Risk Factors Comparison 2025-02-25 to 2024-02-27 Form: 10-K

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

Risks Related to our Business and Operations We are an early commercial ~~-~~ stage biopharmaceutical company with a limited operating history and a single product approved for commercial sale. We have incurred significant losses and negative cash flows from operations since our inception and **could** ~~anticipate that we will~~ continue to incur significant expenses and losses for the foreseeable future. We have one product, XDEMVY **®, formerly known as TP- 03** , which ~~recently~~ obtained **Food Drug and Administration ("** FDA **")** approval for the treatment of Demodex blepharitis in the U. S. in July 2023. We have incurred net losses each year since our company' s formation in 2016. We have funded our operations primarily from the sale and issuance of redeemable convertible preferred stock, convertible promissory notes and the sale of our common stock in our IPO, subsequent Follow- On Public Offerings, and under our **Open Market Sale AgreementTM (the"** 2023 ATM Prospectus **")** , as well as proceeds from product sales, net, our China Out- License and draws from our Credit ~~Facility~~ **Facilities (as defined below)** . For the years ended December 31, **2024,** 2023 **,** and 2022, our net losses were $ **115. 6 million, $** 135. 9 million **,** and $ 62. 1 million, respectively. As of December 31, ~~2023~~ **2024** and December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ **360. 2 million and $** 244. 7 ~~million and $ 108. 8~~ million, respectively. Additionally, the net losses we incur may fluctuate significantly from quarter to quarter such that a period- to- period comparison of our results of operations may not be a good indicator of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. We ~~recently~~ initiated sales and marketing activities to commercialize XDEMVY in August 2023. We ~~expect to~~ **could potentially** incur operating losses over the next several years and for the foreseeable future until our revenue from product sales from XDEMVY and any other approved products exceeds expenses, which may never occur. We may never achieve profitability and, even if we do, we may not be able to sustain or increase our profitability. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our accumulated deficit and working capital. We expect to continue incurring significant expenses and increasing operating losses for the foreseeable future. We expect that our expenses will increase substantially ~~if and~~ as we: • continue to commercialize XDEMVY and any other products for which we may obtain marketing approval; • enhance our product development and planned future commercialization efforts of our product candidates, including through hiring additional clinical, regulatory, quality control and scientific personnel; • seek marketing approvals and reimbursement for our product candidates; • prepare for and initiate additional preclinical, clinical and other studies for our product candidates; • change or add additional manufacturers or suppliers, some of which may require additional permits or other governmental approvals; • create additional infrastructure to support our operations as a public company, including adding operational, financial and management information systems and personnel; • seek to identify, assess, acquire or develop additional product candidates; • acquire or in- license other product candidates and technologies; • make milestone or other payments in connection with the development or approval of our product candidates; • maintain, protect, enforce and expand our intellectual property portfolio; and • experience any delays or encounter issues with any of the above. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase beyond our expectations if, among other things: • there are any delays in establishing appropriate manufacturing arrangements for or completing the development of any of our product candidates; • we are required by regulatory authorities to perform clinical trials or studies in addition to, or different than, those that we currently expect; or • there are any third- party challenges to our intellectual property or we need to defend against any intellectual property- related claim. We expect to continue to expend substantial resources in connection with our commercialization efforts. If we are successful in commercializing more product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect to expand our development, regulatory, operational, sales, marketing, and distribution capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As we advance our research and development programs and commercialization efforts, we expect to experience continued growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, quality, regulatory affairs, manufacturing, quality control, sales, marketing, and distribution. To manage our anticipated future growth, we must: • identify, recruit, integrate, maintain and motivate additional qualified personnel; • manage our development efforts effectively, including the initiation and execution of clinical trials for our product candidates; and • improve our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time, to managing these growth activities. If we do not effectively manage the expansion of our operations, we could experience weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations also could lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third- party contract organizations, advisors and consultants to provide certain services, including assuming substantial

responsibilities for the conduct of our clinical trials and the manufacture of our product candidates. We cannot assure you that the services of such third- party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to successfully commercialize XDEMVY, obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all. Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel. We are highly dependent on the expertise of our executive officers, as well as the other members of our scientific and clinical teams and certain advisors to develop and soundly execute our business strategy. Although we have employment offer letters with each of our executive officers, each of them 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, clinical, and sales and marketing personnel, are critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization 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, gain regulatory approval for and commercialize our product candidates. Competition to hire qualified personnel in our industry 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. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. 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 research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and 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, and our business, prospects, financial condition and results of operations may be adversely affected. Many of our employees have become or will become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees. Our information technology systems, or those of our third- party **contract research organizations ("** CROs **")** or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of XDEMVY and our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business. We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality, availability and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third- party contractors who have access to our confidential information. Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third- party CROs, **contract manufacturing organizations ("** CMO **")** , and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, interruptions or cyber incidents resulting from the conflict between Russia and Ukraine **, conflict in the Middle East** , terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and / or other third parties, or from cyber- attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. Further, due to the political uncertainty involving Russia and Ukraine **and conflict in the Middle East** , there is an increased likelihood that escalation of tensions could result in cyber attacks that could either directly or indirectly impact our operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the commercial operations of XDEMVY and further development of our product candidates could be delayed. While we have not experienced any such system failure, accident or security breach to date, we cannot assure you that our data protection efforts

and our investment in information technology and cybersecurity will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. Our inability to use or access our information systems at critical points in time could adversely affect the timely and efficient operation of our business. Any delayed sales, significant costs or lost customers resulting from these technology failures could adversely affect our business, operations, and financial results. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption to our commercial operations of XDEMVY and further development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our information technology systems or security breaches could result in the loss, misappropriation, and / or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and / or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, including private lawsuits or class actions under the California Consumer Privacy Act **" CCPA")** , which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. We maintain specific coverage to mitigate losses associated with certain cybersecurity incidents that impact our or our third parties' systems, networks, and technologies. Product liability lawsuits against us could cause us to incur substantial liabilities, could divert our resources and could limit or delay our commercialization of XDEMVY or any product candidates that we may develop. We face an inherent risk of product liability exposure related to the commercialization of XDEMVY and the testing of our product candidates in human clinical trials and will continue to face risk if we commercially sell any future products we may develop. The sale of XDEMVY and any approved products in the future as well as the use of product candidates by us in clinical trials may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that XDEMVY or our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in: • the inability or delay of our efforts to commercialize XDEMVY or any products that we may develop; • decreased demand for XDEMVY or any product candidates or products that we may develop; • withdrawal of regulatory approval, recall, restriction on the approval or a black box warning or contraindication for XDEMVY or any future product candidates, if approved; • delay, variation or termination of clinical trials; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial subjects or challenges with clinical trial enrollment; • initiation of investigations by regulators; • significant costs to defend the related litigation and diversion of management' s time and our resources; • substantial monetary awards to study subjects or patients; • product recalls, withdrawals or new labeling requirements, marketing or promotional restrictions; ~~and~~ **or** • loss of revenue. Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as our product candidates advance through clinical trials. Insurance coverage is increasingly expensive, thus 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. If a successful product or clinical trial liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Our employees, independent contractors, including our CROs and CMOs, commercial partners, consultants, suppliers, service providers, and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations. We are exposed to the risk that our employees, independent contractors, including our CROs and CMOs, commercial partners, consultants, suppliers, service providers, and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar foreign regulatory authorities, including those laws that require the reporting of true, complete, and accurate information to such foreign regulatory authorities; manufacturing standards; U. S. federal and state healthcare fraud and abuse, data privacy laws and other similar non- U. S. laws; or laws that require the true, complete, and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our nonclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U. S. healthcare programs, imprisonment, other sanctions, contractual damages, reputational harm, future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of

operations. Health epidemics may affect our ability to initiate and complete preclinical studies and clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations. In addition, health epidemics could cause substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business and operations. Our business, operations and clinical development timelines could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of CROs upon whom we rely. Moreover, our clinical development timelines and plans could be affected by health epidemics as we and the third- party manufacturers and clinical research organizations that we engage may face disruptions. Site initiation and patient enrollment could be delayed or suspended due to prioritization of hospital resources toward the health epidemics or patients not having a desire to enroll in clinical trials due to concerns. In addition, some patients may not be able to comply with clinical trial protocols and the ability to conduct follow up visits with treated patients may be limited if patients do not want to participate in follow up visits due to concerns regarding health epidemics or if quarantines impede patient movement or interrupt healthcare services. There may be shortages in the raw materials used in the manufacturing of our product candidates or laboratory supplies for our preclinical studies and clinical trials, in each case, because of ongoing efforts to address the outbreak. We cannot assure that the inability to collect such clinical data would not have an adverse impact on our clinical trial results. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to health epidemics could be adversely impacted. We may experience disruptions that could severely impact our business, preclinical studies, and clinical trials, including: • delays in receiving approval from local regulatory authorities to initiate our planned clinical trials, including receiving any required **investigational new drug (" IND ")** ; • delays or difficulties in enrolling and retaining patients in our clinical trials; • delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; • manufacturing **and supply chain** disruptions; • delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials; • delays in the transport of clinical trial materials; • changes in local regulations as part of a response to a health epidemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; • diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; • difficulties recruiting or retaining patients for our planned clinical trials if patients are affected by the virus or are fearful of visiting or traveling to clinical trial sites because of the outbreak; • interruption of or changes in key clinical trial activities, such as clinical trial site monitoring, implementation of virtual monitoring, use of local testing labs, or home delivery of study drugs, due to limitations on travel imposed or recommended by federal or state governments, employers and others, use of new digital technologies for subject visits or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data; • risk that participants enrolled in our clinical trials will acquire a particular disease related to a health epidemic while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; • delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; • limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; • interruption or delays in the operations of the FDA which may impact review and approval timelines; • delays in regulatory approvals for our product candidates due to the FDA focusing on clinical trials related to therapies and vaccines targeting health epidemics; • refusal of the FDA to accept data, including from clinical trials in affected geographies or failure to comply with updated FDA guidance and expectations related to the conduct of clinical trials during a health epidemic; and • interruption or delays to our sourced discovery and clinical activities. The response to a health epidemic may redirect resources with respect to regulatory matters in a way that would adversely impact our ability to pursue marketing approvals. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in- person interactions. Furthermore, third parties, including manufacturers, medical institutions, clinical investigators, CROs and consultants with whom we conduct business, are similarly adjusting their operations and assessing their capacity in light of a health epidemic. If these third parties continue to experience shutdowns or business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. The extent to which the health epidemic impacts our business, clinical trials, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration of the pandemic, its severity, the actions to contain the virus or address its impact, and how quickly and to what extent government orders and mandates are lifted and normal economic and operating activities can resume. Further, while the potential economic impact of any health epidemic may be difficult to assess or predict, it could result in significant disruptions of global financial markets, which could reduce our ability to access capital, which could in the future negatively affect our liquidity. To the extent a health epidemic adversely affects our business, clinical trials, results of operations and financial condition, it may also have the effect of heightening many of the other risks described in this " Risk Factors " section. The ultimate impact of a health epidemic is highly uncertain and subject to change. We or the third parties upon whom we depend on may be adversely affected by earthquakes, fires or other natural disasters, or geopolitical events and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Any unplanned event, such as earthquakes, fires, flood, explosion, extreme weather, health epidemics, pandemics, power outages, telecommunication failures, war or other military conflict, terrorist activities or other natural or manmade accidents or incidents could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-

party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Unfavorable global and geopolitical economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global and geopolitical economy and in the global financial markets. Financial pressures may cause government or other third- party payers to more aggressively seek cost containment measures in healthcare and other settings. As a result of global economic conditions, some third- party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships (including inflation) may also affect patients' ability to afford healthcare as a result of increased co- pay or deductible obligations, greater cost sensitivity to existing co- pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, net, business and results of operations. The current inflationary environment related to increased aggregate demand, supply chain constraints and the effects from the armed conflict in Ukraine (including the effects of the sanctions that were implemented in response to the conflict and the resulting impacts on the commodity market and supply chains) **,** and ~~Israel~~ **the current conflict in the Middle East,** have also increased our operating expenses and may continue to affect our operating expenses. Our operational costs, including the cost of energy, materials, labor, distribution and our other operational and facilities costs are subject to market conditions and are being adversely affected by inflationary pressures. Global and geopolitical economic conditions may also adversely affect the ability of our distributors, customers and suppliers to obtain the liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on our product sales, business and results of operations. A significant worsening of global and geopolitical economic conditions could precipitate or materially amplify the other risks described herein. We maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities ~~on~~ **in** our accompanying Balance Sheets. The value of our investments may be adversely affected by interest rate fluctuations, inflation, downgrades in credit ratings, illiquidity in the capital markets, health epidemics and other factors that may result in other- than- temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments. Risks Related to Development and Commercialization We ~~have only recently~~ obtained regulatory approval for XDEMVY in the U. S. **in July 2023** and commenced the commercial launch of XDEMVY **in August 2023** . We have limited experience as a commercial company and generating revenue from product sales. If the commercial launch of XDEMVY is unsuccessful or any future approved products are unsuccessful, we may never be profitable. We ~~recently~~ received approval by the FDA for XDEMVY for the treatment of Demodex blepharitis in the U. S. and began generating revenue from product sales during the third quarter of 2023. Our ability to become and remain profitable is heavily dependent on our ability to **continue to** generate revenue from XDEMVY. The success of our commercialization will depend on a number of factors, including, among others, the continued development of our commercial organization, including our internal sales and marketing team and distribution capabilities, our ability to navigate the significant expenses and risks involved with the development and management of such capabilities, satisfying any post- marketing regulatory requirements, our ability to secure **and maintain** adequate healthcare coverage and the acceptance of XDEMVY by patients, **eye care providers (" "** ECPs **")** and third- party payers. Further, our commercial success is dependent on our ability to educate ECPs, patients and others in the medical community about Demodex blepharitis. If XDEMVY, or any other future approved product, does not achieve an adequate level of acceptance, coverage, pricing or reimbursement, we may not generate significant revenue from product sales and we may not be profitable. Even if we successfully commercialize XDEMVY in the U. S., we may be unable to achieve or maintain profitability, unless XDEMVY is approved in other jurisdictions or for additional indications. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues from product sales of XDEMVY, or any future approved products, or if or when we might achieve profitability. If we are unsuccessful in accomplishing our objectives, or if our commercialization efforts do not develop as planned, we may not be able to successfully commercialize XDEMVY or any future approved products, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. We are heavily dependent on the successful commercialization of XDEMVY and the development, regulatory approval, and commercialization of our current and future product candidates. We currently have one product approved for commercial sale, XDEMVY ~~(lotilaner ophthalmic solution) 0. 25 %~~ , which was approved by the FDA in July 2023 for the treatment of Demodex blepharitis in the U. S. The success of our business, including our ability to generate revenue from product sales in the future, will primarily depend on the **continued** successful commercialization of XDEMVY and the successful development, regulatory approvals and commercialization of our product candidates in one or more jurisdictions. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any future collaborator' s ability, to achieve a number of challenging objectives, including: • timely receipt of regulatory approvals from applicable regulatory authorities for our product candidates for which we successfully complete clinical development; • successful and timely completion of preclinical and clinical development of our product candidates; • successfully educating ECPs about Demodex blepharitis and related diagnosis; • successful commercial launch following any regulatory approval, including leveraging our commercial infrastructure in- house or with one or more collaborators; • commercial acceptance of

XDEMVY and any of our other product candidates by patients, the medical community and third- party payers **, including our planned direct- to- consumer television advertising campaign** ; • establishing and maintaining relationships with ~~contract research organizations (" CROs ")~~ and clinical sites for the clinical development, both in the U. S. and internationally, of our product candidates; • making any required post- marketing approval commitments to applicable regulatory authorities; • establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved; • obtaining an IND prior to commencing clinical trials in the U. S. for drug for a particular indication, such as TP- 04 for the potential treatment of **Ocular** ~~rosacea~~ **Rosacea** and TP- 05 for potential Lyme disease prophylaxis and community malaria reduction; • a continued acceptable safety and efficacy profile both prior to and following any marketing approval of our product candidates; • identifying, assessing and developing new product candidates; • obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the U. S. and internationally; • protecting our rights in our intellectual property portfolio; • defending against third- party interference or infringement claims, if any; • obtaining favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our existing or acquired product candidates; • obtaining coverage and adequate reimbursement for customers and patients from government and third- party payers for XDEMVY and other potential product candidates that we develop; • addressing any competing therapies and technological and market developments; and • attracting, hiring and retaining qualified personnel. We may never be successful in achieving our objectives and, even if we do, may never generate significant revenue that is large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, retain key employees and continue our operations. We may not be successful in educating ECPs and the market about the need for treatments specifically for Demodex blepharitis and other diseases or conditions targeted by XDEMVY or our product candidates. XDEMVY or other product candidates that we may develop may fail to achieve market acceptance by ECPs, other healthcare providers and patients, or adequate formulary coverage, pricing or reimbursement by third- party payers and others in the medical community, and the market opportunity for these products may be smaller than we estimate. XDEMVY, or any current or future product candidate that receives marketing approval, may fail to gain sufficient market acceptance by ECPs or other healthcare providers, patients, third- party payers and others in the medical community. Before the approval of XDEMVY, there was no **FDA-** approved prescription therapeutic for Demodex blepharitis and the only other current treatments include over- the- counter and off- label remedies such as tea tree oil, lid wipes and artificial tears, as well as off- label prescription products. Efforts to educate the medical community, patients and third- party payers on the benefits of XDEMVY and our other product candidates **has required and** may **continue to** require significant resources and **we** may not be successful. Although XDEMVY is approved for the treatment of Demodex blepharitis, ECPs and potential patients may not have sufficient information about, or recognize the need for a treatment specifically targeting Demodex blepharitis. It is possible that ECPs may continue to rely on other treatments for treating symptoms consistent with Demodex blepharitis. A key tenet of our continued commercialization strategy is to educate ECPs on Demodex blepharitis and how to diagnose it with a simple slit lamp examination as well as raise patient awareness of Demodex blepharitis. However, our efforts may prove to be unsuccessful, and we may not be able to develop this new market for XDEMVY. We may still not achieve success in promotional efforts for XDEMVY, and ECPs may continue to use existing treatments rather than XDEMVY or any other product candidate and potential patients may not inquire as to XDEMVY. It is also possible that ECPs and patients may not be willing to adopt XDEMVY for the treatment of Demodex blepharitis because of the possibility that the disease will recur despite mite eradication ~~and the potential~~ **, or after adoption fail to continue to use XDEMVY** for ~~periodic use~~ **the treatment** of ~~XDEMVY~~ **Demodex blepharitis** . In addition, if generic versions of any products that compete with XDEMVY or any of our product candidates are approved for marketing by the FDA or comparable foreign regulatory authorities, they could be offered at a substantially lower price than we expect to offer for XDEMVY or our other product candidates, if approved. As a result, ECPs, patients and third- party payers may choose to rely on such products rather than XDEMVY or our product candidates, if approved. If XDEMVY or any other product candidate that we develop does not achieve an adequate level of acceptance, formulary coverage, pricing or reimbursement we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of XDEMVY or any other product candidate that we develop, if approved for commercial sale, will depend on a number of factors, including: • the efficacy, safety and potential advantages of XDEMVY, or our product candidates, if approved, compared to alternative treatments, including the existing standard- of- care, and the perceptions by members of the healthcare community of the same; • our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments; • the clinical indications for which the product is approved; • the convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of ECPs to prescribe these therapies; • the strength and effectiveness of our marketing and distribution support, which may be adversely impacted by health epidemics; • publicity concerning our products or competing products and treatments; • the timing of market introduction of competitive products; • the perception by patients or physicians that the diseases we are targeting, including Demodex blepharitis, are not burdensome; • the potential for our competitors to limit our access to the market through anti- competitive contracts or other arrangements; • the availability of third- party formulary coverage and adequate reimbursement; • product labeling or product insert requirements of the FDA or other regulatory authorities; • the prevalence and severity of any side effects; and • any restrictions on the use of our products, if

approved, together with other medications. The sales, marketing, and distribution of XDEMVY or any future approved products may be unsuccessful or less successful than anticipated. If we are unable to establish sales and marketing capabilities **for any of our future approved products** or enter into agreements with third parties to sell and market XDEMVY or any future approved products on acceptable terms, we may be unable to successfully commercialize XDEMVY or any future approved products. We ~~recently~~ began commercializing our first product, XDEMVY, in the ~~United States~~ **U. S. in July 2023** . The success of our commercialization efforts for XDEMVY and any future approved products is subject to the effective execution of our business plan, including, among others, the continued development of our internal sales, marketing and distribution capabilities. For example, we have established an internal infrastructure as well as an ECP- focused sales and distribution infrastructure to market XDEMVY and our product candidates in the U. S., and have completed hiring in areas to support commercialization, including sales management, sales representatives, marketing, access and reimbursement, sales support and distribution. There are significant risks involved with establishing our own sales, marketing, and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development of these capabilities could or negatively affect the success of our commercialization efforts and business. For example, the commercialization of XDEMVY may not develop as planned or anticipated, which may require us to, among other items, adjust or amend our business plan and **strategies and** incur significant expenses. Further, given our **limited** ~~lack of~~ experience commercializing products, we do not have a track record of successfully executing on the commercialization of an approved product. If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if the commercialization of XDEMVY or any future approved products does not develop as planned, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry. ~~Further~~ **Additionally** , if we choose to collaborate, either globally or on a territory- by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses. Further, in order to continue to commercialize XDEMVY or commercialize any product candidates, if approved, we must continue to build marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell and market our product candidates. We may not be successful in accomplishing these required tasks. The sizes of the market opportunities for our product or product candidates, particularly XDEMVY for the treatment of Demodex blepharitis ~~and TP- 03 for the treatment of MGD~~ , ~~have not been established with precision and~~ may be smaller than we estimate, possibly materially. If **we** ~~our estimates of the sizes~~ overestimate **the size of** these markets, our sales growth may be adversely affected. We may also not be able to grow the markets for our product candidates as intended or at all. Our assessment of the potential market opportunity for XDEMVY and other product candidates that we develop is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and our own internal epidemiology and market research studies. Industry publications and third- party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third- party research, surveys and studies are reliable, we have not independently verified such data. Similarly, although the studies we have conducted are based on information that we believe to be complete and reliable, we cannot guarantee that such information is accurate or complete. The potential market opportunities for the treatment of Demodex blepharitis ~~and for the treatment of MGD~~ is difficult to precisely estimate, because patients often have multiple ocular surface diseases and the symptoms have significant overlap, leading to frequent misdiagnosis of the various conditions. Therefore, our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third- party research and our own epidemiology studies and market research, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions and the bases of the studies and research we have conducted are reasonable, no independent source has verified such assumptions or bases. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for XDEMVY or any of our other product candidates may be smaller than we expect, and as a result our revenue from product sales may be limited and it may be more difficult for us to achieve or maintain profitability. ~~Due to the patients presenting at ECP clinics with multiple ocular surface diseases, there is overlap in market size estimates for blepharitis and MGD. Therefore, if XDEMVY receives regulatory approval for the treatment of both Demodex blepharitis and MGD, our opportunity could be less than our forecasts because the actual market for XDEMVY might be significantly smaller than our estimates. Even though we obtained regulatory approval with respect to XDEMVY for Demodex blepharitis, we may not be able to obtain regulatory approval for additional indications, such as MGD, or we may be required to conduct additional trials, which would limit our ability to realize the full market potential of XDEMVY or increase the costs of developing TP- 03 for MGD.~~ We ~~are exploring the therapeutic potential for TP- 03 in MGD as an additional indication. If we are successful, the indication for use of TP- 03 could potentially be broadened beyond the treatment of Demodex blepharitis to include MGD as an additional indication. However, there can be no assurance that we will obtain approval for any other indication, including MGD or for any broadened indication beyond the treatment of Demodex blepharitis. If we fail to maintain required approvals for these additional or broadened indications, or if regulatory approvals are~~

~~delayed, we will not realize the full market potential of TP- 03. Additionally, the FDA or other comparable foreign regulatory authority~~ may ~~require us to conduct additional clinical trials before seeking regulatory approval. We~~ face significant **potential** competition **in the future** , and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted. XDEMVY and our product candidates, if approved, will also compete with existing branded, generic and off- label products. The development and commercialization of new drug products is highly competitive. We face **potential** competition with respect to XDEMVY and our product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide and existing treatments. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. 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 our products. Our competitors ~~also~~ may obtain FDA approval or other regulatory authority approval for their products more rapidly than we may obtain approval for ~~ours~~ **our product candidates** , which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third- party payers, particularly Medicare and ~~the~~ **other** ~~competent~~ **comparable foreign regulatory** authorities ~~of the individual EU Member States~~ , seeking to encourage the use of generic products. Generic products are currently being used for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. 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 products 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 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. Additionally, while XDEMVY is approved for the treatment of blepharitis or Demodex blepharitis specifically, a number of other treatments are currently available for blepharitis in the U. S. Current treatments for blepharitis in the U. S. include over the counter remedies such as tea tree oil, lid wipes and artificial tears, as well as off- label prescription products. If ECPs were to continue to prescribe these other existing treatments instead of XDEMVY, our business would be adversely affected. Although we obtained FDA approval of XDEMVY, and even if we obtain FDA approval of any of our product candidates, we may never obtain approval or authorization for such product candidates, including XDEMVY, in any other jurisdiction or commercialize such product candidates in the U. S. or in any other jurisdiction, which would limit our ability to realize their full market potential. In order to market any products, including XDEMVY, outside of the U. S., we will need to comply with additional onerous ~~but~~ **and** varying regulatory requirements of other countries regarding safety and efficacy on a country- by- country basis. Approval by the FDA in the ~~United States~~ **U. S.** does not ensure approval by comparable regulatory authorities in other countries or jurisdictions nor does it ensure that we will be able to successfully commercialize XDEMVY or any other approved products in the U. S. or in other jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Further, successful commercialization in the ~~United States~~ **U. S.** does not guarantee successful commercialization in other jurisdictions. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we, or our collaboration partners, fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our ability to realize the full market potential of our products will be harmed. Our future product candidates may cause significant adverse events, toxicities or other undesirable side effects which may delay or prevent marketing approval or cause us to abandon or limit further clinical development or commercialization of those product candidates. In addition, significant adverse events, toxicities or other undesirable side effects may be identified during post- marketing surveillance for XDEMVY, or future approved products, which could result in regulatory action or negatively affect our ability to market the product. Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the European Commission or other comparable foreign regulatory authorities. During the conduct of clinical trials, subjects report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went

undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large- scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Our understanding of the relationship between our product candidates and these adverse events may change as we gather more information, and additional unexpected adverse events or an increase in adverse event rates may occur. If additional clinical experience indicates that any of our product candidates have side effects or causes serious or life-threatening side effects, participant recruitment for trials and the ability of enrolled subjects to complete trials could be negatively impacted, and the development of the product candidate may fail or be delayed, which would severely harm our business, prospects, operating results and financial condition. Additionally, if we or others later identify undesirable side effects or adverse events caused by XDEMVY or one of our product candidates that receives marketing approval, a number of potentially significant negative consequences could result, including, but not limited to: • regulatory authorities may withdraw approvals of such product or require additional warnings on the label such as a black box warning, a contraindication or other limitations on the product' s approved use, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product; • the product may be seized by regulatory authorities; • there may be a recall of the product; • we may be required to change the way the product is administered or conduct additional clinical trials or post- approval studies; • we may be required to create and implement a **Risk Evaluation Mitigation Strategy (" ** REMS **")** plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, including ECPs, and / or other elements to assure safe use; • the product may become less competitive; • we could be sued and held liable for harm caused to patients; and • our reputation may suffer and there may be resulting harm to physician or patient acceptance of our product. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects. As we participate in the Medicaid Drug Rebate Program and other governmental pricing programs, failure to comply with obligations under these programs could result in additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Under the Medicaid Drug Rebate ~~program~~ **Program** , a participating manufacturer is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by the state Medicaid program as a condition of having federal funds being made available for drugs under Medicaid and Medicare Part B **(" Medicare Part B")** . Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis to **to the Centers for Medicare and Medicaid Services (" ** CMS **")** . These data include the average manufacturer price and, in the case of innovator products, the best price for each drug, which, in general, represents the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the U. S. in any pricing structure, calculated to include all sales and associated rebates, discounts, and other price concessions. If we fail to pay the required rebate amount or report pricing data on a timely basis, we may be subject to civil monetary penalties and / or termination from the Medicaid Drug Rebate ~~program~~ **Program** . Additionally, civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit the required price data on a timely basis, or if we misclassify or misreport product information. CMS could also decide to terminate our Medicaid ~~drug~~ **Drug** ~~rebate~~ **Rebate** ~~agreement~~ **Program** , in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. The ACA (addressed further above in the section on " Business – Government Regulatory – Coverage and Reimbursement ") made significant changes to the Medicaid Drug Rebate Program, and CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate Program under the ACA. CMS also issued a final regulation that modified prior Medicaid Drug Rebate Program regulations to permit reporting multiple best price figures with regard to value based purchasing arrangements; and provide definitions for " line extension, " " new formulation, " and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula. While the regulatory provisions that purported to affect the applicability of the best price and average manufacturer price exclusions of manufacturer- sponsored patient benefit programs, in the context of **pharmacy benefit managers (" ** PBM **")** " accumulator " **and" maximizer"** programs were invalidated by a court, such programs may continue to negatively affect us in other ways. Our failure to comply with these price reporting and rebate payment options, as well as **PBM** ~~pharmaceutical benefit manager~~ " accumulator " **and" maximizer"** programs, could negatively impact our financial results. Federal law requires that a manufacturer also participate in the 340B Drug Pricing program **" (340B program")** in order for federal funds to be available for the manufacturer' s drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B " ceiling price " **(" 340B ceiling price)** for the manufacturer' s covered outpatient drugs to a specified " covered entities, " including community health centers and other entities that receive certain federal grants, as well as hospitals that serve a disproportionate share of low- income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. If we are found to have knowingly and intentionally charged 340B **program** covered entities more than the statutorily mandated ceiling price, we could be subject to significant civil monetary penalties and / or such failure also could be grounds for ~~HRSA~~ **Health Resources and Services** to terminate our agreement to participate in the 340B program, in which case our covered outpatient drugs would no longer be eligible for federal payment under the Medicaid or Medicare Part B program. Further, the IRA ~~establishes~~ **established** a Medicare Part D **Prescription Drug Program (" Medicare Part D")** inflation rebate scheme **,** (**with** the first rebate period ~~is~~ **taking place** in **the** fourth quarter **of** 2022 through **the** third quarter **of** 2023 ~~)~~ **,** and a drug price negotiation program, with the first negotiated prices to take effect in 2026. It also makes several changes to the Medicare Part D benefit, including the creation of a new manufacturer discount program in place of the current coverage gap discount program (beginning in 2025). Manufacturers may

be subject to civil monetary penalties for certain violations of the negotiation and inflation rebate provisions and an excise tax during a noncompliance period under the negotiation program. Drug manufacturers may also be subject to civil monetary penalties with respect to their compliance with the new **Medicare** Part D manufacturer drug discount program. Pricing and rebate calculations are complex, vary across products and programs, and are often subject to interpretation by the manufacturer, governmental agencies, and courts. A manufacturer that becomes aware that its Medicaid reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, is obligated to resubmit corrected data up to three years after those data originally were due. Restatements and recalculations increase the costs for complying with the laws and policies governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. They also may affect the 340B ceiling price and therefore liability under the 340B program. **We accrue rebates for contractually agreed- upon discounts with commercial insurance companies and mandated discounts under government programs such as the Medicaid Drug Rebate Program, Medicare Part D, and other government health care programs in the U. S. Our estimates for expected utilization of commercial insurance rebates are based on data received from its customers. The Company' s estimates for rebates under government programs are based on statutory discount rates and expected utilization as well as historical data it has accumulated since product launch. Our rebate calculations may require estimates, including estimates of customer mix, to determine which product sales will be subject to rebates and the amount of such rebates. We updates our estimates and assumptions on a quarterly basis and records any necessary adjustments to revenue in the period identified. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter' s activity, plus an accrual balance for known prior quarters' unpaid rebates. If actual rebates vary from estimates, due to government invoicing delays or otherwise, we may need to adjust accruals, potentially adversely, which would affect product sales, net in the period of adjustment. An accrued liability is recorded for unpaid rebates related to product for which control has transferred to the customer.** Finally, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare programs and purchased by the Department of Veterans Affairs (" VA "), Department of Defense (" DoD "), Public Health Service, and Coast Guard (**collectively,** the " Big Four agencies ") and certain federal grantees, a manufacturer is required to participate in the VA Federal Supply Schedule (" FSS ") pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its covered drugs available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price (" FCP "), which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the " non- federal average manufacturer price " (" Non FAMP "), which the manufacturer calculates and reports to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non FAMP filing can subject a manufacturer to significant penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements. If we overcharge the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, we will be required to refund the difference to the government. Failure to make necessary disclosures and / or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and any response to government investigation or enforcement action, would be expensive and time- consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Under Section 703 of the National Defense Authorization Act for ~~FY~~ **Fiscal Year** 2008, the manufacturer is required to pay quarterly rebates to DoD on utilization of its innovator products that are dispensed through DoD' s Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non FAMP and FCP for the calendar year that the product was dispensed. A manufacturer that overcharges the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, is required to refund the difference to the government. Failure to make necessary disclosures and / or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations **.** We may expend our limited resources on the commercialization of XDEMVY for the treatment of Demodex blepharitis and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our product candidates on the potential treatment of certain indications. We are currently focused on the commercialization, of XDEMVY for the treatment of Demodex blepharitis. 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 the most viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for **XDEMVY** ~~TP- 03~~ and other product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for XDEMVY ~~, TP- 03~~ for other indications and other product candidates, we may also 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. The terms of approvals and ongoing regulation of XDEMVY and any other current product candidates or product candidates we develop could require substantial expenditure of resources and may limit how we manufacture and market our products, which could materially impair our ability to generate revenue from product sales. XDEMVY, and any other product candidate for which we obtain regulatory 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, the **European Medical Agency ("** EMA **")** and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, **current good manufacturing practice ("** cGMP **")** requirements relating to quality control, quality assurance and corresponding maintenance

of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory 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, or contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the product. Accordingly, we and our contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control for XDEMVY and any other approved products. If we are not able to comply with post- approval regulatory requirements, we could have the regulatory approvals for our products, including XDEMVY, withdrawn by regulatory authorities and our ability to market XDEMVY or any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post- approval regulations may have a negative effect on our business, operating results, financial condition, and prospects. If XDEMVY or any of our product candidates that are approved for marketing are found to have been improperly promoted for off- label uses by us, or if ECPs misuse our products or use our products off- label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed. The FDA and other foreign regulatory authorities strictly regulate the marketing of and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other foreign regulatory authorities as reflected in the product' s approved labeling. Any regulatory approval that the FDA or a foreign regulatory authority grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective. For example, the FDA- approved label for XDEMVY is limited to the treatment of Demodex blepharitis, and we are not permitted to promote XDEMVY for any other uses, unless and until such uses are approved. In addition, although we believe XDEMVY and our product candidates may exhibit a lower risk of side effects or more favorable tolerability profile or better symptomatic improvement than other products for the indications we are studying, without head- to- head data, we will be unable to make comparative claims for XDEMVY or our product candidates, if approved. If we receive regulatory approval for any of our products and are found to have promoted XDEMVY or any of our products or product candidates, if approved, for off- label uses, we may become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off- label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, our management' s attention could be diverted from our business operations, significant legal expenses could be incurred, and our brand and reputation could be damaged. The FDA has also previously requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off- label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action if they determine our business activities constitute promotion of an off- label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations. We cannot, however, prevent an ECP from using XDEMVY or our product candidates in ways that fall outside the scope of the approved indications, as he or she may deem appropriate in his or her medical judgment. ECPs may also misuse XDEMVY or our product candidates, if approved, or use improper techniques, which may lead to adverse results, side effects or injury and, potentially, subsequent product liability claims. Furthermore, the use of XDEMVY or our product candidates, if approved, for indications other than those approved by the FDA and / or other regulatory authorities may not effectively treat such conditions, which could harm our brand and reputation among ECPs and patients. Clinical drug development is a lengthy, expensive and risky process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If clinical trials of our product candidates do not meet safety or efficacy endpoints or are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. The research and development of drugs is an extremely risky industry. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Failure or delay can occur at any time during the clinical trial process. To date, we have focused substantially all of our efforts and financial resources on identifying, acquiring, and developing our product candidates, including conducting preclinical studies and clinical trials. Clinical testing is expensive and can take many years to complete, and we cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials. Our inability to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates. We currently generate revenue from product sales for one product, and we may never be able to develop or commercialize additional marketable products. The results of preclinical and early clinical trials of our product candidates and other products with the same mechanism of action may not be predictive of the results of later- stage clinical trials. For example, we may not be able to replicate the safety and efficacy results of our Phase 2b / 3 clinical trials for Demodex blepharitis in clinical trials for other indications in the future. Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and other challenges with enrolling and maintaining trial subjects, relatively smaller sample size in earlier trials, and failure to

demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. Furthermore, as more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. For example, our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. The failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates or cause regulatory authorities to require additional testing before approving any of our product candidates. If we are unable to complete preclinical or clinical trials of current or future product candidates, due to safety concerns, or if the results of these trials are not satisfactory to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization. Even if we are able to obtain marketing approvals for any of our product candidates, those approvals may be for indications that are not as broad as desired or may contain other limitations that would adversely affect our ability to generate revenue from sales of those products. Moreover, if we are not able to differentiate our product against other approved products within the same class of drugs, or if any of the other circumstances described above occur, our business would be materially harmed and our ability to generate revenue from that class of drugs would be severely impaired. Each of our product candidates will require additional clinical development, management of clinical, preclinical (for some of our product candidates) and / or manufacturing activities, regulatory approval in multiple jurisdictions, achieving and maintaining commercial- scale supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We may experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Any recommendations by the FDA regarding our applications or clinical trials could cause delay of any regulatory approval by the FDA and cause our expenses to increase. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, or any other product candidates that we may develop, including: • we may experience delays in or failure to reach agreement on acceptable terms with prospective CROs, vendors and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, vendors and trial sites; • we may fail to obtain sufficient enrollment in our clinical trials, our enrollment needs may grow larger than we anticipate, or participants may fail to complete our clinical trials at a higher rate than we anticipate; • clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • we may decide, or regulators or **Institutional Review Boards ("** IRBs **")** or ethics committees may require us, to 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; • regulators or IRBs or ethics committees may not authorize us or our investigators to commence a clinical trial at a prospective clinical trial site or at all or may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post- marketing testing requirements to maintain regulatory approval; • regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; • the cost of clinical trials of our product candidates may be greater than we anticipate, and we may need to delay or suspend one or more trials until we complete additional financing transactions or otherwise receive adequate funding; • 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 or may be delayed; • our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate trials; • regulatory authorities may determine that the planned design of our clinical trials is flawed or inadequate; • regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution; • we may not be able to timely or at all obtain INDs for a product candidate; • we may modify a preclinical study or clinical trial protocol; • third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we may be unable to establish clinical endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities consider likely to predict clinical benefit; • we may experience delays due to the outbreak of health epidemics, including with respect to the conduct of ongoing clinical trials, receipt of product candidates or other materials, submission of NDAs, filing of INDs, and starting any clinical trials for other indications or programs; and • we may experience manufacturing delays due to health epidemics in our supply chain caused by a shortage of raw materials, a lack of employees on site at our suppliers due to illness, or a lack of productivity at our suppliers due to local or national government quarantine restrictions on coming to the workplace. 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, if there are safety concerns or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may: •

incur unplanned costs; • be delayed in obtaining marketing approval for our product candidates; • not obtain marketing approval at all; • obtain marketing approval in some countries and not in others; • 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; • be subject to additional post- marketing testing requirements; or • have the product removed from the market after obtaining marketing approval. We cannot be certain whether any of our planned clinical trials will begin on schedule or any preclinical studies we plan to initiate will begin on our intended schedule, or whether any such studies or clinical trials will need to be restructured or will be completed on schedule, or at all. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, or are unable to achieve clinical endpoints due to unforeseen events, such as health epidemics, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to generate additional revenue from product sales. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations. Our product candidates still require significant testing. We only recently began clinical trials to test TP- 04 and TP- 05 in humans and, as a company, we have limited experience in this area. We are early in our development efforts for our product candidates and indications, including TP- ~~03 for the treatment of MGD, TP-~~04 for the treatment of **Ocular** ~~rosacea~~ **Rosacea** and TP- 05 for potential Lyme disease prophylaxis and community malaria reduction. The risk of failure for product candidates in early development is high. Extensive clinical trials are necessary to demonstrate the safety and efficacy of such product candidates in humans. Clinical trials may fail to demonstrate that such product candidates are safe for humans and effective for indicated uses. Further, we intend to leverage data from the TP- 03 preclinical studies and clinical safety assessments for the treatment of Demodex blepharitis to satisfy the preclinical study requirements for TP- ~~03 for the treatment of MGD, and TP-~~04 and TP- 05 and other indications ~~. For MGD, we announced the enrollment of our first patient in the Phase 2a Ersa trial studying TP- 03 for the potential treatment of MGD and in December 2023 reported positive topline results~~ . For rosacea, we conducted the Phase 1 Galatea trial with TP- 04 and initiated the Phase 2a Galatea trial, for the treatment of rosacea in March 2023. In February 2024, we announced positive topline results and **in January 2025, we announced** ~~plan~~ **plans** to ~~discuss and determine~~ **initiate a Phase 2 study in** the **second half of 2025** ~~potential regulatory path with the FDA~~ . With respect to Lyme disease, in December 2022 we announced positive topline results from the completed Callisto trial and enrollment of the first patient in the Carpo trial. The Carpo trial, evaluating TP- 05, a novel ~~investigative~~ **investigational** oral, non- vaccine pharmacological prophylactic for the potential prevention of Lyme disease in humans is a randomized, double- blind, placebo- controlled trial that evaluated the efficacy of TP- 05 in killing lab grown, non- disease carrying ticks after they have attached to the skin of healthy volunteers, as well as confirm the safety, tolerability, and blood concentration of TP- 05. In February 2024, we announced positive topline results from the Carpo trial **. In December 2024, we met** ~~and plan to discuss and determine the potential regulatory path~~ with the FDA **about our Lyme disease program. The FDA agreed to our proposed approach for a Phase 2b clinical trial, which would include several hundred subjects. Additionally, the FDA confirmed that a Phase 3 clinical study would require a disease prevention field study that would likely require the enrollment of thousands of patients** . The FDA may reject our use of data from TP- 03 preclinical studies for the treatment of Demodex blepharitis for other indications or require additional studies to augment the data to advance for clinical development. The FDA may also reject our use of data from preclinical studies conducted by third parties for Lyme disease and require us to conduct additional preclinical studies before advancing to additional clinical trials. In addition, data from preclinical studies conducted by third parties may not be as reliable as data from studies conducted by us and since we did not conduct the studies, there may be weaknesses in the studies design or results that we may not be aware of. In part because of our limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, we cannot be certain that our clinical trials will be completed on time, that our planned clinical trials will be initiated on time, if at all, that our planned development programs would be acceptable to the FDA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized. We have and may continue to encounter difficulties or delays enrolling patients in our clinical trials, which could cause delays in or adverse effects of our clinical development activities. We have and may continue to experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We have and may continue to experience difficulties in patient enrollment in our clinical trials for a variety of reasons. For example, we ~~recently~~ experienced delays related to our Carpo trial with topline results **pushing** ~~pushed out~~ to February 2024 as a result of patient enrollment delays. The enrollment of patients depends on many factors, including: • the patient eligibility criteria defined in the protocol; • size of the patient population required for analysis of the trial' s primary endpoints; • the proximity of patients to study sites; • the design of the trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; • our ability to obtain and maintain patient consents; • costs to, or lack of adequate compensation for, prospective patients; • difficulties of enrolling patients or patients continuing to participate in follow- up visits due to ongoing or new health epidemics; and • the risk that patients enrolled in clinical trials will drop out of the trials before completion. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition would reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some

of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Moreover, potential patients and their doctors may be inclined to use existing therapies rather than enroll patients in any future clinical trial. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue from product sales and adversely affect our commercial prospects. Before we can initiate clinical trials in the U. S. for our product candidates, we must submit the results of preclinical testing and any previous clinical studies to the FDA along with other information, including information about product candidate chemistry, manufacturing and controls ~~(“ CMC ”)~~ and our proposed clinical trial protocol, as part of an IND. The initiation of clinical trials in the EU Member States will be subject to similar requirements concerning approval by competent national authorities and the receipt of a positive opinion from the relevant ethics committees. We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to: • the FDA or comparable foreign regulatory authorities placing the clinical trial on hold; • subjects failing to enroll or remain in our trial at the rate we expect; • subjects choosing an alternative treatment or other product candidates, or participating in competing clinical trials; • lack of adequate funding to continue the clinical trial; • subjects experiencing severe or unexpected drug- related adverse effects; • failure to demonstrate efficacy of the product; • any interruptions or delays in the supply of our product candidates for our clinical trials; • a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross- contaminations of product candidates in the manufacturing process; • any changes to our manufacturing process that may be necessary or desired; • any failure or delay in reaching an agreement with CROs, vendors and clinical trial sites; • third- party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (" GCP") or regulatory requirements or other third parties not performing data collection or analysis in a timely or accurate manner; • third- party contractors becoming debarred, disqualified or suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; • one or more ~~Institutional Review Boards (" IRBs ")~~, other ethics committees refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or • changes in regulatory requirements and policies, which may require us to amend clinical trial protocols to comply with these changes and resubmit our clinical trial protocols to IRBs or ethics committees for reexamination. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize the commercial prospects of our product candidates and our ability to generate revenue from product sales. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. For example, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly. Any termination of any clinical trial of our product candidates will harm our commercial prospects and our ability to generate revenue from product sales. Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties, such as our China Out- License ~~with LianBio~~. We are evaluating the opportunities for the development and commercialization of our product candidates in other foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including: • our customers’ ability to obtain reimbursement for our product candidates in foreign markets; • our inability to directly control commercial activities if we are relying on third parties; • the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements; • different medical practices and customs in foreign countries affecting acceptance in the marketplace; • import or export licensing requirements; • longer accounts receivable collection times; • longer lead times for shipping; • language barriers for technical training and the need for language translations; • reduced protection of intellectual property rights in some foreign countries; • the existence of additional potentially relevant third- party intellectual property rights; • foreign currency exchange rate fluctuations; and • the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute. For example, the pharmaceutical industry in the China Territory is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in the China Territory regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased

compliance costs on our business or cause delays in or prevent the successful development of TP- 03 by ~~LianBio~~ **GrandPharma** under the China Out- License and reduce the current benefits we believe are available to us. The China Territory authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by ~~LianBio~~ **GrandPharma** or our other partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our partner' s business activities in the China Territory. Additionally, to the extent that we enter into collaborations with third parties for development and / or commercialization of our products or product candidates in foreign markets, we will be unable to directly control development and commercial activities or whether such third parties continue to develop or commercialize such products or product candidates. For example, ~~on~~ **in** February ~~13,~~ 2024, LianBio announced its completion of a comprehensive strategic review and determined to initiate the wind down of its operations, including the sale of remaining pipeline assets, the delisting of its American Depositary Shares, deregistration under Section 12 (b) of the Exchange Act, and workforce reductions. **In March 2024, we executed the Novation Agreement with GrandPharma and LianBio to transition the rights to develop and commercialize TP- 03 in China for the treatment of Demodex blepharitis and MGD.** As of the date of this filing, it is uncertain if and when we will receive any future milestone consideration under the China Out- License ~~, including but not limited to the milestone achievement of an additional drug supply agreement execution~~ . Another example of the changing regulatory requirements is that in the **European Union ("** EU **")** , the European Commission has presented a proposal to reform the current EU pharmaceutical legislation. The proposal intends to reduce the regulatory data protection period and orphan market exclusivity period for new medicinal products. It is currently uncertain if the proposal will be adopted in its current form and it is uncertain if and when the revised legislation would enter into force. Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. In some countries, particularly the countries in Europe, 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 drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. We have conducted a number of our completed **clinical trials and may conduct ongoing** clinical trials for our product candidates at sites outside the U. S., and the FDA may not accept data from trials conducted in such locations. Although the FDA may accept data from clinical trials conducted outside the U. S., acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with certain ethical and policy principles, including GCP standards. Among other requirements, the trial data must be applicable to the U. S. population and U. S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with certain U. S. laws and regulations. There can be no assurance the FDA will accept data from clinical trials conducted outside of the U. S. There can also be no assurance that the comparable foreign regulatory authority in any jurisdiction in which we seek regulatory approval for our product candidates will accept data from clinical trials conducted outside such jurisdiction. If the FDA or any such foreign regulatory authority does not accept the data from any trial that we have conducted outside the U. S., it would likely result in the need for additional trials, which would be costly and time- consuming and could delay or permanently halt our development of the applicable product candidates. In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the U. S. and if we conduct trials outside of the U. S., we may face risks, such as: • regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials; • foreign exchange rate fluctuations; • manufacturing, customs, shipment and storage requirements; • cultural or legal differences in the standards for medical practice and clinical research; • diminished protection of intellectual property in some countries; • different cultural attitudes to self- reported adverse events (such as burning, stinging, blurry vision) leading to a different safety profile; and • the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought. Managing our obligations under our in- license and out- license agreements and other strategic agreements may divert management time and attention, causing delays or disruptions to our business. We have entered into two license agreements with Elanco **Tiergesundheit AG" (Elanco")** : (i) **a license agreement for exclusive worldwide rights to certain intellectual property for the development and commercialization of lotilaner in the treatment or cure of any eye or skin disease or condition in humans, as amended in June 2022 ("** Eye and Derm Elanco Agreement **")** and (ii) **a license agreement with Elanco granting it a worldwide license to certain intellectual property for the development and commercialization of lotilaner for the treatment, palliation, prevention, or cure of all other diseases and conditions in humans (i. e., beyond that of the eye or skin), as amended in June 2022 (the"** the All Human Uses Elanco Agreement **" and with the Eye and Derm Elanco Agreement, the" Elanco Agreements")** , and have also entered into the China Out- License as discussed elsewhere herein. We also may in the future enter into in- license or out- license agreements with multiple licensors and strategic agreements, which, subject us to various obligations, including diligence obligations, reporting and notification obligations, payment obligations for achievement of certain milestone as well as other material obligations. We may need to devote substantial time and attention to ensuring that we successfully integrate these transactions into our existing operations and are compliant with our obligations under these agreements, which may divert management' s time and attention away from our research and development programs or other day- to- day activities. Our in- license, out- license, and strategic agreements are also complex and certain provisions in those agreements may be susceptible to multiple interpretations. In the event of any disagreement about the interpretation of these provisions, our management may need to devote a disproportionate amount of its attention to resolving these disagreements.

Such disruptions may cause delays in our research and development programs and other business objectives. Our operating activities may be restricted by certain covenants in our license and other strategic agreements, which could limit our development and commercial opportunities. In connection with our in- license, out- license, or other collaborations or strategic alliances, we may agree to and be bound by negative covenants which may limit our development and commercial opportunities. For example, pursuant to the ~~Eye and Derm~~ Elanco ~~Agreement~~ **Agreements** ~~and the All Human Uses Elanco Agreement~~, we made certain covenants to only engage with third party suppliers previously approved by Elanco, and only under certain circumstances. These provisions may inhibit our development efforts, prevent us from forming strategic collaborations to develop and potentially commercialize any other product candidates and may materially harm our business, financial condition, results of operations and prospects. Interim top- line and preliminary results from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures, which could result in material changes in the final data. From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary or top- line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common stock to fluctuate significantly. Risks Related to our Financial Position and Need for Additional Capital Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We commenced activities in 2016. Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing our company, raising capital, identifying and developing product candidates, establishing licensing arrangements and / or acquiring necessary technology, undertaking research, preclinical studies and clinical trials of our product candidates, establishing arrangements for the manufacture of XDEMVY and other product candidates and longer-term planning for commercialization efforts of XDEMVY and our other potential product candidates. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have limited experience in obtaining marketing approvals, manufacturing commercial scale product or arranging for a third party to do so on our behalf, or conducting sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions ~~you make~~ **made** about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing products. In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We may not be successful as we transition from a company with a research and development focus to a company capable of supporting commercial activities. Due to the **ongoing** ~~recently initiated~~ commercialization of XDEMVY and our continued development of our pipeline of product candidates through clinical trials and other indications, our capital requirements are difficult to predict and may change. We may need to obtain substantial additional funding to achieve our goals and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, reduce or eliminate our product development programs, commercialization efforts or other operations. Since our inception, we have funded our operations through private placements of preferred stock, convertible promissory notes, the sale of our common stock in our IPO and the Follow- On Public Offerings, and the 2023 ATM Prospectus, as well as proceeds from product sales, net, our China Out- License, and draws on our Credit ~~Facility~~ **Facilities**. We expect our expenses to increase substantially and we will require a larger amount of capital to fund our commercialization efforts, the development of our product candidates and the maintenance and expansion of our operations and capabilities. These expenditures will include costs associated with marketing and selling any products approved for sale, including XDEMVY, conducting non- clinical studies and clinical trials, obtaining regulatory approvals, securing manufacturing and supply of product candidates, costs associated with in- licensing assets consistent with our core strategy and other unanticipated costs. Further, as a public company, we incur significant legal, accounting and other costs associated with operating as a public company. We believe that our cash, cash equivalents and marketable securities of $ ~~227~~ **291**. 4 million as of December 31, ~~2023~~ **2024** and expected sales of XDEMVY is sufficient to fund our current and planned operations for at least the next twelve months from the date of filing this Annual Report on Form 10- K. We will need to raise substantial additional capital to complete the development and commercialization of XDEMVY and our other product candidates through one or more of: equity offerings, draws from our Credit ~~Facility~~ **Facilities**, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Due to the complexities of our transition to a commercial ~~-~~stage company, it is challenging to estimate the actual amounts necessary to successfully commercialize any products approved for sale. We may need to raise additional funds earlier than currently anticipated if we choose to pursue additional indications for our product candidates, acquire new product candidates or otherwise expand our business more rapidly than we presently planned. We have based these estimates on assumptions that may prove to be incorrect or require adjustment because of our ongoing business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including: • the cost and timing, receipt and amount of sales and marketing capabilities of any current and future products, including the success of our commercialization efforts involving XDEMVY; • market acceptance of our current and future products, including XDEMVY, and the impact of any competing products; • the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for any current or future products; • the scope and costs of manufacturing development and commercial manufacturing activities and our ability to

scale them up; • the scope, rate of progress, costs and results of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates; • the number and scope of clinical programs we decide to pursue; • the extent to which we acquire or in- license other product candidates and technologies; • the cost, timing and outcome of regulatory review of our product candidates, including the potential for regulatory authorities to require that we conduct more studies and trials than those that we currently expect to conduct and the costs of post- marketing studies or **REMS** ~~risk evaluation and mitigation strategies~~ that could be required by regulatory authorities; • suspensions or delays in enrollment of our ongoing and future clinical trials, issues with data collection, or changes to the number of subjects we decide to enroll in clinical trials, including as a result of health pandemics, competing trials, or otherwise; • the costs of commercialization activities for any current or future products that are approved for sale, including marketing, sales, and distribution costs, and any discounts or rebates to obtain access; • potential changes in the regulatory environment and enforcement rules; • the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property- related claims; • our ability to establish and maintain collaborations on favorable terms, if at all; • our ability to satisfy our outstanding debt obligations; • our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the sales and marketing activities associated with the commercialization of our products, including XDEMVY, and the development of our product candidates; • potential changes in pharmaceutical pricing and reimbursement infrastructure; • the costs related to any future collaboration or licensing partners upon the achievement of negotiated milestones; • the costs associated with any product liability or other lawsuits related to our products; • the expense needed to attract and retain skilled personnel; and • the costs associated with being a public company. Commercialization efforts of any current or future products, including our commercialization efforts involving XDEMVY, identifying potential product candidates and conducting preclinical studies 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 marketing approval for our product candidates. In addition, our product candidates, if approved, may not achieve adequate product sales or commercial success. Although we initiated commercialization of XDEMVY for the treatment of Demodex blepharitis in August 2023, we will need to continue to sustain our existing capital resources to fund our future operating expenses and capital expenditure requirements. Adequate additional financing may not be available to us on acceptable terms, or at all, and may be impacted by the economic climate and market conditions. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, limit, reduce or eliminate our research and development programs or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of management from day- to- day activities and distract from our research and development efforts. Alternatively, 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. ~~In February .~~ 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 **as** we can generate substantial revenue from product sales,including from XDEMVY,our only approved product,we expect to finance our cash needs through possible combinations of equity offerings,debt financings,collaborations,strategic alliances and licensing arrangements.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.For example,in May 2022, **August 2023, and March 2024,** we ~~executed~~ **completed the Follow- On Public Offerings, in which we received total net proceeds of $ 74. 2 million, $ 99. 3 million, and $ 107. 7 million, respectively, (after deducting underwriting discounts, commissions and** ~~the~~ **other estimated offering- related expenses) through the issuance of 5, 889, 832 shares of our common stock in the May 2022 Public Offering, 6, 069, 449 shares of our common stock in the August 2023 Public Offering, and 3, 281, 250 shares of our common stock and, in lieu of common stock to a certain investor, pre- funded warrants to purchase 312, 500 shares of our common stock in the March 2024 Public Offering. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions. For example, the 2024** Credit Facility **restricts our ability to pursue certain transactions that we may believe to be in our best interests without the prior written consent of Pharmakon , including but not limited to:disposing of certain properties or assets,incurring** additional **indebtedness,granting** liens ~~(including a negative pledge on intellectual property),engaging in mergers,acquisitions and consolidations;conducting asset sales or exclusively licensing our assets in a transaction that constitutes legal transfer to such licensee ~~,making investments ~~and loans~~ , ~~engaging~~ **paying dividends or making distributions or certain other restricted payments** in ~~certain corporate changes~~ **respect of equity , prepaying** ~~transacting with affiliates,declaring dividends or making other distributions,and making payments on certain~~ other indebtedness **,entering into restrictive agreements,undertaking fundamental changes or amending certain material contracts,in each case subject to certain customary exceptions and negotiated carve outs** .If we raise funds through collaborations,strategic alliances or licensing arrangements with third parties,we may have to relinquish valuable rights to our technologies,future revenue streams,research programs or product candidates or grant licenses on terms that may not be favorable to us.If we raise funds through research grants,we may be subject to certain requirements,which may limit our ability to use the funds or require us to share information from our research and development.Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders,and may cause the market price of our shares to decline.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 product development or continued and future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.Adverse developments affecting the financial services industry,such as ~~amended~~ **actual events or concerns involving liquidity, defaults or non- performance by financial institutions or transactional counterparties, could adversely affect our business and our**

financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in ~~January~~ **the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, in March** 2023 ~~and August 2023 (see Note 10) with Hercules Capital~~ , ~~Inc. (" Hercules ") and~~ Silicon Valley Bank ~~, a division of First- Citizens Bank & Trust Company~~ (~~" ~~**"**~~ ~~SVB ~~"~~ ~~**"**~~) ~~. Concurrent with the execution of the Credit Facility, the Company made a $ 20. 0 million draw. As of December 31, 2023, the Credit Facility provides for a remaining aggregate principal amount of up to $ 125. 0 million with tranched availability as follows: $ 15. 0 million related to the NDA- submission for TP- 03, $ 35. 0 million which became available in July 2023 upon FDA approval of XDEMVY, $ 50. 0 million upon achievement of certain quarterly revenue thresholds, and $ 25. 0 million upon lender approval. On March 15, 2023 and September 15, 2023, respectively, we made separate draws of $ 5. 0 million (including SVB' s commitment of $ 1. 25 million) from the $ 25. 0 million tranche associated with the NDA- submission of TP- 03. Each of the tranches may be drawn down in $ 5. 0 million increments at our election. As reported elsewhere, on March 10, 2023, SVB~~ was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (" FDIC"), as receiver, and SVB **was subsequently** ~~' s deposits and substantially all of SVB' s assets were~~ transferred into a new entity, Silicon Valley Bridge Bank ~~, N. A.~~ (" SVBB"). ~~On~~ **In** March ~~12, 2023, the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception. Such parties also announced, among other items, that SVBB had assumed the obligations and commitments of former SVB and commitments to advance under existing credit agreements with former SVB will be honored by SVBB pursuant to the terms of such credit agreements. On March 27,~~ 2023, First Citizens Bank assumed all of SVBB' s obligations and commitments, and SVBB began operating as ~~Silicon Valley Bank, a division of First Citizens Bank. Unless otherwise noted herein, all references to~~ SVB or Silicon Valley Bank shall refer to..... SVBB began operating as Silicon Valley Bank , a division of First Citizens Bank. Unless otherwise noted herein, all references to SVB or Silicon Valley Bank shall refer to Silicon Valley Bank, a division of First Citizens Bank. In light of the foregoing, the Company does not believe it has exposure to loss as a result of SVB' s receivership. We currently maintain cash held on deposit at financial institutions in the U. S., including at SVB. These deposits are insured by the FDIC in an amount up to $ 250, 000 for any depositor. To the extent we hold cash deposits in amounts that exceed the FDIC insurance limitation, we may incur a loss in the event of a failure of any of the financial institutions where we maintain deposits, to the extent such loss exceeds the FDIC insurance limitation, and such a failure could have a material adverse effect upon our liquidity, operations and our results of operations. Additionally, we and other parties with whom we conduct business may be unable to access funds in such deposit account or other accounts, including money market funds, held with a financial institution or lending arrangements with such a financial institution. Our ability and any of our counter- party' s ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from financial institutions in the future and uncertainty remains over liquidity concerns in the broader financial services industry. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Our existing indebtedness may limit our flexibility in financing and operating our business and adversely affect our business, financial condition and results of operations. In ~~February~~ **April** ~~2022~~ **2024** we entered into the **2024** Credit Facility with ~~Hercules and SVB,~~ **Pharmakon. The 2024 Credit Facility provides a $ 75. 0 million initial term loan which** ~~as~~ **was** ~~amended~~ **drawn** in ~~January~~ **April** ~~2023~~ **2024** ~~and August~~ **, a portion of which was utilized to repay all outstanding indebtedness, for total net proceeds of $ 39. 6 million. The** ~~2023~~ **2024** ~~. As of December 31, 2023, the~~ Credit Facility provides for ~~a remaining aggregate~~ **three potential additional term loan tranches in** principal ~~amount~~ **amounts** ~~of~~ up to $ ~~125~~ **25** . 0 million ~~with~~ **, $ 50. 0 million, and $ 50. 0 million, respectively, subject to customary conditions to funding and, in the case of the last two** ~~tranched~~ **tranches** ~~availability. In addition to these amounts~~ , ~~we~~ **achieving minimum net sales milestones, which** may **be requested** ~~borrow substantial funds in the future to provide a portion of the capital needed in our business and may secure the repayment of such borrowings by placing additional liens or other encumbrances~~ on ~~our~~ **or** ~~assets~~ **prior to December 31, 2024, June 30, 2025 and December 31, 2025, respectively** . ~~Our~~ **We did not draw on the related $ 25. 0 million first tranche prior to December 31, 2024. The 2024** Credit Facility contains **representations** ~~customary conditions to borrowing, events of default~~ and **warranties,** affirmative and negative covenants **in each case** , ~~including~~ **which is customary for financings of this type. Certain of the customary negative** covenants **limit** ~~that restrict~~ our ability to **, among other things, dispose of certain properties or assets,** incur additional indebtedness, **grant** ~~incur additional~~ liens ~~, conduct asset sales or exclusively license our assets in a transaction that constitutes legal transfer to such licensee~~ , make investments ~~and loans~~ , ~~engage in~~ **pay dividends or make distributions or** certain ~~corporate~~ **other restricted payments in respect of equity, prepay other indebtedness, enter into restrictive agreements, undertake fundamental** changes ~~, transact with affiliates, or declare dividends or make other distributions to holders of our~~ **or** ~~stock~~ **amend certain material contracts, in each case subject to certain customary exceptions and negotiated carve outs. However, there are no financial covenants** . Such restrictions could limit our ability to take certain actions and could reduce our flexibility to run and

manage our business which could have an adverse effect on our results of operations. ~~The~~ **Our** obligations under the **2024** Credit Facility are secured by a ~~first priority~~ lien ~~on~~ **in** substantially all of our assets, ~~excluding our intellectual property on which there is a negative pledge,~~ subject to ~~customary exceptions~~ **certain exclusions**. If we were unable to repay amounts due under the **2024** Credit Facility, **Pharmakon** ~~Hercules and SVB~~ could proceed against such assets. Any declaration by **Pharmakon** ~~Hercules or SVB~~ of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause ~~or~~ **us** to incur debt or assume contingent liabilities, and subject us to other risks. In the future, we may enter into transactions to acquire other businesses **, product candidates**, products or technologies or enter into strategic partnerships, including licensing. If we do identify suitable acquisition or partnership candidates, we may not be able to make such acquisitions or partnerships on favorable terms, or at all. Any acquisitions or partnerships we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders ~~. For example, our Credit Facility may restrict our ability to pursue certain mergers, acquisitions or consolidations without obtaining the prior consent of Hercules and SVB or repaying our outstanding loan amounts~~. We could incur losses resulting from undiscovered liabilities of the acquired business or partnership that are not covered by the indemnification we may obtain from the seller or our partner. In addition, we may not be able to successfully integrate any acquired personnel, technologies and operations into our existing business in an effective, timely and non- disruptive manner. Acquisitions or partnerships may also divert management attention from day- to- day responsibilities, lead to a loss of key personnel, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or partnerships or the effect that any such transactions might have on our operating results. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses during our history which we expect to continue, we do not expect to become profitable in the near future, and we may never achieve profitability. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ~~(the " Code ")~~, if a corporation undergoes an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period, the corporation' s ability to use its pre- change **NOL** ~~net operating loss~~ carryforwards ~~(" NOLs ")~~, and other pre- change tax attributes (such as research tax credits) to offset its post- change income or taxes may be limited. We have not yet completed an ownership change analysis. If a requisite ownership change occurs, the amount of remaining tax attribute carryforwards available to offset taxable income and reduce income tax expense in future years may be restricted or eliminated. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows. We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition. The rules dealing with U. S. federal, state, and local income taxation are complex and are constantly under review by legislators, the U. S. **Department of** Treasury ~~Department~~, and the Internal Revenue Service. Changes to tax laws (which may have retroactive application) have occurred and are likely to continue to occur in the future, which could adversely affect our shareholders. Risks Related to Reliance on Third Parties We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We do not have the ability to independently conduct our clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and planned clinical trials of TP- 03, TP- 04 and TP- 05 and other product candidates, and we expect to continue to rely upon third parties to conduct additional clinical trials of potential future product candidates. Third parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third party, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, it would delay our development activities. Our reliance on these third parties for such development activities will reduce our control over these activities but will not relieve us of our regulatory 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 GCP standards, regulations 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. The EC also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EC or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP or other applicable regulations. In addition, our clinical trials must be conducted with product produced under current applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. 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 certain timeframes. Failure to do so can result in fines, adverse

publicity and civil and criminal sanctions. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. In addition, the operations of our CROs and other third- party service providers may be constrained or disrupted by health epidemics. 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 efforts to, successfully commercialize our product candidates. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays can occur, which could materially impact our ability to meet our desired clinical development timelines. Although we plan to carefully manage our relationships with our CROs, investigators and other third parties, we may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, financial condition and prospects. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of any product candidates. We contract with third parties for the commercial manufacture of XDEMVY and for the manufacture of our product candidates for preclinical studies, clinical trials and eventual commercialization. **In some instances, we or our third party contract manufacturers rely on single source suppliers for certain of the materials for our product and product candidates.** This reliance on third parties **and single source suppliers** increases the risk that we will not have sufficient quantities of XDEMVY or our product candidates or compounds or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our commercialization or development efforts. We do not have any, and have no plans to acquire any, manufacturing facilities. We produce in our laboratory relatively small quantities of compounds for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the commercial manufacture of XDEMVY and the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture of our product candidates, if approved. **If the third parties we engage with are unable to supply us with sufficient quantities of XDEMVY or our product candidates, and we are unable to timely establish an alternate supply from one or more third- party manufacturers, we will experience delays in our commercialization and development efforts as we seek to locate and qualify new manufacturers. In particular, any replacement of our third- party manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements or capacity could be limited at each of the qualified replacements.** We currently have limited manufacturing arrangements and expect that XDEMVY and each of our product candidates will only be covered by **third party manufacturers, which exacerbates these and other related risks for us. Additionally, we and our third party contract manufacturers rely and we expect that we will continue to rely on single-source suppliers for certain of the materials for our products and product candidates for the foreseeable future. For example, we purchase our API for XDEMVY, lotilaner, from Elanco, who sources through a single source supplier. This reliance on third parties, including** single source suppliers ~~for the foreseeable future. For example~~, ~~we purchase our API for XDEMVY, lotilaner, from Elanco, who sources through a single source supplier. This reliance~~ increases the risk that we will not have sufficient quantities of XDEMVY or our product candidates or any future approved products, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our commercialization or development efforts **. If current or future suppliers are delayed or unable to supply sufficient materials to manufacture our products and product candidates, we may experience delays in our commercialization and development efforts, which would have an adverse affect on our business and results of operations** . Furthermore, all entities involved in the preparation of XDEMVY for commercial sale or other therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for XDEMVY and our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of XDEMVY, investigational products and future products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of XDEMVY or our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA on a timely basis and must adhere to the FDA' s Good Laboratory Practice regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Foreign regulatory authorities, including the European Commission and the competent authorities of the EU Member States, may require compliance with similar requirements. The facilities and quality systems of our third- party contractor manufacturers must pass a pre- approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP regulations. We have little or no control over the production processes of third- party manufacturers, CMOs or other suppliers. The third- party manufacturing facilities used in the production of API and our drug products are located outside of the U. S. and require FDA approval, which our third- party manufacturers may have limited experience with obtaining. Our CMOs and other suppliers are subject to inspection by the FDA and may receive observations that they may not be able to resolve in a timely or effective manner, which could impact whether

our products can be approved on a timely basis, if at all. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of XDEMVY, components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture XDEMVY or other materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture XDEMVY or our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture XDEMVY or our product candidates. If we elect to or are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. If any of 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 XDEMVY or our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer. Our or a third party' s failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways, including: • an inability to meet commercial demands for XDEMVY or any other future product that is approved; • requirements to cease development or to recall batches of XDEMVY or our product candidates; • an inability to initiate or continue clinical trials of our product candidates under development; • delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates; • loss of the cooperation of an existing or future collaborator, including by Elanco **and** under the ~~license agreements with~~ Elanco **Agreements** ; and • subjecting third- party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities. XDEMVY, our product candidates and any future products that we may develop may compete with other products and product candidates for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could prevent or delay commercialization efforts of XDEMVY or any future products, if approved, clinical development of product candidates or marketing approval of current or future product candidates. We or our third- party manufacturers may encounter shortages in the raw materials or ~~active pharmaceutical ingredients (" APIs "~~ **API** ~~")~~ necessary to produce XDEMVY or our product candidates in the quantities needed in sufficient quantities for our commercialization or to meet an increase in demand, or for our clinical trials, as a result of capacity constraints or delays or disruptions in the market for the raw materials or APIs, including shortages caused by the purchase of such raw materials or APIs by our competitors or others. The failure of us or our third- party manufacturers to obtain the raw materials or APIs necessary to manufacture sufficient quantities of XDEMVY or our product candidates, may have a material adverse effect on our business. We, or our third- party manufacturers, may be unable to successfully scale- up manufacturing of XDEMVY or our product candidates in sufficient quality and quantity, which would delay or prevent us from commercializing, conducting clinical trials and developing our product candidates. In order to successfully commercialize XDEMVY and to conduct clinical trials of our product candidates, we will need to manufacture XDEMVY and our product candidates in large quantities. We, or our manufacturing partners, may be unable to maintain or successfully increase the manufacturing capacity for XDEMVY or any of our product candidates in a timely or cost- effective manner, or at all. In addition, quality issues may arise during scale- up activities. If we, or our manufacturing partners, are unable to successfully scale up the manufacture of XDEMVY or our product candidates in sufficient quality and quantity, the commercialization of XDEMVY or the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and commercialization of XDEMVY or marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates progress through preclinical to late stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue. Risks Related to Intellectual Property Changes in patent law in the U. S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect XDEMVY or our product candidates. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time- consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U. S. could increase the uncertainties and costs. ~~Recent patent~~ **Patent** reform legislation in the U. S. and other countries, including the Leahy- Smith America Invents Act (the " Leahy- Smith Act "), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost- effective avenues for

competitors to challenge the validity of patents. These include allowing third- party submission of prior art to the U. S. Patent and Trademark Office (“ USPTO ”) during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. After March 2013, under the Leahy- Smith Act, the U. S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. 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 have a material adverse effect on our business, financial condition, results of operations and prospects. 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. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The U. S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh- Dole Act **of 1980 (the" Bayh- Dole Act")** . The federal government retains a nonexclusive, nontransferable, irrevocable, paid- up license for its own benefit. The Bayh- Dole Act also provides federal agencies with “ march- in rights **,** ” ~~.~~March- in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a nonexclusive, partially exclusive, or exclusive license to a responsible applicant or applicants. If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co- own or license in technology that is critical to our business that is developed in whole or in part with federal funds subject to the Bayh- Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected. Additionally, the new unitary patent system that came into effect in Europe in June 2023 has increased the complexity and uncertainty of European patent laws and would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (“ UPC ”). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC 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. The development and commercialization of our products, including our lead product XDEMVY, for the treatment of Demodex blepharitis, TP- ~~03~~ **04** for the potential treatment of **Ocular** ~~MGD, TP- 04 for the potential treatment of rosacea~~ **Rosacea** and TP- 05 for potential Lyme disease prophylaxis and community malaria reduction, is dependent on intellectual property we license from Elanco. If we breach our agreements with Elanco or the agreements are terminated, we could lose license rights that are important to our business. Pursuant to the ~~Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement (each an" Elanco Agreement" and together the"~~ Elanco Agreements ~~")~~ we acquired exclusive, worldwide, sublicensable licenses to certain intellectual property of Elanco for the development, marketing and commercialization of lotilaner for (i) the treatment, prevention, palliation or cure of any eye or skin disease or condition in humans and (b) all other applications in humans, respectively. The Elanco Agreements impose various development, regulatory, commercial diligence, financial and other obligations on us. If we fail to comply with our obligations under the Elanco Agreements, or otherwise materially breach either Elanco Agreement, and fail to remedy such failure or cure such breach within 60 days, Elanco will have the right to terminate the applicable Elanco Agreement. If we fail to meet any milestones by the achievement deadlines set forth in either Elanco Agreement for any reason other than those outside of our reasonable control, and such milestones remain unmet for 120 days after Elanco notifies us thereof, Elanco may terminate the applicable Elanco Agreement. If either Elanco Agreement is terminated or if our field of use in the Eye and Derm Elanco Agreement is reduced to eye and skin conditions only by Elanco, we would lose our applicable license in the country where such license was terminated and all rights therein to the licensed intellectual property would revert to Elanco. The loss of the license from Elanco would prevent us from developing and commercializing **XDEMVY,** TP- 03, TP- 04 and TP- 05 in any country where the license is terminated and could subject us to claims of breach of contract and patent infringement by Elanco if any continued research, development, manufacture or commercialization of **XDEMVY,** TP- 03, TP- 04 or TP- 05 is covered by the affected patents. If Elanco terminates the Eye and Derm Elanco Agreement for our failure to achieve a development milestone by the specified achievement deadline, then we must grant Elanco a non- exclusive, sublicensable, royalty- free license to our patents and know- how relating to lotilaner to develop, manufacture and commercialize lotilaner and any licensed products for the treatment, palliation, prevention or cure of any eye or skin disease or condition in humans. If Elanco terminates the All Human Uses Elanco Agreement for our failure to achieve a development milestone by the specified achievement deadline, then we must grant Elanco a non- exclusive, sublicensable, royalty- free license to our patents and know- how relating to lotilaner to develop, manufacture and commercialize lotilaner and any licensed products for all applications in humans other than the treatment, palliation, prevention or cure of any eye or skin disease or condition. Accordingly, the loss of our license or the termination of our license for skin diseases and conditions or of our license for other use in humans with Elanco would materially harm our business. If we are unable to obtain and maintain sufficient intellectual property protection for XDEMVY or our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected. We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to XDEMVY, our development programs and product candidates. Our success depends in large part on our ability to

obtain and maintain patent protection in the U. S. and other countries with respect to XDEMVY, our product candidates and research programs. We seek to protect our proprietary position by filing patent applications in the U. S. and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued that protect XDEMVY or our product candidates or their intended uses or that effectively prevent others from commercializing competitive technologies, products or product candidates. Obtaining and enforcing patents is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and / or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, **CROs** ~~contract research organizations~~ , **CMOs** ~~contract manufacturers~~ , consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. 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, resulting in court decisions, including **U. S.** Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the scope of patent protection outside of the U. S. is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the U. S., or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. With respect to both owned and in- licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing or will pursue will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors **. As noted above, the Novation Agreement amended the $ 15. 0 million future development milestone payable on China regulatory approval of the China Out- License agreement with a combined condition of patent issuance related to TP- 03 in China. If we are not able to obtain the aforementioned patent issuance in China, the likelihood we achieve the associated milestone, as well as commercialization in the China Territory, would be substantially decreased** . Further, we may not be aware of all third- party intellectual property rights potentially relating to XDEMVY or our product candidates or their intended uses, and as a result the impact of such third- party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third- party intellectual property upon our ability to commercialize our products, is highly uncertain. Because we have not yet conducted a formal patent landscape analysis related to XDEMVY or our product candidates, we may not be aware of issued patents that a third party might assert are infringed by XDEMVY or one of our current or future product candidates, which could materially impair our ability to commercialize XDEMVY or our product candidates. Even if we diligently search third- party patents for potential infringement by our products or product candidates, including XDEMVY, TP- 03, TP- 04 or TP- 05, we may not successfully find patents that our products or product candidates, including XDEMVY, TP- 03, TP- 04 or TP- 05, may infringe. If we are unable to confirm that our products do not infringe third- party patents, others could preclude us from commercializing XDEMVY or our product candidates. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries and patent applications in the U. S. and other jurisdictions are typically not published until 18 months after filing or, in some cases, not published at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patents or pending patent applications may be challenged in the courts or patent offices in the U. S. and abroad. For example, we may be subject to a third party pre- issuance submission of prior art to the **USPTO** ~~U. S. Patent and Trademark Office~~ , or become involved in post- grant review or interference procedures, oppositions, derivations, revocations, reexaminations, or inter partes review proceedings, in the U. S. or elsewhere, 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 product candidates 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. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize XDEMVY or our current or future product candidates. Our owned and licensed patent estate includes patent applications, many of which are at an early stage of prosecution. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in- licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in- licensed patents may be challenged in the courts or patent offices in the U. S. and abroad. Such challenges may result in loss of exclusivity or ability to sell our products without infringing third- party patents or patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, 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. Furthermore, our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. As a result, our owned and in- licensed patent portfolio may not provide us with sufficient rights to exclude

others from commercializing technology and products similar or identical to any of our technology and product candidates. Furthermore, while we seek to protect the trademarks we use in the U. S. and in other countries, we may be unsuccessful in obtaining registrations and / or otherwise protecting these trademarks. If that were to happen, we may be prevented from using our names, brands and trademarks unless we enter into appropriate royalty, license or coexistence agreements, which may not be available or may not be available on commercially reasonable terms. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, service marks and domain names, then we may not be able to compete effectively, resulting in a material adverse effect on our business. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted or declared generic, or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trademarks and trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Effective trademark protection may not be available or may not be sought in every country in which our products are made available. Any name we propose to use for our products in the U. S. must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, that does not infringe the existing rights of third parties and that is acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and / or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and / or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications relating to XDEMVY or our product candidates, our competitive position, business, financial condition, results of operations and prospects would be adversely affected. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the U. S. and abroad that is relevant to or necessary for the commercialization of XDEMVY or our product candidates in any jurisdiction. Because we have not yet conducted a formal patent landscape analysis related to XDEMVY or our product candidates, we may not be aware of issued patents that a third party might assert are infringed by one of XDEMVY or our current or future product candidates, which could materially impair our ability to commercialize XDEMVY or our product candidates. Even if we diligently search third- party patents for potential infringement by our products, including XDEMVY, or product candidates, we may not successfully find patents that our products or product candidates may infringe. If we are unable to confirm that our products, including XDEMVY, do not infringe third- party patents, others could preclude us from commercializing XDEMVY or our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U. S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market XDEMVY or our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products, including XDEMVY. We may wish to acquire rights to future assets through in- licensing or may attempt to form collaborations in the future with respect to XDEMVY or our product candidates, but may not be able to do so, which may cause us to alter or delay our commercialization or development plans. The commercialization of XDEMVY and the development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. In 2019 and 2020, we entered into the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement, respectively. We **have** ~~plan to utilize~~ **utilized** these license rights in developing and marketing XDEMVY, and our TP- 03, TP- 04 and TP- 05 product candidates. We may, in the

future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of XDEMVY in other jurisdictions or our product candidates. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for the commercialization of XDEMVY in other jurisdictions or the development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of XDEMVY or that product candidate to the third party. Our ability to 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 following: • the potential market for the product candidate; • the costs and complexities of manufacturing and delivering such product candidate to patients; • the design or results of clinical trials; • the likelihood of approval by the FDA or comparable foreign regulatory authorities; • the potential of competing products; • the existence of uncertainty with respect to our ownership of technology or other rights, 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 XDEMVY or our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all 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 and changes to the strategies of the combined company. As a result, 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 one or more of our other development programs, delay the commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing 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. Collaborations that we have entered into and may enter in the future may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations pose a number of risks, including the following: • collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected; • collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that divert resources or create competing priorities; • collaborators may not pursue commercialization of any product or product candidates that achieve marketing approval or may elect not to continue or renew commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that may 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; • we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with XDEMVY or our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under 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 may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product; • a collaborator may seek to renegotiate or terminate their relationship with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons; • a collaborator with marketing and distribution rights to one or more of our product candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of such product or products; • disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations 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 obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; • disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations; • collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary 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 our products or product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our collaborators. In the future, we may need to obtain additional licenses of third- party technology that may not be available to us or are available only on commercially unreasonable terms or we may fail to comply with our obligations under such agreements and our business could be harmed. In addition to the ~~Eye and Derm~~ Elanco ~~Agreement~~ **Agreements** ~~and the All Human Uses Elanco Agreement~~ , from time to time we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third- party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and / or other forms of compensation. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly. Additionally, if we fail to comply with our obligations under any license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. In each of the ~~Eye and Derm~~ Elanco ~~Agreement~~ **Agreements** ~~and the All Human Uses Elanco Agreement~~ , Elanco retains, and future licensors could retain, the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce such licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. If our licensors do not adequately protect such licensed intellectual property, competitors may be able to use such intellectual property and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates and delay or render impossible our achievement of profitability. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects. In addition to the above risks, intellectual property rights that we license in the future may include sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed. Disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation related issues; • the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • the priority of invention of patented technology. In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions,

results of operations and prospects. We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that our patents or patents based on our patent applications will not be challenged and rendered invalid and / or unenforceable. Although we have pending U. S. and foreign patent applications in our portfolio, we cannot predict: • if and when patents may issue based on our patent applications; • the scope of protection of any patent issuing based on our patent applications; • whether the claims of any patent issuing based on our patent applications will provide protection against competitors; • whether or not third parties will find ways to invalidate or circumvent our patent rights; • whether or not others will obtain patents claiming aspects similar to those claimed in our patents and patent applications; • whether we will need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; and / or • whether the patent applications that we own or in- license will result in issued patents with claims that cover our products or product candidates or uses thereof in the U. S. or in other foreign countries. We cannot be certain that the claims in our pending patent applications directed to our products or product candidates and / or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the " prior art, " information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the U. S. or foreign countries. If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates. Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time consuming and, even if resolved in our favor, are likely to divert significant resources from our core business, including distracting 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 and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market 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 adequately conduct such litigation or proceedings. 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 and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. There is a substantial amount of intellectual property litigation in the biotechnology and biopharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents are directed to various types of products or methods of use. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties. The scope of patents is subject to interpretation by the courts, and the interpretation is not always uniform. The legal threshold for initiating litigation or contested proceedings is low, so even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the U. S., proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If we are found to infringe a third party' s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and 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, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects. If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed. In the U. S., the term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non- U. S. jurisdictions to extend the term of a patent that covers an approved drug. While we may apply for patent term extensions on patents covering XDEMVY and other product candidates that may receive FDA approval, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the U. S. or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed. We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product. To counter infringement or unauthorized use, we may be required to file infringement or other intellectual property- related claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from making, using, or selling the invention at issue. In patent litigation in the U. S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the U. S. or abroad, even outside the context of litigation. Such mechanisms include re- examination, post- grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from making, using or selling the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks, which could materially harm our business and negatively affect our position in the marketplace. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There also 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 have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk- adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the

more prudent course of action is to simply monitor the situation or initiate or seek some other non- litigious action or solution. Changes in patent law in the U. S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time- consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the U. S. could increase the uncertainties and costs. Recent patent reform legislation in the U. S. and other countries, including the Leahy- Smith Act signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post- grant review, inter partes review, and derivation proceedings. After March 2013, under the Leahy- Smith Act, the U. S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. 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 have a material adverse effect on our business, financial condition, results of operations and prospects. **The U. S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh- Dole Act. The federal government retains a nonexclusive, nontransferable, irrevocable, paid- up license for its own benefit. The Bayh- Dole Act also provides federal agencies with " march- in rights ". March- in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a nonexclusive, partially exclusive, or exclusive license to a responsible applicant or applicants. If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co- own or license in technology that is critical to our business that is developed in whole or in part with federal funds subject to the Bayh- Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.** We may not be able to protect our intellectual property rights throughout the world. Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U. S. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling or importing products made using our inventions in and into the U. S. or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling or importing products made using our inventions in and into the U. S. or other jurisdictions. Furthermore, certain foreign and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We may rely on trade secret and proprietary know how which can be difficult to trace and enforce, and if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidate, including processes for their preparation and manufacture, may involve proprietary know- how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know- how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Trade secrets and know- how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We further seek to protect our potential trade secrets, proprietary know- how, and information in part, by entering into non- disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, **CROs** ~~contract research organizations~~, **CMOs** ~~contract manufacturers~~, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Despite these efforts, our assignment agreements may not be self-executing and any of these parties may breach the agreements and disclose our proprietary information, including our trade

secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially, and adversely affect our business, financial condition, results of operations, and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees. The assignment risks of this paragraph could also pertain to any intellectual property licensed- in to us. In addition, some courts inside and outside the U. S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them 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 or other third party, our competitive position would be harmed. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies, or at research institutions. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We or our licensors may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed; • we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed; • we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates; • we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages; • the **U. S.** Supreme Court ~~of the U. S.~~, other U. S. federal courts, **U. S.** Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our or our licensors' patents; • patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time; • we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others; • we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire; • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property; • we may not develop additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business, results of operations and prospects. Patent terms may be inadequate to protect our competitive position on our product candidates and preclinical programs for an adequate amount of time. Patent rights are of limited duration. In the U. S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. A patent term extension based on regulatory delay may be available in the U. S. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Risks Related to Government Regulation Our industry is highly regulated by the FDA and comparable foreign regulatory authorities. We must comply with extensive, strictly

enforced regulatory requirements to develop, obtain, and maintain marketing approval for XDEMVY or any of our product candidates, if approved. XDEMVY and any product candidates we develop and the activities associated with their development and commercialization, including their design, testing, manufacturing, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution are very heavily regulated. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and have relied and expect to continue to rely on third- party **CROs** ~~contract research organizations~~ to assist us in this process. Securing FDA or comparable foreign regulatory approval such as a marketing authorization from the European Commission or the competent authorities of the individual EU Member States requires the submission of extensive preclinical and clinical data and supporting information for each therapeutic indication to establish the product candidate' s safety and efficacy for its intended use. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. It takes years to complete the testing of a new drug and development delays and / or failure can occur at any stage of testing. Any of our present and future clinical trials may be delayed, halted, not authorized, or approval of any of our products may be delayed or may not be obtained due to any of the following: • any preclinical study or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or comparable foreign regulatory authorities; • preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent marketing approval; • negative or inconclusive results from a preclinical study or clinical trial or adverse events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a development program to be terminated, even if other studies or trials relating to the development program are ongoing or have been completed and were successful; • the FDA or comparable foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that subjects enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury; • the facilities that we utilize, or the processes or facilities of third- party vendors, including without limitation the contract manufacturers who are or will be manufacturing drug substance and drug product for us or any potential collaborators, may not satisfactorily complete inspections by the FDA or comparable foreign regulatory authorities; and • we may encounter delays or rejections based on changes in FDA regulations, standards or policies or the regulations, standards or policies of comparable foreign regulatory authorities during the period in which we develop a product candidate or the period required for review of any final marketing approval before we are able to market any product candidate. In addition, information generated during the clinical trial process is susceptible to varying interpretations that could delay, limit, or prevent marketing approval at any stage of the approval process. Moreover, early positive preclinical or clinical trial results may not be replicated in later clinical trials. As more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Failure to demonstrate adequately the quality, safety and efficacy of any of our product candidates would delay or prevent marketing approval of the applicable product candidate. We cannot assure you that if clinical trials are completed, either we or our potential collaborators will submit applications for required authorizations to manufacture or market potential products or that any such application will be reviewed and approved by appropriate regulatory authorities in a timely manner, if at all. 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. Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations. In the U. S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could restrict or regulate post- approval activities, impact pricing and reimbursement and affect our ability to profitably sell XDEMVY or any other product candidates for which we obtain marketing approval and prevent or delay marketing approval of product candidates. Among policy makers and payers both federally and on the state level in the U. S. and elsewhere, including in the **EU** ~~European Union~~, 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 U. S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. The **ACA** ~~Affordable Care Act of 2010~~ substantially changed the way healthcare is financed by both the government and private insurers, and significantly ~~impacts~~ **impacted** the U. S. pharmaceutical industry. The **ACA** ~~Affordable Care Act~~, among other things: (i) introduced a new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee- for- service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (iii) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (iv) expanded the list of covered entities eligible to participate in the 340B ~~drug pricing~~ program; (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70 % (increased from 50 % in 2019) point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D (which, under the IRA, will be replaced by a new manufacturer discount program starting in 2025); (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133 % of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vii) created a licensure framework for follow on biologic products; and (viii) established a Center for Medicare & Medicaid Innovation ~~(" CMMI")~~, at the ~~Center for Medicare & Medicaid Services (" CMS ")~~ to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Since its

enactment, there have been judicial challenges to certain aspects of the **ACA** ~~Affordable Care Act~~, as well as efforts by Congress to modify, and agencies to alter the implementation of, certain aspects of the **ACA** ~~Affordable Care Act~~. For example, Congress eliminated the tax penalty for not complying with the **ACA** ~~Affordable Care Act~~' s individual mandate to carry health insurance. Further, the Bipartisan Budget Act of 2018, among other things, amended the **ACA** ~~Affordable Care Act~~, effective January 1, 2019, to increase from 50 ~~percent~~ **%** to 70 ~~percent~~ **%** the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D to close the coverage gap in most Medicare drug plans, commonly referred to as the" donut hole" (which, under the IRA, will be replaced by a new manufacturer discount program starting in 2025). In the future, Congress may consider other legislation to modify elements of the **ACA** ~~Affordable Care Act~~ or other health care reform measures, agencies may further alter their implementation of elements of the **ACA** ~~Affordable Care Act~~ or other such measures, and other judicial challenges to elements of the **ACA** ~~Affordable Care Act~~ or other such measures may be brought. The extent to which any such changes may impact our business or financial condition is uncertain. It is possible that the **ACA** ~~Affordable Care Act~~, as currently enacted or may be amended in the future, as well as other healthcare reform measures including those that may be adopted in the future, may result in more rigorous coverage criteria, and less favorable payment methodologies, or other downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement or restriction on coverage under Medicare or other government programs may result in a similar reduction or restriction by private payers. Other legislative changes have been proposed and adopted since the **ACA** ~~Affordable Care Act~~ was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws. Subsequent legislation extended the 2 % reduction, generally to 2031. Sequestration is currently set at 2 % and will increase to 2. 25 % for the first half of fiscal year 2030, to 3 % for the second half of fiscal year 2030, and to 4 % for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. The American Taxpayer Relief Act of 2012 ~~(" ATRA")~~ among other things, also reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and related services and, accordingly, the results of our financial operations. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015 ~~(" MACRA ")~~ which first affected physician payment in 2019. It is unclear how the introduction of the Medicare quality payment program will impact our business. The ~~Inflation Reduction Act of 2022 (" IRA ")~~ introduces several changes to the Medicare Part D benefit, including a limit on annual out- of- pocket costs and a change in manufacturer liability under the program which could negatively affect the profitability of our product candidates. The IRA sunsets the current **Medicare** Part D coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA establishes a Medicare Part B inflation rebate scheme and a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the price of a **Medicare** Part B or Part D drug increases faster than the pace of inflation. Failure to timely pay a **Medicare** Part B or **Part** D inflation rebate is subject to a civil monetary penalty. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologics without generic or biosimilar competition will be capped by reference to, among other things, a specified ~~non~~ **Non** - **FAMP** ~~federal average manufacturer price~~ starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and / or a civil monetary penalty. This or any other legislative change could impact the market conditions for our products. In the EU, the European Commission has published a proposal that intends to reduce the regulatory data protection period and orphan market exclusivity period for new medicinal products. Although it is currently uncertain if the proposal will be adopted in its current form and it is uncertain if and when the revised legislation would enter into force, this reform can impact our product candidates in the EU. There has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills and initiatives, as well as state efforts, designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the U. S. have become increasingly active in passing legislation and implementing 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. Additionally, states have established Prescription Drug Affordability Boards (or similar entities) to review high- cost drugs and, in some cases, set upper payment limits. We expect that these and other healthcare reform measures in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may hinder us in generating revenue, attaining profitability or commercializing our drugs, once marketing approval is obtained. In the EU, the European Commission has published a proposal that intends to reduce the regulatory data protection period for new medicinal products, which would allow generic competitors to obtain marketing authorization for generic products relying on our data earlier than under the current laws and we may be faced with earlier generic competition and lower prices for our product on the EU market. The legislative process for this reform is expected to take several years. Although it is currently uncertain if the proposal will be adopted in its current form and it is uncertain if and when the revised legislation would enter into force, this reform could impact our product candidates in the EU. In the **EU** ~~European Union~~, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of EU Member States. The requirements may differ across the

EU Member States. In markets outside of the U. S. and the **EU** ~~European Union~~, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Also, at the national level, actions have been taken to enact transparency laws regarding payments between pharmaceutical companies and health care professionals. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the U. S., the **EU** ~~European Union~~ or any other jurisdiction. If we or any third parties we may engage with are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Our employees, independent contractors, clinical trial investigators, **CROs** ~~contract research organizations~~, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the U. S. and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. We adopted a code of conduct applicable to all of our employees immediately following the completion of our IPO, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U. S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We, and the third parties with whom we share our facilities, 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. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of 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. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain general liability insurance as well as 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, hazardous or radioactive 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 and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third- party contract manufacturers become subject to injunctions or other sanctions as a result of their non- compliance with environmental, health and safety laws and regulations. For example, we source our API for XDEMVY, lotilaner, from Elanco, who sources through a single source supplier. If such manufacturers become subject to such injunctions or sanctions due to non- compliance, it could delay, prevent or impair our commercialization efforts, which could have an adverse effect on our business. The pharmaceutical legislation reform as proposed by the European Commission in April 2023 would, if adopted, also impose stricter rules regarding the '

Environmental Risk Assessment' that pharmaceutical manufacturers are obliged to perform. Under the proposal for new legislation, non- compliance with the Environmental Risk Assessment requirements could result in the withdrawal or refusal of a marketing authorization. We may be subject to federal, state and foreign healthcare and abuse laws and false claims laws, as well as information privacy and security laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties, criminal sanctions, contractual damages, reputational harm, and diminished profits and future earnings. ECPs and third- party payers will play a primary role in the recommendation and prescription of XDEMVY and any future product candidates we may develop and any product candidates for which we obtain marketing approval. Our arrangements with ECPs, patients, third- party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect our business or financial arrangements and relationships through which we market, sell and distribute our products. As a biopharmaceutical company, federal and state healthcare laws and regulations pertaining to fraud and abuse are applicable to our business and may affect our ability to operate. ~~These laws are further described in the section titled " Business- Government Regulation- Other Regulatory Matters. "~~ We have entered into consulting and scientific advisory board arrangements with physicians and other ECPs, including some who could influence the use of XDEMVY or our product candidates, if approved. Because of the complex and far- reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use of XDEMVY or our product candidates, if approved, to be in violation of applicable laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Various state and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the U. S. Congress continues to strengthen the arsenal of enforcement tools. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Efforts to ensure that our collaborations or business arrangements with third parties, and our business generally, comply with applicable healthcare laws and regulations will likely be costly. 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 and regulations. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgements, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations. U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as " Trade Laws ", prohibit, among other things, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We also expect our non- U. S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. For XDEMVY, or if we receive marketing approval for another product candidate, we are and will continue being subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved. Obtaining coverage and reimbursement approval for a product from a government or other third- party payer is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the

use of our products to the payer. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. 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, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. 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 products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the U. S. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third- party payers often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Coverage and reimbursement by a third- party payer may depend upon a number of factors, including the third- party payer' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. We cannot be sure that reimbursement will be available for XDEMVY or any other product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Reimbursement may impact the demand for, and the price of, XDEMVY or any other product for which we obtain marketing approval. Assuming we obtain coverage for XDEMVY or another given product by a third- party payer, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third- party payers to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. We expect to experience pricing pressures in connection with the sale of XDEMVY or any of our other product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product. Outside of the U. S., many countries require approval of the sale price of a product before it can be marketed and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. 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 candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval. Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), significant fines, private litigation, and / or adverse publicity and could negatively affect our financial condition, operating results and business. We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i. e., laws and regulations that address privacy and data security). In the U. S., numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e. g., Section 5 of the **Federal Trade Commission Act (the"** FTC **Act"**), that govern the collection, use, disclosure, and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 (" HIPAA"). Though we are not directly subject to HIPAA information privacy and security provisions – other than with respect to providing certain employee benefits, depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly receive individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. Furthermore, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, in California, the CCPA, as amended by the **California Privacy Rights Act ("** CPRA **")** , creates transparency requirements, grants to California consumers (as that term is broadly defined) several rights with regard to their personal information, and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide disclosures to California

consumers, and provides such consumers with ways to opt- out of certain sales of personal information. The CPRA introduced significant amendments to the CCPA and established and funded the CPPA. The amendments introduced by the CPRA went into effect on January 1, 2023, and implementing regulations continue to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or potential statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and potential damages. Other states including Virginia, Colorado, Utah, Indiana, Iowa, Tennessee, Montana, Texas, and Connecticut, have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business and we continue to assess the impact of these state legislations on our business as additional information and guidance becomes available. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in areas affecting our business. The CCPA and other state laws could impact our business activities depending on how they are interpreted and exemplify the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and have been proposed and enacted in other states. The **Federal Trade Commission ("** FTC **")** also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5 (a) of the FTC Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions. Activities outside of the U. S. require adherence to local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non- compliance. EU Member States and the United Kingdom (" UK "), as well as other jurisdictions where we may in the future operate, have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU General Data Protection Regulation (" GDPR ") imposes certain obligations and restrictions on the ability to collect, analyze, use, store, disclose, transfer, or otherwise process personal data, including health-related information from clinical trial subjects. The GDPR imposes a broad range of obligations and restrictions relating to the processing and protection of personal data, including ~~obligatoins~~ **obligations** to having a legal basis for processing personal data (which may result in some instances in obtaining the consent of the individuals to whom the personal data relates), providing detailed information about the processing activities disclosed to the individuals, dealing with restrictions on sharing of personal data with third parties, and the transferring of personal data out of the EU, having contractual arrangements in place where required (such as with clinical trial sites and vendors), reporting in certain instances personal data breaches to data protection authorities and / or affected individuals, appointing data protection officers, conducting data protection impact assessments, responding to privacy rights requests, and keeping records of processing activities. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers, or to alleviate problems caused by such breaches. This may be onerous and if our efforts to comply with the GDPR or other applicable EU laws and regulations are not successful, it could adversely affect our business. Recent scrutiny and reevaluation of legal mechanisms to allow for the transfer of personal data from the **European Economic Area ("** EEA **")**, Switzerland, or UK to the U. S. may impact our ability to transfer personal data or otherwise may cause us to incur significant costs to do so legally. Although there are legal mechanisms to allow for the transfer of personal data from the EEA, Switzerland, and the UK to the U. S., uncertainty about compliance with EU data protection laws remains and data protection authorities from the different EU Member States may interpret the GDPR differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the **EU** ~~European Union~~ . Enforcement by EU and UK regulators is generally active, and failure to comply with the GDPR or applicable **EU** Member State / UK local law may result in substantial fines, amongst other things (such as notices requiring compliance within a certain timeframe). The GDPR provides for fines and other administrative penalties in the event of any non- compliance, including fines of up to 10, 000, 000 Euros or up to 2 % of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20, 000, 000 Euros or up to 4 % of our total worldwide annual turnover for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with data protection authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Further, the UK Government may amend / update UK data protection laws, which may result in changes to our business operations and potentially incur commercial cost. Additionally, European / UK data protection laws, including the GDPR, generally restrict the transfer of personal data from the EEA (including the EU), UK, and Switzerland, to the U. S. and most other countries (except those deemed to be adequate by the European Commission / UK Secretary of State as applicable) unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. This may cause us to incur significant compliance costs for implementing lawful transfer mechanisms, conducting data transfer impact assessments, and implementing additional measures where necessary to ensure that personal data transferred are adequately protected in a manner essentially

equivalent to the EU. The GDPR provides different transfer mechanisms we can use to lawfully transfer personal data from the EU to countries outside the EU. An example is relying on adequacy decisions of the European Commission, such as the EU- U. S. Data Privacy Framework which was adopted by the European Commission in 2023 **(" EU- U. S. Data Privacy Framework")** . The adequacy decision concludes that the U. S. ensures an adequate level of protection (compared to that of the EU) for personal data transferred from the EU to U. S. companies participating in the EU- U. S. Data Privacy Framework. The adequacy decisions of the European Commission are subject to periodic reviews and may be amended or withdrawn. Another example of a lawful transfer mechanism under the GDPR is using the EU Standard Contractual Clauses (" EU SCCs ") as approved by the European Commission in 2021. In order to use the EU **SCCs** ~~Standard Contractual Clauses~~ mechanism, the exporter and the importer must ensure that the importer may guarantee a level of personal data protection in the importing country' s level of protection must be adequate that is essentially equivalent to that of the EEA. It follows from case law of the Court of Justice of the **EU** ~~European Union (" CJEU ")~~ and the European Data Protection Board that compliance with EU data transfer obligations involves conducting transfer impact assessments, which includes documenting detailed analyses of data access and protection laws in the countries in which data importers are located, which can be costly and time- consuming. Data importers must also expend resources in analyzing their ability to comply with transfer obligations, including implementing new safeguards and controls to further protect personal data In the UK, international transfer mechanisms have been approved, including: the International Data Transfer Agreement and the International Data Transfer Addendum to the EU SCCs. The UK Information Commissioner' s Office has issued and maintains guidance on how to approach undertaking risk assessments for transfers of UK data to non- adequate countries outside the UK. A lack of valid transfer mechanisms for data subject to EU / UK data protection laws could increase exposure to enforcement actions as described above, and may affect our business operations and require commercial cost (including potentially limiting our ability to collaborate / work with certain third parties and / or requiring an increase in our data processing capabilities in the EU / UK). Further, the ~~European~~ **EU** / UK data protection laws (including laws on international data transfers as set out above) may also be updated / revised, accompanied by new guidance and / or judicial / regulatory interpretations, which could entail further impacts on our compliance efforts and increased cost. Failure to comply with U. S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), significant fines, private litigation, and / or adverse publicity and could negatively affect our financial condition, operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain personal data, as well as the providers who share this personal data with us, may contractually limit our ability to use and disclose the personal data. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy and data protection laws and regulations and / or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security- related safeguards will protect us from the risks associated with the third- party processing, storage and transmission of such information. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. Risks Related to Ownership of our Common Stock The stock price of our common stock may be volatile or may decline regardless of our operating performance and you could lose all or part of your investment. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including: • our failure to achieve product development or commercialization goals or regulatory approval milestones in the timeframe we announce; • overall performance of the equity markets; • our operating performance and the performance of other similar companies; • results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors; • delays in the commencement, enrollment and the ultimate completion of clinical trials; • changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock; • regulatory actions with respect to our product or product candidates; • regulatory or legal developments in the U. S. and other countries; • the level of expenses related to future product candidates or clinical development programs; • changes in hospital or ECP practices; • announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors; • developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights; • recruitment or departure of key personnel; • the economy as a whole and market conditions in our industry; • variations in our financial results or the financial results of companies that are perceived to be similar to us; • financing or other corporate transactions, or inability to obtain additional funding; • trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock; • the expiration of market standoff or contractual lock- up agreements; • the size of our market float; and • any other factors discussed in this report. In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many biopharmaceutical companies. Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If securities or industry analysts cease coverage of us, the trading price for

our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline. ~~We are~~ **As of December 31, 2024, we no longer qualified as** an ~~"~~ emerging growth company **or a** ~~" and"~~ smaller reporting company ~~"~~ and ~~we cannot be~~ **, as a result, are no longer able to avail ourselves of** certain ~~if the~~ reduced reporting requirements applicable to emerging growth companies ~~will make our~~ **or** ~~common stock less attractive to investors. We are an emerging growth company as defined in the Jumpstart our Business Startups Act of 2012, as amended (the " JOBS Act ") and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including: • the option to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure; • not being required to comply with the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley Act of 2002, as amended (the" Sarbanes- Oxley Act"); • not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; • not being required to disclose certain executive compensation- related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer' s compensation to median employee compensation; and • not being required to submit certain executive compensation matters to stockholder advisory votes, such as" say- on- pay,"" say- on- frequency," and" say- on- golden parachutes." The JOBS Act permits an emerging growth company such as us, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected to opt out of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) December 31, 2025, the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (b) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $ 1. 235 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non- affiliates exceeds $ 700 million as of the prior June 30th and (2) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. We are also a smaller reporting company as defined in the Exchange Act of 1934. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to~~ smaller reporting companies **, subject** ~~and will be able~~ to ~~take advantage of~~ **applicable transition relief. On June 28, 2024,** ~~these~~ -- **the** ~~scaled disclosures for so long as~~ **last business day of the second quarter of 2024, the aggregate market value of the shares of** our ~~voting and non- voting~~ common stock held by non- ~~affiliates~~ - **affiliate stockholders exceeded** ~~is less than~~ $ ~~250~~ **700** . 0 million ~~measured~~ **. As a result, we became a large accelerated filer as of December 31, 2024, as defined in Rule 12b- 2 under the Exchange Act, and ceased to qualify as an emerging growth company. Effective December 31, 2024, due to large accelerated filer status, we no longer qualify as a smaller reporting company and accordingly are not permitted to take advantage of the reduced reporting requirements for smaller reporting companies, subject to a transition period that allows us to use smaller reporting company scaled disclosure for our Annual Report** on **Form** ~~the last business day of our second fiscal quarter, or our annual revenue is less than $ 100~~ - **10- K for** ~~. 0 million during~~ the ~~most recently completed fiscal~~ year ~~and~~ **ending December 31, 2024. With the transition to becoming a large accelerated filer, we did not elect to use the smaller reporting company scaled disclosures. As a result of** our ~~voting and non- voting common stock held by non- affiliates is less~~ **loss** ~~than $ 700. 0 million measured on the last business day~~ of **emerging growth company** ~~our second fiscal quarter. Investors may find our common stock less attractive to the extent we rely on the exemptions~~ and **smaller reporting company status, we expect** ~~relief granted by the JOBS Act. If some investors find~~ our ~~common stock less attractive~~ **operating costs to increase** as ~~a result, there may be a less active trading market for our common stock and our stock price may decline or~~ **our** ~~become more volatile~~ **compliance, reporting and other costs increase** . Sales of a substantial number of shares of our common stock in the public market could cause the price of our common stock to fall. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to decline. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of ~~February 21~~ **December 31** , 2024, we had **38,** ~~34~~ **349** , **826** ~~218, 886~~ shares of common stock outstanding. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act of 1933 **, as amended, (" Securities Act")** and various vesting agreements. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding warrant or options, or the perception that such sales may occur, could adversely affect the market price of our common stock. We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, including pursuant to our **2023** ATM ~~program~~ **Prospectus** , convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. For example, in ~~August~~ **March** ~~2023~~ **2024** we completed a follow- on public

offering of ~~5~~ **3** . ~~7~~ **3** million shares of our common stock at a public offering price of $ ~~17~~ **32** . ~~50~~ **00** per share **and, in lieu of common stock to a certain investor, pre- funded warrants to purchase 312, 500 shares of our common stock at a price of $ 31. 9999 per pre- funded warrant,** for **aggregate** net proceeds of approximately $ ~~99~~ **107** . ~~3~~ **7** million (after deducting underwriting discounts, commissions and other estimated offering- related expenses) and in ~~the fourth quarter of~~ 2023 we raised approximately $ 19. 2 million, after deducting broker commissions and fees, through sales under our **2023** ATM ~~program~~ **Prospectus** . To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval. As of December 31, ~~2023~~ **2024** , our officers, directors and the holders of more than 5 % of our outstanding stock collectively beneficially own approximately ~~67~~ **50** % of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial. Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention. As a public company, we are subject to the reporting requirements of the Exchange Act ~~of 1934~~ , or the other rules and regulations of the ~~Securities and Exchange Commission (the "~~ SEC ~~")~~ , or any securities exchange relating to public companies. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management and we will incur significant legal, accounting and other expenses. We cannot assure you that we will satisfy our obligations as a public company on a timely basis. In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may 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 personnel to serve on our ~~board~~ **Board** of ~~directors~~ **Directors** , our board committees or as executive officers. If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business. We are subject to the reporting requirements of the Exchange Act ~~of 1934~~ , the Sarbanes- Oxley Act and the rules and regulations of ~~the~~ Nasdaq. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. We must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes- Oxley Act. Therefore, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engaging outside consultants, continue to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This requires us to incur substantial professional fees and internal costs to maintain compliance. 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 over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities including equivalent foreign authorities. We do not intend to pay dividends for the foreseeable future. We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Our **2024** Credit Facility also contains a negative covenant that prohibits us from paying dividends subject to limited exceptions. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment. We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance. Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Our operating results may fluctuate due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following: • the cost of manufacturing XDEMVY or our other product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers; • the level of demand for XDEMVY or our product candidates should they receive approval, which may vary significantly; • the risk / benefit profile, cost and reimbursement policies with respect to XDEMVY or our product candidates, if approved, and existing and potential future drugs that compete with our product candidates; • the gross- to- net yields for

XDEMVY or our other product candidates, if approved; • the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; • our ability to successfully recruit patients for preclinical studies and clinical trials, and any delays caused by difficulties in such recruitment efforts; • our ability to obtain regulatory approval for our product candidates, and the timing and scope of any such approvals we may receive; • the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time; • our ability to attract, hire and retain qualified personnel; • expenditures that we will or may incur to develop additional product candidates; • the changing and volatile U. S., ~~European~~ **EU** and global economic environments, including the impact of current or future health pandemics; and • future accounting pronouncements or changes in our accounting policies. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock. Our status as a Delaware corporation and the anti- takeover provisions of the Delaware General Corporation Law **("DGCL")** may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following: • a classified ~~board~~ **Board** of ~~directors~~ **Directors** with three- year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our ~~board~~ **Board** of ~~directors~~ **Directors** ; • the ability of our ~~board~~ **Board** of ~~directors~~ **Directors** to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror; • the exclusive right of our ~~board~~ **Board** of ~~directors~~ **Directors** to elect a director to fill a vacancy created by the expansion of our ~~board~~ **Board** of ~~directors~~ **Directors** or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our ~~board~~ **Board** of ~~directors~~ **Directors** ; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • the requirement that a special meeting of stockholders may be called only by a majority vote of our entire ~~board~~ **Board** of ~~directors~~ **Directors** , the ~~chairman~~ **Chairman** of our ~~board~~ **Board** of ~~directors~~ **Directors** ~~or our~~ **or our** ~~chief~~ **Chief** ~~executive~~ **Executive** ~~officer~~ **Officer** , which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; • the requirement for the affirmative vote of holders of at least 66 2 / 3 % of the voting power of all of the then- outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; and • advance notice procedures with which stockholders must comply to nominate candidates to our ~~board~~ **Board** of ~~directors~~ **Directors** or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror' s own slate of directors or otherwise attempting to obtain control of us. In addition, as a Delaware corporation, we are subject to Section 203 of the **DGCL** ~~Delaware General Corporation Law~~ . These provisions may prohibit large stockholders, in particular those owning 15 % or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our ~~board~~ **Board** of ~~directors~~ **Directors** or initiate actions that are opposed by our then- current ~~board~~ **Board** of ~~directors~~ **Directors** , including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U. S. federal district courts are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the **DGCL** ~~Delaware General Corporation Law~~ , our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act ~~of 1934~~ . Furthermore, Section 22 of the Securities Act ~~of 1933~~ creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our certificate of incorporation will further provide that the U. S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those

designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. This 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 and may discourage these types of lawsuits. 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.