilities and, instead, enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to sell and distribute any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. XIPERE and any of our product candidates that receive marketing approval, may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. XIPERE and any of our product candidates that receive marketing approval may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. Suprachoroidal injection of drugs is a novel approach and physicians, patients or third- party payors may be hesitant to deviate from or change the current standard of care. If XIPERE or our product candidates do not achieve an adequate level of market acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of XIPERE and our product candidates, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and potential advantages compared to alternative treatments; • our ability to offer our drugs for sale at competitive prices; • the convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the willingness of the healthcare community and patients to adopt new technologies and our novel approach of SCS injection of drugs; • the willingness of uveitis and retina specialists to expend the time necessary to receive proper training on injecting drugs into the SCS using our SCS Microinjector; • the ability to manufacture our products in sufficient quantities and yields; • the strength of marketing and distribution support provided by us or our collaborators; • the availability of third- party payor coverage and adequate reimbursement; • the prevalence and severity of any side effects; and • any restrictions on the use of our drugs together with other medications. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We also are aware of companies that are developing suprachoroidal injectors which may compete with our SCS Microinjector. With respect to XIPERE, we face competition from other commercially available forms of TA and other injectable and implantable corticosteroids. Bristol- Myers Squibb markets TA under the brand name Kenalog, for which a number of generic equivalents are currently available. Kenalog is indicated only for intramuscular or intraarticular injection; however, it is commonly used off- label for intraocular inflammation using intravitreal and periocular administration. In addition, **Harrow' s (acquired by** Alcon **)** ~~' s~~ injectable TA, Triesence, is approved in the United States for the treatment of uveitis and other ocular inflammatory conditions unresponsive to topical corticosteroids, although it is not **specifically** indicated for the treatment of macular edema associated with uveitis. Ozurdex, marketed by Allergan, is a bioerodable extended release implant that delivers the corticosteroid dexamethasone and is approved for the treatment of non- infectious uveitis affecting the posterior segment of the eye and for macular edema due to RVO in both the United States and in the European Union. Ozurdex is also approved in the United States for the treatment of DME. Retisert and Yutiq, both intravitreal implants of fluocinolone acetonide, are marketed by Bausch and Alimera, respectively, and are approved in the United Sates for the treatment of chronic non- infectious uveitis affecting the posterior segment of the eye **. In addition, Oxular was developing OXU- 001 which is dexamethasone delivered via the Oxulumis suprachoroidal device for the treatment of DME. Oxular was acquired by Regeneron in December 2024. It is possible physicians may use OXU- 001 off label to treat macular edema associated with uveitis if further developed and ultimately approved** . CLS- AX faces competition with anti- VEGF drugs, the current standard of care for RVO and wet AMD, as well as other drug candidates in development for ocular use for the treatment of wet AMD, such as other ~~TKI~~ **TKIs** ~~' s~~. Axitinib, also known by its brand name Inlyta, is not currently approved for an ocular indication but is approved by the FDA and marketed by Pfizer for the treatment of advanced renal cell carcinoma. Genentech has several products which serve as competitors in this space, including anti- VEGF agents Lucentis, Avastin, and Susvimo. Lucentis is currently approved in the United States and European Union for the treatment of wet AMD, macular edema following RVO, and diabetic retinopathy in patients with DME. Avastin is an anti- VEGF drug routinely used off- label by uveitis and retina specialists in both the United States and in certain countries of the European Union for the treatment of numerous retinal diseases. Susvimo, an ocular implant that releases ranibizumab over time, received approval from the FDA in October 2021 for the treatment of wet AMD in patients who have previously responded to anti- VEGF therapy. Additionally, Genentech' s product, Vabysmo (faricimab- svoa), an intravitreal injection which blocks two disease pathways, including (Ang- 2) and vascular endothelial growth factor- A (VEGF- A), received approval in January 2022 for the treatment of wet AMD and **DME** ~~diabetic macular edema~~. In addition to Genentech' s products, Regeneron' s anti- VEGF product, Eylea 2 mg and 8 mg and Novartis' product, Beovu, also present potential competition for CLS- AX in both the United States and Europe. Eylea is approved for the treatment of wet AMD, macular edema following RVO and diabetic retinopathy and DME in the United States and for the treatment of wet AMD, RVO and DME in the European Union. Novartis' Beovu was approved in 2019 for the treatment of wet AMD in the United States and in 2020 in Europe. Ocular drug candidates being investigated for treatment of wet AMD may also represent potential competition for CLS- AX. Ocular Therapeutics and Eyepoint are companies currently investigating TKIs for ocular use in late- stage clinical trials. We expect other established companies will seek to develop new products in the ocular space with the goal of superior efficacy and duration over the current standard of care. REGENXBIO, Adverum, and 4D Molecular Therapeutics are currently conducting mid to late- stage clinical trials with various ocular gene therapies for the treatment of wet AMD. These gene- based

treatments could potentially compete with CLS- AX due to their potential to be long acting treatments. The SCS Microinjector faces competition from other devices being developed to access ocular posterior tissues via the SCS. ~~Oxular Limited and~~ Everads **Therapy and Uneedle** both have developed competing products and are in various stages of early- stage clinical development **.** Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in product approval delays if a competitor obtains market exclusivity from the FDA or our competitors establishing a strong market position before we or our collaborators are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors seeking to encourage the use of generic drugs. For some of the indications that we are pursuing, drugs used off- label, such as Kenalog and Avastin, serve as cheaper alternatives to our product candidates. Their lower prices could result in significant pricing pressure, even if our product candidates are otherwise viewed as a preferable therapy. Additional drugs may become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic drugs. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. XIPERE and our product candidates may be subject to unfavorable pricing regulations, third- party coverage and reimbursement policies or healthcare reform initiatives. Our and our collaborators' ability to commercialize XIPERE and any of our product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for XIPERE and our product candidates will be available from government payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, managed care plans and other third- party payors. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which medical products they will pay for and establish reimbursement levels. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs and products. Coverage and reimbursement may not be available and, even if these are available, the level of reimbursement may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining coverage and adequate reimbursement for our drugs may be difficult. We or our collaborators may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement compared to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we or our collaborators may not be able to successfully commercialize XIPERE and any other product candidates for which marketing approval is obtained. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and other third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. By way of example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for outpatient drug purchases by those covered by Medicare under a new Part D program and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician- administered drugs, including drugs currently on the market used by physicians to treat the clinical indications for which we are currently seeking FDA approval and likely XIPERE and our other product candidates, if approved. As a result of this legislation and the expansion of federal coverage of drug products, there is additional pressure to contain and reduce costs. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. These cost reduction initiatives and other provisions of the MMA could decrease the coverage and reimbursement that we receive for any approved products and could seriously harm our business. Further, from time to time, typically on an annual basis, payment amounts are updated and revised by third- party payors. Because we expect that customers who use XIPERE and our other product candidates, if approved, will be separately reimbursed for the procedure administering our products, these updates could directly impact the demand for our products. An example of payment updates is the Medicare program updates to physician payments, which is done on an annual basis using a prescribed statutory formula. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. However, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit- based Incentive Payment System, or MIPS. Under both APMs and MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our products or lowers reimbursement for procedures using our products could materially affect our business. There may be significant delays in obtaining coverage and reimbursement for

newly approved drugs, and coverage may be more limited than the indications for which the product is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. We believe that physicians who use XIPERE and our other product candidates, if approved, may be reimbursed by third- party payors for both the suprachoroidal injection using our SCS Microinjector and for the drug itself. On July 1, 2016, the American Medical Association, or AMA, approved a new Category III Current Procedural Terminology, or CPT, code for the suprachoroidal injection of pharmacologic agents. Category III codes are a set of temporary codes maintained by the AMA for emerging technology, services and procedures. Payment for these services or procedures are based on the coverage policies of individual payors, including private insurers and government- funded programs, like Medicare, and Medicare administrative contractors. CPT code 0465T became effective on January 1, 2017. In November 2023, AMA assigned XIPERE the Category 1 CPT code 67516. We believe the Category 1 code may facilitate better access and adoption of XIPERE and the suprachoroidal injection method. Additionally, there is no guarantee that these billing codes or the payment amounts, if any, associated with such codes will be sufficient to successfully commercialize any approved product and, even if adequate payment amounts are obtained, they could change in the future. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, no uniform policy requirement for coverage and reimbursement for drug products exists among third- party payors in the United States. Therefore, coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Additionally, coverage policies and reimbursement rates may change at any time. **Thus, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.** For example, beginning on January 1, 2023, certain manufacturers will be required to pay quarterly refunds to **the Centers for Medicare & Medicaid Services, or** CMS for discarded amounts of single- dose container and single- use package drugs covered under Medicare Part B. Refunds will be based on the discarded volume above 10 % of the total allowed amount, except in unique circumstances, as determined by CMS. Our or our collaborators' inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved drugs that we develop could significantly harm our operating results, our ability to raise capital and our overall financial condition. Further, any changes in coverage and reimbursement that further restricts coverage of our products or lowers reimbursement for procedures using our products could materially affect our business. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues able to be generated from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in XIPERE and one or more product candidates, even if our other product candidates obtain marketing approval. There can be no assurance that XIPERE and our other product candidates, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost- effective by third- party payors, that coverage or an adequate level of reimbursement will be available, or that third- party payors' reimbursement policies will not adversely affect our ability to sell XIPERE and our other product candidates profitably if they are approved for sale. Product liability lawsuits against us could cause us to incur substantial liabilities. We face an inherent risk of product liability exposure related to the sale of XIPERE as well as the testing of our product candidates in human clinical trials. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or products that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards paid to trial participants or patients; • loss of revenue; • reduced resources of our management to pursue our business strategy; and • our or our collaborators' inability to commercialize any drugs that we may develop. We currently hold $ 10. 0 million in product liability insurance coverage in the aggregate, with a per incident limit of $ 10. 0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we or our collaborators commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Risks Related to Employee Matters and Managing Our Growth Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers and senior management, as well as the other members of our scientific and clinical development teams. Our

executive officers may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or employees. Recruiting and retaining qualified scientific and clinical personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop and gain regulatory approval of our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. Risks Related to Our Intellectual Property If we are unable to obtain and maintain patent protection for our technology and product candidates, or if our licensors are unable to obtain and maintain patent protection for the technology or product candidates that we license from them, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired. Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We and our licensors seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technology and product candidates. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection or that we have published an invention prior to filing a relevant patent application. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. For example, we do not control the prosecution of the patent applications licensed to us under the Emory / GT License described below. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States or visa- versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and may also affect patent litigation. The ~~United States~~ **U. S.** Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could significantly harm our business and financial condition. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our owned and licensed patents and patent applications. Moreover, we may be subject to a third- party preissuance submission of prior art to the U. S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection and may not be of sufficient scope or strength to provide us with any commercial advantage. Our competitors may be able to design around our owned or licensed patents by developing similar or alternative technologies or drugs without infringing on our intellectual property rights. In addition, the issuance of a patent is not

conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States 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 drugs, or limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours, and our business will suffer. 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. The United States has enacted and implemented wide- ranging patent reform legislation. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the federal courts and the ~~USPTO~~ **U. S. Patent and Trademark Office** , the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment, or PTA, for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in future and whether patent expiration dates may be impacted. 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, a new unitary patent system **was** ~~will likely be~~ introduced **in** ~~by the end of~~ 2023, which ~~would~~ significantly ~~impact~~ **impacted** European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications ~~will soon~~ have the option, upon grant of a patent, of becoming a Unitary Patent which **is** ~~will be~~ subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, ~~there is~~ **its** ~~no precedent for the court~~ **body of case law remains limited** , 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 **are** ~~will 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 any potential changes. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which would undermine our competitive position. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm business. Our commercial success depends upon our ability, and the ability of any collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. In particular, we are focused on developing product candidates based on widely used therapeutic agents, many of which are protected by proprietary rights of third parties, and we are developing proprietary formulations of these therapeutic agents specifically for suprachoroidal injection using our proprietary SCS Microinjector. Although we seek to develop our proprietary drug formulations that don' t infringe the intellectual property rights of others, we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drugs or other aspects of our technology, including interference or derivation proceedings before the U. S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our technology and drugs. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Competing products may be sold in countries in which our patent coverage might not exist or be as strong. If we lose a patent lawsuit alleging our infringement of a competitor' s patent, or if FDA approval is stayed pending the outcome of patent litigation, we could be prevented from marketing our products. As a result, our ability to grow our business and compete in the market may be harmed. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public

announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could hurt the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings 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 compromise our ability to compete in the marketplace. If we fail to comply with our obligations under our existing intellectual property licenses with third parties, we could lose license rights that are important to our business. We are a party to a license agreement with Emory University and Georgia Tech Research Corporation, or the Emory / GT License, and may enter into additional license agreements in the future. Our existing license agreement imposes, and we expect that future license agreements would impose, various diligence, milestone payment, royalty, insurance and other obligations on us. For example, under the Emory / GT License, we are required to use commercially reasonable efforts to develop and commercialize licensed products under the agreement and to satisfy other specified obligations, including the payment of license fees and minimum royalty payments. If we fail to comply with our obligations under our license agreements, our licensors may have the right to terminate these license agreements, in which event we might not be able to market any product that is covered by these agreements, or to convert the license to a non- exclusive license, which could impair the value of the product candidate being developed under the license agreement. Termination of these license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. If our licensors under the Emory / GT License were to terminate their license agreement with us for any reason, we would lose access to critical technology related to our SCS Microinjector. We may need to license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us or our collaborators to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to cease development of one or more or our product candidates or accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed. We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non- competition or non- solicitation agreement. Litigation may be necessary to defend against these potential claims. In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our or our collaborators' ability to commercialize our product candidates. Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business. We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. Other than the trade name XIPERE, we have not yet selected trademarks for our product candidates or begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. In addition, third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. If our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. Some intellectual property that we have in- licensed may have been discovered through a government funded program and may be subject to certain federal regulations. Some of the intellectual property rights we have licensed, including such rights licensed from Emory University and Georgia Tech Research Corporation, may have been generated through the use of U. S. government funding and may therefore be subject to certain federal regulations. As a result, the U. S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh- Dole Act of 1980, or Bayh- Dole Act. These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government may have the right to require us to grant exclusive, partially exclusive or non- exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention, (ii) government action is necessary to meet public health or

safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). The U. S. government also could take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U. S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. manufacturers may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, our competitors may independently develop knowledge, methods and know- how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we and our collaborators will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired. Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export, and reporting of safety and other post- market information, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency, or EMA, and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent us, or any collaborator to whom we grant rights, from commercializing the product candidate. We expect to rely on third- party CROs to assist us in preparing some or all aspects of the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use, which could limit sales of the product. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired. If the FDA does not conclude that a product candidate satisfies the requirements for the Section 505 (b) (2) regulatory approval pathway, or if the requirements under Section 505 (b) (2) are not as we expect, the approval pathway for our product candidates in this pathway will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful. We believe that certain of our product candidates, including our proprietary drug formulations packaged together with our SCS Microinjector, will be regulated under the drug provisions of the FDCA, enabling us to submit NDAs for approval of our product candidates. The Drug Price Competition and Patent Term Restoration

Act of 1984, also known as the Hatch- Waxman Amendments, added Section 505 (b) (2) to the FDCA. Section 505 (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. If the FDA does not allow us to pursue the Section 505 (b) (2) regulatory pathway for a product candidate as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with our product candidates, would likely substantially increase. We may need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505 (b) (2) regulatory pathway could result in competitive products reaching the market before our product candidates, which could impact our competitive position and prospects. Even if we are allowed to pursue the Section 505 (b) (2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization, or that a competitor would not obtain approval first, including subsequent market exclusivity from the FDA, thereby delaying potential approval of our product. In addition, notwithstanding the approval of a number of products by the FDA under Section 505 (b) (2) over the last few years, some pharmaceutical companies and others have objected to the FDA' s interpretation of Section 505 (b) (2). If the FDA' s interpretation of Section 505 (b) (2) is successfully challenged, the FDA may be required to change its Section 505 (b) (2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2). Additional time may be required to obtain regulatory approval for our product candidates because of the complexity involved with co- packaging a drug- device combination product. Our product candidates require coordination within the FDA and similar foreign regulatory agencies for review of the drug along with the SCS Microinjector. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. In addition, to date, the FDA has not requested a separate medical device authorization submission for our SCS Microinjector. However, the FDA may request a separate medical device authorization submission for our SCS Microinjector in the future, which could delay the development and commercialization of our product candidates. Additionally, other jurisdictions may have additional requirements for any drug and device combination, which may cause delays in product approval. Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad. In order to market and sell our products in the European Union and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing or requirements. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals in order for us or our collaborators to commercialize our products in any market. A variety of risks associated with marketing our product candidates internationally could affect our business. We may seek regulatory approval for our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including: • differing regulatory requirements in foreign countries; • the potential for so- called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally; • unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; • differing payor reimbursement regimes, governmental payors or patient self- pay systems and price controls; • difficulties staffing and managing foreign operations; • workforce uncertainty in countries where labor unrest is more common than in the United States; • potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geo- political actions, including war and terrorism. These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and

national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Any product candidate for which we obtain marketing approval could be subject to post- marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved. Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could involve requirements for, among other things, a medication guide, special training for prescribers and dispensers, and patient registries. If any of our product candidates receives marketing approval, the accompanying label may limit its approved uses, which could limit sales of the product, or include a black box warning to highlight a specific health risk. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post- approval marketing and promotion of products to ensure products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Physicians, on the other hand, may prescribe products for off- label uses. Although the FDA and other regulatory agencies do not regulate a physician' s choice of drug treatment made in the physician' s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off- label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with the product' s FDA approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use and if we do not market our drugs for their approved indications, we may be subject to enforcement action for off- label marketing. Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, such as the federal civil False Claims Act, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our drugs, including device malfunctions, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have negative consequences, including: • restrictions on such drugs, manufacturers or manufacturing processes; • restrictions on the labeling or marketing of a drug; • restrictions on drug distribution or use; • requirements to conduct post- marketing studies or clinical trials; • warning letters; • recall or withdrawal of the drugs from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • clinical holds; • safety alerts; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of our drugs; • product seizure; or • injunctions or the imposition of civil or criminal penalties. Non-compliance with European Union requirements regarding safety monitoring, or pharmacovigilance, and with requirements related to the development of drugs for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union' s requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Even though we have received orphan drug designation in the European Union for the treatment of non- infectious uveitis, we may not be able to obtain orphan drug marketing exclusivity for this product candidate. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. We have received orphan drug designation from the EMA for the treatment of non- infectious uveitis, and we may seek orphan drug designation from the FDA or EMA for our future product candidates. However, we cannot pursue orphan drug designation from the FDA for the treatment of uveitis. Regulation (EC) No 141 / 2000 and Regulation (EC) No 847 / 2000 provide that a product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life- threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives the medicinal product is unlikely to be developed. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity in all EU Member States and in addition a range of other benefits during the development and regulatory review process including scientific assistance for study protocols, authorization through the centralized marketing authorization procedure covering all member countries and a reduction or elimination of registration and marketing authorization fees. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten- year period with the

consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. In addition, the period of market exclusivity may be reduced to six years if it can be demonstrated based on available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity. There is no guarantee that we will be able to obtain or maintain orphan exclusivity even if we receive marketing authorization in Europe. Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other misconduct or failure to comply with applicable regulatory requirements. Misconduct by employees and independent contractors, such as principal investigators, CROs, consultants, commercial partners and vendors, could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of substantial civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, imprisonment, diminished profits and future earnings, additional reporting requirements and / or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate. Our current and future relationships with healthcare professionals, principal investigators, consultants, customers and third- party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to penalties. Healthcare providers, including physicians, and third- party payors in the United States and elsewhere ~~will~~ play a primary role in the recommendation and prescription of **XIPERE and** any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal civil False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market and distribute **XIPERE and** any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws (including privacy and cybersecurity laws and regulations) that may affect our ability to operate include the following: • the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid; • federal civil and criminal false claims laws, including, without limitation, the federal civil False Claims Act which permits private individuals, on behalf of the government, to bring civil whistleblower or qui tam actions to enforce the law, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, including federal health care programs, such as, the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent; • the Health Insurance Portability and Accountability Act, or HIPAA, which created additional federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2019, or HITECH, and their respective implementing regulations, which impose obligations on “ covered entities, ” including

certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective " business associates " that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity and their subcontractors that use, disclose, access, or otherwise process individually identifiable health information, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • the Physician Payments Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, imposed annual reporting requirements for certain manufacturers of drugs, devices, biologics and medical supplies for certain payments and " transfers of value " provided to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; **and** • analogous state and foreign laws, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts ~~; • U. S. data privacy regulations, such as the CCPA, which creates new individual privacy rights for consumers and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt- out of certain sales of personal information, and allows for a new cause of action for data breaches; • new U. S. data privacy regulations, such as the California Privacy Rights Act of 2020, or CPRA, which establishes a new California Privacy Protection Agency to implement and enforce the CPRA. Other states, such as Virginia, Colorado, Utah, and Connecticut have also passed comprehensive privacy laws that have or will go into effect during 2023, and similar laws are being considered in several other states, as well as at the federal and local levels. While these new state laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors); • foreign data privacy regulations, such as the General Data Protection Regulation (2016 / 679), or GDPR, which applies to identified or identifiable personal data in electronic or paper form. Under the GDPR, fines of up to € 20. 0 million or up to 4 % of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non- compliance. The GDPR includes more stringent operational requirements for processors and controllers of personal data and creates additional rights for data subjects, including a private right of action. Also under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions. Other such foreign data privacy obligations include the EU GDPR as it forms part of United Kingdom, or UK, law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or UK GDPR; and • In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK' s standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups~~ . Further, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti- Kickback Statute and the healthcare fraud statute. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines,

imprisonment, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and / or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations, as well as reputational harm, which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to the same criminal, civil and administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, ~~President Obama~~ **the Affordable Care Act was** signed into law ~~the Affordable Care Act~~ , **which** ~~a sweeping law~~ intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. ~~The Affordable Care Act among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point- of- sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; imposed a non- deductible annual fee on pharmaceutical manufacturers or importers who sell certain " branded prescription drugs " to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.~~ There have been judicial and congressional challenges **and amendments** to certain aspects of the Affordable Care Act **For example** ~~. On June 17~~ , ~~2021 the U. S. Supreme Court dismissed a challenge~~ on ~~procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Further, prior to the U. S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. The Affordable Care Act may be subject to additional judicial or Congressional challenges in the future. On~~ August 16, 2022, ~~President Biden signed~~ the Inflation Reduction Act of 2022, or IRA, **was signed** into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a new manufacturer discount program. It is unclear how any additional healthcare reform measures of the ~~Biden~~ **second Trump** administration will impact the Affordable Care Act and our business. In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will stay in effect through 2032, unless additional Congressional action is taken. Additionally, on March 11, 2021, ~~President Biden signed~~ the American Rescue Plan Act of 2021 **was signed** into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024 ~~. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years~~ . These new laws may result in additional reductions in Medicare and other healthcare funding, which could negatively impact customers for our product candidates, if approved, and, accordingly, our financial operations. Further, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drug products. ~~At the federal level, in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the Department of Health and Human Services, or~~ **For example** ~~HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance~~

~~these principles. In addition~~ , the IRA, among other things, (i) directs **the U. S. Department of Health and Human Services, or** HHS **,** to negotiate the price of certain high- expenditure, single- source drugs ~~and~~ biologics **that have been on the market for at least 7 years** covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated " maximum fair price " for such drugs and biologics under the law **(the " Medicare Drug Price Negotiation Program ")** , and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions ~~take~~ **began to** effect ~~progressively~~ starting in fiscal year 2023. On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list~~ **agreed-upon price** of the first ten drugs that **were** ~~will be~~ subject to price negotiations, although the Medicare ~~drug~~ **Drug** ~~price~~ **Price** ~~negotiation~~ **Negotiation** ~~program~~ **Program** is currently subject to legal challenges. ~~It is unclear how the IRA~~ **On January 17, 2025, HHS selected fifteen additional drugs covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products** will **become subject** ~~be implemented but is likely~~ to ~~have a significant impact on the pharmaceutical industry. In response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three~~ -- **the Medicare Drug Price Negotiation Program** ~~new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future~~ . Further, on December 7, 2023, ~~the Biden administration announced~~ an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act **was announced** . On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that other healthcare reform measures that may be adopted in the future **, particularly in light of the recent U. S. Presidential and Congressional elections** , may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for drugs. We cannot be 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 testing and other requirements. Governments outside the United States tend to impose strict price controls, which may affect our revenue, if any. In some countries, particularly the countries 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. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. Risks Related to Ownership of Our Common Stock The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses. Our stock price has been and may continue to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated or disproportionate to the operating performance of particular companies. Broad market and industry factors, including potentially worsening economic conditions, inflation and other adverse effects or developments may negatively affect the market price of our common stock, regardless of our actual operating performance. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including: • actual or anticipated variations in our operating results; • changes in financial estimates by us or by any securities analysts who might cover our stock; • conditions or trends in our industry; • changes in the structure of healthcare payment systems; • stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry; • announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures; • announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us; • capital commitments; • investors' general perception of us and our business; • recruitment or departure of key personnel; • sales of our common stock, including sales by our directors and officers or specific stockholders; and • general political and economic conditions. In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management' s attention and resources from our business. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to initiate or to continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market

price of our common stock. Even if we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline. The issuance of additional stock and other equity- linked securities in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our stock incentive plans or otherwise. For example, we, among other things, issued warrants to purchase 11, 111, 111 shares of common stock to certain investors in a registered direct offering ~~. As~~ **, all of which were outstanding as** of March ~~5~~ **24** , ~~2024~~ **2025** ~~, we had outstanding warrants to purchase an aggregate of 11, 111, 111 shares of common stock~~ . The exercise of our outstanding warrants could result in significant dilution to existing stockholders, adversely affect the market price of our common shares and impair our ability to raise capital through the sale of additional equity securities **. In addition, the expectation of such exercises could encourage the short selling of our common stock, which could place further downward pressure on the trading price of our common stock** . Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline. If we fail to meet all applicable requirements of Nasdaq and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. On ~~September 27~~ **February 7** , ~~2023~~ **2025** , we received a letter from Nasdaq, notifying us that, **from December 18, 2024** ~~for the previous 30 consecutive business day periods prior~~ to **February 4, 2025** ~~the date of the letter~~ , the closing bid price for our common stock was below $ 1. 00. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A) we were provided an initial period of 180 calendar days, or until ~~March 25~~ **August 6** , ~~2024~~ **2025** , to regain compliance with Nasdaq' s bid price requirement. **If** ~~On December 12~~ , **at any time before August 6,** ~~2023~~ **2025** , ~~as a result of~~ **the bid price for** our common stock ~~trading over~~ **closes at** $ 1. 00 ~~for~~ **or more for a minimum of** 10 consecutive business days, we **will** ~~received a notice from the Nasdaq Listing Qualifications Office indicating that we regained~~ -- **regain** compliance with the ~~minimum~~ bid price requirement ~~under~~ **, unless** Nasdaq ~~Listing Rule 5450 (a) (1)~~ **staff exercises its discretion to extend this 10-day period pursuant to Nasdaq rules** . There can be no assurance that we will ~~maintain~~ **regain** compliance with the requirements for listing our common stock on Nasdaq. If we are unable to satisfy the Nasdaq criteria for continued listing, our common stock would be subject to delisting. A delisting of our common stock could negatively impact us by, among other things, reducing the liquidity and market price of our common stock; reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; decreasing the amount of news and analyst coverage of us; and limiting our ability to issue additional securities or obtain additional financing in the future. In addition, delisting from Nasdaq may negatively impact our reputation and, consequently, our business. If a significant number of our shares are sold into the market, it could cause the market price of our common stock to drop significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act in the case of our affiliates. In addition, we have filed registration statements on Form S- 8 registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. These registered shares will be available for sale in the public market subject to vesting arrangements and exercise of options and, in the case of our affiliates, the restrictions of Rule 144. Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result. There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10, 000, 000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders. Our charter documents also contain other provisions that could have an anti-takeover effect, including: • only one of our three classes of directors are elected each year; • stockholders are not entitled to remove directors other than by a 66 2 ⁄ 3 % vote and only for cause; • stockholders are not permitted to take actions by written consent; • stockholders cannot call a special meeting of stockholders; and • stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings. In addition, we are subject to the anti- takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive

forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. However, this exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act. The choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. We are a " smaller reporting company " and as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors. We are a " smaller reporting company, " meaning that the market value of our shares held by non- affiliates is less than $ 700 million and our annual revenue was less than $ 100 million during the most recently completed fiscal year. We will continue to be a smaller reporting company if either (i) the market value of our shares held by non- affiliates is less than $ 250 million or (ii) our annual revenue was less than $ 100 million during the most recently completed fiscal year and the market value of our shares held by non- affiliates is less than $ 700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10- K and we have reduced disclosure obligations regarding executive compensation. In addition, as a smaller reporting company and non- accelerated filer, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile. We have broad discretion in the use of our cash and cash equivalents and may invest or spend our cash in ways with which investors do not agree. We have broad discretion over the use of our cash and cash equivalents. Investors may not agree with our decisions, and our use of our cash may not yield any return on investment. Our failure to apply our resources effectively could compromise our ability to pursue our growth strategy. Investors will not have the opportunity to influence our decisions on how to use our cash and cash equivalents. Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be the sole source of gains and investors may never receive a return on their investment. Investors should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, our prior loan agreement prohibited us from paying dividends without the consent of the lenders under the agreement, and we expect that the terms of any future debt agreements would likewise preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be investors' sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock. General Risk Factors If our information technology systems or those third parties upon which we rely or our data ~~,~~ are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we rely, process, collect, receive, store, process, generate, use, transfer, disclose, and share proprietary, confidential, and sensitive data, including personal data (such as health- related data), intellectual property, and trade secrets. Our internal computer systems, and those of our CROs, contract manufacturing organizations and other third parties on whom we rely, are vulnerable to damage from computer viruses, unauthorized access, security breaches, natural disasters, terrorism, war and telecommunication and electrical failures. Cyberattacks, malicious internet- based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect and threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. These threats come from a variety of sources. In addition to traditional computer " hackers, " threat actors, personnel (such as through theft or misuse), sophisticated nation- states, and nation- state- supported actors now engage in attacks. We and the third parties upon which we rely **are** ~~may be~~ subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Remote work has ~~become more common and has~~ increased risks to our information technology systems and data, as ~~more of~~ our employees **may** utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in

acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. We rely on third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. Any of the foregoing could result in a material disruption of our clinical and product development activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. For example, the loss or compromise of clinical trial data from completed or ongoing clinical trials 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 incident was to result in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, or any personal data for which we are responsible, we could incur significant unexpected losses, expenses and liabilities, we could face litigation or suffer reputational harm and the further development of our product candidates could be delayed. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. **We and the third parties with whom we work are subject to stringent and evolving U. S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third- party data, and other sensitive data the Company may process, e. g., business plans, transactions, or financial information. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, the federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. Numerous U. S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $ 7, 500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U. S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties with whom we work, and our customers. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union' s General Data Protection Regulation, or EU GDPR, and the United Kingdom' s GDPR, or UK GDPR (collectively, " GDPR "), Australia' s Privacy Act, and China' s Personal Information Protection Law, or PIPL, impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR or, in each case, 4 % of annual global revenue, whichever**

is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. We also target customers in Asia and may be subject to new and emerging data privacy regimes in Asia, including China' s Personal Information Protection Law, Japan' s Act on the Protection of Personal Information, and Singapore' s Personal Data Protection Act. For example, China' s PIPL imposes a set of specific obligations on covered businesses in connection with their processing and transfer of personal data and imposes fines of up to RMB 50 million or 5 % of the prior year' s total annual revenue of the violator. India' s new privacy legislation, the Digital Personal Data Protection Act, or DPDP, may also apply to our operations. In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area, or EEA, and the United Kingdom have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and United Kingdom to the United States in compliance with law, such as the EEA standard contractual clauses, the United Kingdom' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the United Kingdom extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the United Kingdom or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We also publish privacy policies, marketing materials, whitepapers, and other statements concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. The 2017 comprehensive tax reform bill, as modified by the CARES Act, the Inflation Reduction Act, and possible future changes in tax laws or regulations could adversely affect our business and financial condition. ~~On December 22~~ **The Tax Act** , ~~2017, President Trump~~ signed into law ~~the Tax Act~~ **on December 22** , ~~which~~ **2017,** significantly revised the Internal Revenue Code of 1986, as amended, or the Code. In March 2020, the Tax Act was modified in certain respects by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. More recently, the Inflation Reduction Inflation of 2022, or the IRA, was enacted which includes provisions that impact the U. S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. Future guidance from the U. S. Internal Revenue Service and other tax authorities with respect to the Tax Act, as modified by the CARES Act, and the IRA, may affect us, and certain aspects of the Tax Act, CARES Act and IRA could be repealed or modified in future legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U. S. operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act, the CARES Act, the IRA, or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U. S. tax expense. The foregoing items, as well

as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the IRA, or any newly enacted federal tax legislation. Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts. We are subject to taxation in numerous U. S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places in which we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements. We plan to use potential future operating losses and our federal and state NOL carryforwards to offset future taxable income, if any. However, our ability to use existing NOL carryforwards could be limited as a result of issuances of equity securities. As of December 31, ~~2023~~ **2024**, we had ~~approximately~~ $ ~~225~~ **240** . ~~9~~ **6** million of federal and $ ~~89~~ **96** . ~~3~~ **1** million of state net operating loss, or NOL, carryforwards. If not utilized, the portion of these federal NOL carryforwards arising in tax years beginning before 2018 will begin to expire at various dates beginning in 2034, and these state NOL carryforwards will begin to expire at various dates beginning in 2027. Under the Tax Act, as modified by the CARES Act, federal NOLs incurred in taxable years beginning in 2018 and in later years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited for taxable years beginning after ~~2020~~ **2021** to 80 % of taxable income. Certain states have conformed to the federal NOL rules included in the Tax Act and CARES Act. However, under Section 382 of the Code of 1986, as interpreted by the U. S. Internal Revenue Service, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur ownership changes. The completion of our IPO, follow- on public offerings, private placements and other transactions that have occurred, and future offerings of our securities have triggered, and may in the future trigger additional, ownership changes ~~. We have determined that three such ownership changes have occurred in the past. We have determined that $ 38, 000 and $ 2, 000 of our deferred tax assets related to federal NOL and R & D credits, respectively, will expire due to Section 382~~ . In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo ownership changes in the future. Any such additional limitations may significantly reduce the value of our NOL carryforwards before they expire, which could result in greater tax liabilities than we would incur in the absence of such limitations. At the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes- Oxley Act and the rules and regulations of The Nasdaq Stock Market. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Because we are a smaller reporting company and a non- accelerated filer, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act. However, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in this report and future annual reports on Form 10- K, as required by Section 404 of the Sarbanes- Oxley Act. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by The Nasdaq Stock Market, the Securities and Exchange Commission or other regulatory authorities. We incur significant costs and demands upon management as a result of being a public company. As a public company listed in the United States, we incur significant legal, accounting and other costs, which we expect to increase if we cease to be a smaller reporting company under SEC rules. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management. Climate change, extreme weather

events, earthquakes and other natural disasters could adversely affect our business. In recent years, extreme weather events and changing weather patterns such as storms, flooding, droughts, fires and temperature changes have become more common. As a result, we are potentially exposed to varying natural disaster or extreme weather risks such as hurricanes, tornadoes, fires, droughts or floods, or other events that may result from the impact of climate change on the environment, such as sea level rise. The potential impacts of climate change may also include increased operating costs associated with additional regulatory requirements and investments in reducing energy, water use and greenhouse gas emissions. Adverse global economic conditions and geopolitical tensions could have a negative effect on our business, results of operations and financial condition and liquidity. In recent years, concerns about the global economic outlook have adversely affected market and business conditions in general. Macroeconomic weakness and uncertainty could make it more difficult for us or the licensing partners on whom we depend to commercialize XIPERE to manage our respective operations. Geopolitical tensions, such as Russia' s recent incursion into Ukraine, ongoing conflicts between the United States and China, tariff and trade policy changes, economic sanctions and increasing potential of conflict involving countries in Asia, including countries that are part of the Arctic Territory under our license agreement with Arctic Vision, create uncertainty for us and for global commerce generally. Sustained or worsening of global economic conditions and increasing geopolitical tensions may increase our cost of doing business, limit our ability to access capital, disrupt our supply chain operations or the supply chain operations of our licensing partners and intensify pricing pressures. Any or all of these factors could negatively affect our business, financial condition and result of operations.