

Risk Factors Comparison 2025-03-18 to 2024-03-21 Form: 10-K

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Our business involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this Annual Report on Form 10-K, including our financial statements and related notes appearing at the end of this Annual Report on Form 10-K. The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment. This Annual Report on Form 10-K also contains forward-looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks Related to Our Financial Position and Need for Additional Capital We are a clinical stage **biopharmaceutical oncology** company with a limited operating history and have incurred significant losses since our inception. ~~We expect~~ **and anticipate that we will continue** to incur losses over at least the next several years and may never achieve or maintain profitability. We are a clinical stage **biopharmaceutical oncology** company with a limited operating history. Since our inception, we have incurred significant operating losses. We reported net losses of \$ **77.3 million and \$ 73.8 million** and \$ 120.7 million for the years ended December 31, **2024 and 2023** and 2022, respectively. As of December 31, **2023-2024**, we had an accumulated deficit of \$ **286.363.26** million. To date, we have not generated any **revenue-revenues** from product sales and have financed our operations primarily through ~~sales of our equity interests~~ **offerings**. As such, we expect that it will be several years, if ever, before we have a product candidate ready for regulatory licensure and commercialization. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. To become and remain profitable, we must succeed in developing, obtaining marketing licensure for and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including, without limitation, procuring clinical- and commercial- scale manufacturing, successfully completing preclinical studies and clinical trials of our product ~~candidates-~~ **candidate**, establishing arrangements with third parties for the conduct of our clinical trials, obtaining marketing licensure for our product ~~candidates-~~ **candidate**, manufacturing, marketing and selling any products for which we may obtain marketing licensure, discovering or obtaining rights to additional product candidates, identifying collaborators to develop product candidates we identify or additional uses of existing product candidates and successfully completing development of product candidates for our collaboration partners. ~~In addition, for certain of our licensees from whom we are entitled to receive royalty payments if they successfully develop and commercialize any products covered by the licenses we acquired in the Merger, there is no guarantee that their product development and commercialization will lead to any such payments even if any such product candidates receive regulatory approval for commercial sale. For Beovu (brovacizumab-dblb), which is currently commercialized by Novartis, and we are now receiving, sales-based royalties that are currently fully constrained and recorded as deferred revenue on our consolidated balance sheet, as discussed below, there is still no guarantee of ongoing payment of royalties, as Novartis has disputed its obligation to pay royalties to Apexigen under the ESBA Tech Agreement and continues to pay such royalties under protest. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we:~~

- **manufacture product candidates and continue to develop and, conduct clinical trials for our ADC product candidate, PYX-201, and seek regulatory approvals for micvotabart pelidotin**
- **our IO product candidates, PYX-106 and PYX-107;**
- **continue research and select antibody programs to take into development, manufacture activities for other product candidates, conduct IND enabling studies and submit INDs and initiate, conduct and successfully complete clinical trials;**
- **scale up external manufacturing capabilities for later stage trials and to commercialize our products;**
- **expand, maintain and protect our intellectual property portfolio** ~~seek marketing licenses for any product candidates that successfully complete clinical trials;~~
- **ultimately establish a sales, marketing and distribution infrastructure for which we may obtain marketing licensure;**
- **leverage the APXiMAB Platform and FACT Platform to identify and then advance additional product candidates into preclinical and clinical development;**
- **expand, maintain and protect our intellectual property portfolio;**
- **hire additional clinical, regulatory, scientific, operational, financial and management information personnel;** and
- **continue to operate as a public company.**

Our expenses could increase beyond our expectations if we are required by the U. S. Food and Drug Administration (~~-, or FDA~~), the European Medicines Agency (~~-, or EMA~~) or other comparable regulatory authorities to perform trials in addition to those that we currently expect to perform, or if we experience any delays in establishing appropriate manufacturing arrangements for completing our clinical trials or the clinical development of ~~any of our product candidates-~~ **candidate**. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue operations. A decline in the value of our company, or in the value of our common stock, could also cause investors to lose all or part of their investment. ~~If one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing those approved product candidates.~~ Even if we are able to generate revenues from the sale or out-licensing of any approved products, we may not become profitable and may need

to obtain additional funding to continue operations. We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and product development programs or future commercialization efforts. The development of biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing **and planned** activities, particularly as we continue our clinical trials ~~of for micvotabart pelidotin. We currently expect that~~ our product candidates **PYX-106 and PYX-107** ~~existing cash, cash equivalents and short-term investments of \$ 126.9 million as of December 31, 2024, will fund~~ **existing cash, cash equivalents and short-term investments of \$ 126.9 million as of December 31, 2024, will fund** ~~other~~ **the second half** preclinical research and development programs. For example, to refocus development efforts and spending towards our most advanced programs, we have elected to pause preclinical development of **2026 PYX-203 and PYX-102**. Even if ~~one or our~~ **one or more of** the product candidates ~~candidate~~ that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other comparable regulatory authorities to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Accordingly, we will need to obtain substantial additional funding in order to continue our operations. ~~As of December 31, 2023, we had approximately \$ 119.3 million in cash, cash equivalents, and short-term investments. Following the end of fiscal year 2023, on January 30, 2024, we issued additional shares under our ATM offering program that resulted in net proceeds of \$ 10.6 million, after deducting placement agent commissions. Additionally, on February 29, 2024, we completed the Private Placement, as described below, which resulted in gross proceeds of \$ 50 million, before deducting placement agent commissions and other offering expenses. We believe that our cash, cash equivalents and short-term investments as of December 31, 2023, along with proceeds from the ATM and the proceeds from the Private Placement will be sufficient to fund our operations into the second half of 2026. Our estimate as to how long we expect to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, including market volatility resulting from global economic developments, political unrest, high inflation and other factors, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. We intend to use our cash and cash equivalents for development and regulatory activities relating to our product candidates candidate, discovery programs, business development activities and other general corporate purposes. Advancing the development of our product candidates candidate will require a significant amount of capital. Our cash and cash equivalents will not be sufficient to fund any of our product candidates candidate through regulatory licensure. Because the length of time and activities associated with successful research and development of any individual product candidate are highly uncertain, we are unable to estimate the actual funds we will require for development, marketing licensure and commercialization activities. The timing and amount of our operating expenditures will depend largely on:~~

- ~~the manufacture of product candidates~~ **cost associated with dose escalation and conduct of Phase I dose expansion mono and combo** clinical trials for **PYX-201 our product candidate**; • **the manufacture of drug products and drug substance** **PYX-106** and clinical trials for **PYX-107 our product candidate**;
- the timing and progress of our other preclinical and clinical development activities;
- the number and scope of other preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into in-licensing, collaborations and research and development agreements;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates candidate for which we receive marketing licensure;
- our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting, maintaining and enforcing **and expanding** patent and other intellectual property rights;
- ~~any delays or interruptions that we experience in our preclinical studies, clinical trials and/or supply chain~~;
- the cost and timing of regulatory licenses; and
- **insurance** our efforts to hire additional clinical, **legal and other** regulatory **compliance expenses to operate as a public company**, scientific, operational, financial and management personnel.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our ~~research and development programs and preclinical studies or clinical trials~~, ~~if any~~, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. ~~We do not expect to realize any revenue from sales of products or any significant revenue from royalties from licensed products in the foreseeable future, if at all, and not until our product candidates are clinically tested, licensed for commercialization and successfully marketed. To date, we have primarily financed our operations through the sale of equity securities. We will be required to seek additional funding in the future and our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. For example, market volatility resulting from global economic developments, political unrest, high inflation and other factors could adversely impact our ability to access capital as and when needed. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. 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~~

incorporated in 2018 and staffing and meaningful operations commenced in mid-2019 and our operations to date have been focused on developing and conducting preclinical and, since the first quarter of 2023, initiating Phase 1 clinical trials of our product candidates. To date, we have not yet demonstrated our ability to successfully complete a clinical trial, obtain marketing licenses, manufacture a commercial scale product directly or through a third party, or conduct sales, marketing, and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or if we had already successfully completed some or all of these types of activities. In addition, as a clinical stage biopharmaceutical company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities and we may not be successful in making that transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition or results of operations. Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations.

Risks Related to the Development of our Product Candidate Clinical testing and product development is a lengthy and expensive process with an uncertain outcome. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete future strategic acquisitions, the clinical testing and the development and commercialization of or our successfully integrate strategic acquisitions product candidate. Before obtaining marketing approval from regulatory authorities for the sale of our product candidate, we or our collaborators must conduct extensive trials to demonstrate the safety and efficacy of the product candidate. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the timing and outcome. A failure of one or more clinical trials can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, clinical trials, which could delay adversely affect our or prevent our business and financial condition. Our inability -- ability to complete any future strategic acquisitions receive marketing licensure or commercialize or our product candidate, including: • delays in reaching, or the failure to successfully integrate any new reach, a consensus with regulators on clinical trial design; • the supply or quality of or our previous strategic acquisitions could product candidate or other materials necessary to conduct clinical trials of our product candidate may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing and delivery of product candidate to the clinical sites by us or by third parties with whom we have a contracted to perform certain of those functions; • delays in reaching, or the failure to reach, agreement on acceptable clinical material --- reaching, or the failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; • the failure of regulators or institutional review boards to authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • difficulty in designing clinical trials and in selecting endpoints for diseases that have not been well studied and for which the natural history and course of the disease is poorly understood; • the selection of certain clinical endpoints that may require prolonged periods of clinical observation or analysis of the resulting data; • we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials; • the number of patients required for clinical trials of our product candidates candidate may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may fail during screening or drop out of these clinical trials at a higher rate than we anticipate or fail to return for post-treatment follow-up or the failure to recruit suitable patients to participate in our clinical trials; • our product candidates candidate may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate our clinical trials; • we may have to suspend or terminate clinical trials of our product candidates candidate for various reasons, including a finding that the participants are being exposed to unacceptable health safety risks or that the benefit-risk ratio is negative; • the third parties with whom we contract may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • the requirement from regulators or institutional review boards that we or our investigators suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements or unacceptable safety risks; • clinical trials of our

product candidates— **candidate** may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product candidate development and discovery programs; • the cost of clinical trials of our product candidates— **candidate** may be greater than we anticipate; • imposition of a clinical hold by regulatory authorities as a result of a serious adverse—adverse effect on— **event, concerns with the class of our product candidate** our— or after business. We may continue to seek attractive opportunities to acquire businesses, enter into joint ventures and— **an inspection of our clinical trial operations, trial sites or manufacturing facilities; • occurrence of serious adverse events associated with other— the investments product candidate** that are complementary—viewed to **outweigh its potential benefits; • regulators may revise the requirements for approving our product candidate, our— or existing strengths. There such requirements may not be as we anticipate; and • delays in developing and validating any companion diagnostic to be used in the trial, to the extent we** are to the extent we are required to do so. **The** FDA may modify or enhance clinical trial requirements which may affect enrollment and retention of patients. In August 2023, **the** FDA published a guidance document, Informed Consent, Guidance for **Institutional Review Boards (IRBs)**, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. FDA’s new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial, which may increase costs and delay clinical programs. Further, in December 2023, **the** FDA published a final rule, Institutional Review Board Waiver or Alteration of Consent for Minimal Risk Clinical Investigations, which allows exceptions from informed consent requirements when a clinical investigation poses **no more than no assurances more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, however safety, and welfare of human subjects. If we are required to conduct additional clinical trials or other testing of our product candidate beyond those** that a final rule, Institutional Review Board Waiver or Alteration of Consent for Minimal Risk Clinical Investigations, which allows exceptions from informed consent requirements when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. 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— **candidate** or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • be delayed in obtaining marketing licenses— **licensure** for our product candidates— **candidate**; • not obtain marketing licensure at all; • obtain licensure for indications or patient populations that are not as broad as intended or desired; • obtain licensure with labeling that includes **significant use or distribution restrictions or safety warnings; • be required to perform additional clinical trials to support marketing licensure; • have regulatory authorities withdraw or suspend their license, or impose restrictions on distribution of the product candidate in the form of a modified REMS; • be subject to additional post- marketing testing requirements or changes in the way the product is administered; • fail to receive approval of any companion diagnostics** strategic acquisition opportunities will arise or, if they do, that may they will be required by the FDA consummated. Certain acquisitions may be difficult to complete for— or a number— **comparable foreign regulatory authorities in connection with approval** of reasons, including the need to satisfy customary closing conditions, the need for antitrust and / or our therapeutic product candidate; or • have our product removed from the market after obtaining marketing licensure. For example, the FDA launched Project Optimus in 2021 as an initiative to reform the dose optimization and dose selection paradigm in oncology drug development, which was driven by the FDA’s concerns that the current paradigm for dose selection may result in doses and schedules of molecularly targeted therapies that are inadequately characterized before initiating pivotal trials. Through collaboration with the biopharmaceutical industry, academia and other stakeholders regulatory approvals, the FDA’s goal for this initiative is to advance an oncology dose-finding and dose optimization paradigm that emphasizes dose selections that maximize efficacy as well as **disputes safety and tolerability. In support of this initiative and as described in a 2023 draft guidance “Optimizing the Dosage of Human Prescription Drugs and Biological Products** or for litigation— **the Treatment of Oncologic Diseases” the FDA will likely request sponsors of oncology product candidates to conduct dose optimization studies pre- approval. Any strategic acquisition—The FDA also continues to develop and finalize guidance documents and implement initiatives regarding the development and clinical research of oncology product candidates. Our product development costs also will increase if we may complete—may experience delays in preclinical studies or clinical trials or in obtaining marketing licensure. We do not know whether any of our preclinical studies or clinical trials will need to be made—restructured or will be completed on schedule, or at all. Significant preclinical study** a substantial premium over the fair value of the net identifiable assets of the acquired company and thus our— or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates— **candidate**, or could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates— **candidate**, which may harm our business, results of operations, financial condition and prospects. Further, cancer therapies sometimes are characterized as first -line, second -line or third -line. The FDA often approves or licenses new oncology therapies initially only for third -line or later use, meaning for use after two or more other treatments have failed. When cancer is detected early enough, first -line therapy, usually **hormone therapy, surgery, realization— - radiation therapy, immunotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second line and third line therapies are administered to patients when prior therapy is not effective. Our clinical trials are, and any future clinical trials will be, with patients with difficult to treat cancer. We expect that we would initially seek regulatory licensure for use of this product candidate in appropriate treatment settings** value relies on successful integration and continued operations—. We Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek licensure potentially as a first line therapy, but any product candidate we develop, even if approved for second line or third line therapy, may not be **approved** able to integrate acquired businesses successfully into our existing businesses, make such

businesses profitable, retain key employees or **for first line therapy and** realize anticipated cost savings or synergies, if **prior to seeking and / or receiving** any **licensures**, from these acquisitions, which could adversely affect our business and financial condition. Further, our ongoing business may be disrupted, and our management's attention may be diverted by acquisitions, investments, transition and / or **for first line therapy** integration activities. **Risks Related to the Merger** We may fail to realize the benefits and synergies expected from the Merger, which could adversely affect our stock price. The anticipated benefits and synergies we expect from the Merger are, necessarily, based on projections and assumptions about the combined businesses of Pyxis Oncology and Apexigen, which may **have** not materialize as expected or which may prove to be inaccurate. **conduct additional clinical trials**. The value of our common stock could be adversely affected if we are unable to realize the anticipated benefits and synergies from the Merger on a timely basis or at all. We cannot predict with certainty if or when any benefits and synergies from the Merger will be realized, or the extent to which they will actually be achieved. Whether we realize any benefits or synergies could be affected by the factors described in other risk factors contained in this report and a number of factors beyond our control, including, without limitation, general economic conditions, increased operating costs and regulatory developments. We may be unable to appropriately integrate the business, operations and assets of Apexigen into our existing business. Achieving the benefits of the Merger will depend, in part, on our ability to integrate the business, operations and assets of Apexigen successfully and efficiently with our business. The challenges involved in this integration, which will be complex and time-consuming, include, without limitation, the following: • difficulties integrating new and existing technologies, systems and processes into our platform and operations; • successfully managing relationships with the combined supplier base of Pyxis Oncology and Apexigen; • coordinating and integrating independent research and development teams across platforms while reducing costs; • consolidating and integrating procurement, research and development activities and processes and management and administrative functions; • limitations or encumbrances on certain Apexigen intellectual property or other difficulties integrating Apexigen intellectual property into our portfolio; • the increased scale and complexity of our operations resulting from the Merger; and • minimizing the diversion of our management's attention from other important business objectives. If we do not successfully manage these and other challenges inherent in integrating an acquired business of the size and complexity of Apexigen into our business, then we may not achieve the anticipated benefits of the Merger and our expenses, operating results and financial condition could be materially and adversely affected. The acquisition of Apexigen may result in significant charges or other liabilities that could adversely affect the financial results of the combined company. The financial results of the combined company may be adversely affected by cash expenses and non-cash accounting charges incurred in connection with Pyxis Oncology's integration of the business and operations of Apexigen. The amount and timing of these possible charges are not yet known. Further, our failure to identify or accurately assess the magnitude of certain liabilities we are assuming in the Merger could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, unexpected increases in taxes due, a loss of anticipated tax benefits or other adverse effects on our business, operating results or financial condition. The price of our common stock could decline to the extent the combined company's financial results are materially affected by any of these events. Pyxis Oncology's future results will suffer if it does not effectively manage its expanded operations following the Merger. The size and scope of operations of the business of the combined company has increased beyond the size and scope of operations of either Pyxis Oncology's or Apexigen's businesses prior to the completion of the Merger. Our future success depends, in part, upon our ability to manage our expanded business, which may pose substantial challenges for our management, including challenges related to the management and monitoring of new operations, products and locations and associated increased costs and complexity. There can be no assurances that we will be successful in managing such expanded business or that we will realize the expected economies of scale, synergies and other benefits currently anticipated from the Merger. **Risks Related to the Discovery and Development of our Product Candidates** We are heavily dependent on the success of **our product candidate, micvotabart pelidotin** PYX-201 and PYX-106, which **are-is** in the early stages of **clinical** development. **If micvotabart pelidotin**, and PYX-107, which is in a Phase II clinical trial. If PYX-201, PYX-206 and / or PYX-107 are not successful in clinical trials or **do does** not receive regulatory approval or licensure or **are-is** not successfully commercialized, our business will be materially and adversely affected. To date, we have invested a significant portion of our efforts and financial resources in the development of **micvotabart pelidotin** PYX-201 and PYX-106, and Apexigen had invested a significant portion of its efforts and financial resources in the development of PYX-107. Our future success is substantially dependent on our ability to successfully initiate and complete clinical development for, obtain regulatory licensure for, and successfully commercialize **micvotabart pelidotin** PYX-201, PYX-106 and PYX-107, which may never occur. We currently have no products that are approved or licensed for commercial sale and may never be able to develop a marketable product. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the **development of, and related clinical and other activities associated with, advancing PYX-201, PYX-106 and PYX-107, which will require** clinical development, management of clinical and manufacturing activities, regulatory licensure, establishing commercial scale manufacturing, and significant sales, marketing, and distribution efforts **related to micvotabart pelidotin** before we can generate any revenues from any commercial sales. We cannot be certain that we will be able to successfully complete any of these activities or that, even if **micvotabart pelidotin** PYX-201, PYX-106 and PYX-107, **receive-receives** regulatory licensure, such **products- product** will be able to successfully compete against therapies and technologies offered by other companies. The research, testing, manufacturing, labeling, licensure, sale, packaging, marketing, and distribution of biological products are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries. We are not permitted to market **micvotabart pelidotin** PYX-201, PYX-106 or PYX-107, in the **United States U. S.** until we receive licensure of a **Biologics License Application, or BLA**, or **New Drug Application, or NDA**; from the FDA for such product **candidates- candidate**, as appropriate. Further, we are not permitted to market **micvotabart pelidotin** PYX-201, PYX-106 or PYX-107, in any foreign countries until we receive the requisite licensure or approvals from such countries. We have not submitted a BLA or NDA to the FDA or comparable applications to any other comparable

regulatory authorities for **micvotabart pelidotin** PYX-201, PYX-106 or PYX-107. We will not be in a position to do so for several years, if ever. If we are unable to obtain the necessary regulatory licensure or approvals for **micvotabart pelidotin** PYX-201, PYX-106 or PYX-107, in a country, we will not be able to commercialize such product candidate in that country. As a result, our financial position will be materially adversely affected, and we may not be able to generate sufficient revenue revenues to continue our business. The outcome of preclinical testing for PYX-201 and PYX-106 and early clinical trials for PYX-107 may not predict the success of later clinical trials, and the results of clinical trials for PYX-107 may not satisfy the requirements of the FDA, EMA, or comparable foreign regulatory authorities. PYX-201, PYX-106 and PYX-107 is in the early stages of development and is not currently approved for sale and there is no guarantee that it will ever be marketable. Clinical failure can occur at any stage of clinical development. We are required to demonstrate with substantial evidence through well-controlled clinical trials the safety and efficacy of PYX-201, PYX-106 and PYX-107 in a diverse population before we can seek marketing approvals for its commercial sale. Success in preclinical studies for PYX-201, PYX-106 and early-stage clinical trials for PYX-107 does not mean that future larger registration clinical trials will be successful. This is because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. We do not know whether any clinical trials we may conduct for PYX-201, PYX-106 and PYX-107 will demonstrate consistent or adequate efficacy and safety results sufficient to obtain marketing approval. For example, clinical trial subjects treated with PYX-107 have experienced adverse events that have been considered treatment-related. The majority of these events were mild/moderate in severity, responded to symptomatic treatment and/or were transient and resolved with time. Serious, including sometimes fatal, adverse events, or SAEs, have been reported in clinical studies with PYX-107. The majority of these SAEs were considered unrelated to PYX-107 by the investigators. Some SAEs were considered at least possibly related to PYX-107 as well as possibly to other therapies it was combined with. These possibly related events have included infusion-related reactions, cytokine release syndrome, elevated liver enzymes, bilirubin, fever, and colitis. Less frequent related SAEs reported in one patient each have included kidney injury, hepatic failure, bleeding, immune-mediated encephalitis, myositis, and optic neuritis. Many of these SAEs were also considered possibly related to the chemotherapy, radiation or anti-PD(L)-1 agent that were used in combination or were assessed as not related to PYX-107 after a safety review by the trial sponsor. In addition, even if PYX-107 is approved for commercial sale, the success of PYX-107 would depend on a number of factors beyond our control, including emerging and competing therapies and the market acceptance and adoption of PYX-107 versus actual or perceived competing therapies. Our product candidates—**candidate** may fail in development or suffer delays that materially and adversely affect their/its commercial viability. If we or our existing or future collaborators are unable to initiate and complete clinical development of, obtain regulatory approval or licensure for or commercialize our product candidates—**candidate** or experience significant delays in doing so, our business will be materially harmed. We have no products on the market and only three of our product candidates are currently in clinical development. As a result, the risk of failure for such products is high. Our ability to achieve and sustain profitability depends on obtaining regulatory licensure for and successfully commercializing our product candidates—**candidate**, either alone or with third parties. Before obtaining regulatory licensure for the commercial distribution of our product candidates—**candidate**, we or an existing or future collaborator must conduct extensive preclinical studies and clinical trials to demonstrate the safety, purity and potency in humans of our product candidates. In addition, the development of novel antibodies is complex and difficult. Although our discovery and preclinical programs may initially show promise in identifying potential product candidates, they may not translate into product candidates for clinical development for a number of reasons, including that the target selection methodology we use may not be successful due to our inability to generate an applicable antibody candidate. In addition, several of our product candidates are in-licensed or acquired and we continue to look for additional product candidates to in-license or acquire. Our preclinical studies or clinical trials may not replicate or advance the results of the research programs and pre-clinical studies that were completed prior to our in-licensing or acquisition of product candidates. We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory licensure of, or our ability to commercialize, a product candidates—**candidate**, including: • negative or inconclusive results from preclinical studies or clinical trials leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program; • product-related side effects experienced by participants in our clinical trials or by individuals using therapeutic biological products similar to our product candidates—**candidate**; • failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced; • conditions imposed by the FDA, the EMA or other comparable authorities regarding the scope or design of our clinical trials; • delays in enrolling patients in clinical trials; • high drop-out rates of patients; • inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials; • greater than anticipated clinical trial costs; • poor effectiveness of our product candidates—**candidate** during clinical trials; • unfavorable FDA or other comparable regulatory agency inspection and review of a clinical trial site; • failure of our third party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all; • delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or • varying interpretations of data by the FDA, the EMA and other comparable foreign regulatory authorities; or • **landscape changes around market access and pricing policies that may impact reimbursement and product sales**. If any of the foregoing circumstances occur, we could experience significant delays or an inability to successfully commercialize our product candidates—**candidate**, which could materially harm our business. Moreover, if we do not receive regulatory approvals, we may not be able to continue our operations. We have no experience as a company completing a clinical trial or submitting a BLA or NDA and may be unable to successfully do so for **micvotabart pelidotin** PYX-201, PYX-106 and PYX-

107. The conduct of a clinical trial is a long, expensive, complicated and highly regulated process. Although certain of our employees have conducted successful clinical trials and made regulatory submissions in the past across many therapeutic areas while employed at other companies, we, as a company, have not completed any clinical trials, or submitted a BLA or NDA, and as a result may require more time and incur greater costs than we anticipate. Failure to commence or complete, or delays in, our clinical trials or planned regulatory submissions would prevent us from, or delay us in, obtaining regulatory approval of and commercializing **micvotabart pelidotin** PYX-201, PYX-106 and PYX-107, which would adversely impact our financial performance. Large-scale clinical trials would require significant additional financial and management resources and **heavier** reliance on third-party clinical investigators **research organizations (CROs)** and consultants. Relying on third-party ~~clinical investigators~~, CROs, and consultants may cause us to encounter delays **or other operational issues** that are outside of our control. **Although our** ~~In addition, relying on third parties~~ **are required** in the conduct of our preclinical studies or clinical trials ~~exposes us to a risk that they may not adequately~~ comply with good laboratory practice (~~, or GLP, or~~) and good clinical practice (~~, or GCP~~), ~~as required~~ for any studies or trials we plan to submit to a regulatory authority ~~, and have historically~~ **complied, relying on third parties in the conduct of our preclinical studies or clinical trials exposes us to a risk that they may not adequately comply with GLP or GCP in the future**. We may be unable to identify and contract with sufficient investigators, CROs and consultants on terms that are acceptable to us on a timely basis or at all. We may not be able to submit INDs to commence additional clinical trials on the timelines we expect and, even if we are able to, the FDA may not permit us to proceed. We may submit additional INDs in the future. We may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing us to commence clinical trials or that, once begun, issues will not arise that lead to the suspension or termination of our clinical trials. Additionally, even if the applicable regulatory authorities agree with the design and implementation of the clinical trials set forth in our INDs, we cannot guarantee that those regulatory authorities will not change their requirements in the future, or that circumstances will not arise under which FDA or other regulatory authorities may place our clinical trials on partial or full clinical hold. These considerations apply to the INDs described above and also to new clinical trials we may submit as amendments to existing INDs or as part of new INDs in the future. Any failure to submit INDs on the timelines we expect or to obtain authorization to proceed with our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, purity and potency of ~~any of our product candidates~~ **candidate**, which would prevent or delay development, regulatory approval or licensure and commercialization. Before obtaining regulatory licensure for the commercial sale of ~~any of our product candidates~~ **candidate**, including PYX-201, PYX-106 and PYX-107, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product ~~candidates~~ **candidate** ~~are is~~ safe, pure, and potent, as required under a BLA. Preclinical and clinical testing is expensive and can take many years to complete and the outcome of these activities is inherently uncertain. Failure can occur at any time during the preclinical ~~study studies~~ and clinical trial processes and, because our product ~~candidates~~ **candidate** ~~are is~~ in an early stage of development, there is a high risk of failure. In addition, any failures or adverse outcomes in preclinical or clinical testing seen by other developers of similar product candidates could materially impact the success of our ~~programs~~ **program**. We may never succeed in developing marketable products. It is also possible that the results of preclinical studies and early clinical trials of our product ~~candidates~~ **candidate** may not be predictive of the results of later-stage clinical trials. Although ~~our~~ product ~~candidates~~ **candidate** may demonstrate promising results in preclinical studies and early clinical trials, ~~they it~~ may not prove to be effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and, therefore, the results of animal studies may not accurately predict human experience. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety, purity, and potency profile despite having progressed successfully through preclinical studies and / or initial clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety, purity and potency in large-scale pivotal clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of potency, insufficient durability of potency or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved or licensed for commercialization. In addition, preclinical studies or clinical trials we conduct may contradict, undermine or otherwise not replicate or advance the results of the research programs and ~~pre-clinical~~ **preclinical** studies that were completed prior to our in-licensing or acquisition of product candidates, which may materially and adversely affect our business, results of operations and prospects. Additionally, our PYX-201 and PYX-106 ~~101~~ Phase 1 clinical trials ~~trial is~~ ~~are, and~~ ~~an~~ **we expect that the first clinical trials for our other product candidates may be, open-label studies study**, where both the patient and investigator know whether the patient is receiving the investigational product candidate ~~or an existing licensed biological product~~. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. ~~The~~ **For instance, the** FDA may also not consider open-label clinical trials to be adequate and well controlled trials sufficient to support BLA licensure. Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, purity, and potency necessary to obtain regulatory licensure to market our product ~~candidates~~ **candidate**. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, purity, and potency of our product ~~candidates~~ **candidate**, if we do not meet the clinical endpoints with statistical and clinically meaningful significance or if there are safety concerns associated with our product ~~candidates~~ **candidate**, we may be

prevented or delayed in obtaining marketing licensure for ~~those~~ **the** product ~~candidates~~ **candidate**. In some instances, there can be significant variability in safety, purity, and potency results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. If that were to occur, or if other developers of similar products were to find an unacceptable severity or prevalence of side effects with their candidates, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny licensure of our product ~~candidates~~ **candidate** for any or all targeted indications. Product-related side effects could also affect patient recruitment or the ability of enrolled patients to complete an ongoing trial or result in potential product liability claims. ~~See also “The outcome of preclinical testing for PYX-201 and PYX-106 and early clinical trials for PYX-107 may not predict the success of later clinical trials, and the results of clinical trials for PYX-107 may not satisfy the requirements of the FDA, EMA, or comparable foreign regulatory authorities.”~~ Any of these occurrences may significantly harm our business, financial condition and prospects. Further, our product ~~candidates~~ **candidate** could cause undesirable side effects in clinical trials related to on-target toxicity. If ~~on-target toxicity~~ **an unacceptable safety profile** is observed or if our product ~~candidates~~ **candidate** ~~have~~ **has** characteristics that are unexpected, we may need to abandon ~~their~~ **its** development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early ~~stage~~ testing for treating cancer have later been found to cause side effects that prevented further development of the compound. **Interim** Our preclinical programs may experience ~~delays or may never advance to~~ **top-line and preliminary data from our** clinical trials **that we announce**, which would adversely affect our ~~or publish from~~ ability to obtain regulatory approval or licensure or commercialize these programs on a timely ~~time basis or at all to time~~ **may change as more patient data become available and are subject to audit and verification procedures that could result in material changes to the final data**. In order ~~From time to time, we may~~ **publish interim** to **top** obtain FDA, European Commission (based on the opinion of the EMA’s Committee for Human Medicinal Products, or CHMP) or other comparable licensure to market a new biological product, we must demonstrate proof of safety, purity and potency or efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled ~~line or preliminary data from our~~ clinical trials. ~~Before~~ **For example, in November 2024, we can commence announced preliminary data from our Phase I clinical trial of micvotabart pelidotin. Preliminary data from** clinical trials ~~that for a product candidate, we must~~ **may** complete extensive preclinical studies are subject to the risk ~~that support one~~ **our** or ~~planned~~ INDs **more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Preliminary or top-line data may include, or for similar example, data regarding a small percentage of the patients enrolled in a clinical trial applications, and such preliminary data should not** or CTAs, in foreign countries. We cannot be ~~viewed as~~ certain of the timely completion or outcome of our preclinical studies and ~~an indication, belief~~ cannot predict if the FDA or ~~guarantee that~~ other **patients enrolled in such clinical trial** comparable foreign authorities and independent ethics committees will **achieve similar** accept our proposed clinical programs or if the outcome of our preclinical studies will ultimately support the further development of our programs. As a result ~~results or~~, we cannot be sure that we ~~the preliminary results from such patients~~ will be **maintained. As a result** able to submit INDs or similar applications for our preclinical programs on the timelines we expect, **interim** if at all, and we cannot **preliminary data should** be **viewed with caution until** sure that submission of INDs or similar applications will result in the FDA or other ~~the final data~~ regulatory authorities or independent ethics committees allowing clinical trials to begin. Conducting preclinical studies is **available** a lengthy, time-consuming and expensive process. **Differences between preliminary or interim data** The length of time may vary substantially according to the type, complexity and **final data could significantly harm** novelty of the program, and often can be several years or **our business prospects and** more per program. Any delays in preclinical studies conducted by us or potential future partners ~~may cause us to incur~~ additional operating expenses. The commencement and rate of completion of preclinical studies for a product candidate may be delayed by many factors, including, for example, the **trading price of** inability to generate sufficient preclinical or **our common stock** other in vivo or in vitro data to **fluctuate** support the initiation of clinical trials and..... obtain licensure with labeling that includes significant **significantly** use or distribution restrictions or safety warnings..... may have to conduct additional clinical trials. Any failures or setbacks involving the FACT Platform or the APXiMAB Platform, including adverse events, could have a detrimental impact on our research pipeline and future success. **Our business depends not only on our ability to successfully develop, obtain regulatory licensure for, and commercialize our product candidate, but to continue to generate new product candidates through our FACT Platform and APXiMAB Platform (the Platforms).** Any failures or setbacks involving the **FACT Platform Platforms** or the **APXiMAB Platform**, including adverse events, could have a detrimental impact on our research pipeline and future success. For example, we may uncover a previously unknown risk associated with the **FACT Platform Platforms** or the **APXiMAB Platform** or other issues that may be more problematic than we currently believe, which may prolong the period of observation required for obtaining regulatory approval, necessitate additional clinical testing or result in the failure to obtain regulatory licensure. If the **FACT Platform Platforms** or the **APXiMAB Platform** or any of their respective components that are used in our product candidates are not safe, we would be required to abandon or redesign other product candidates we develop via the **FACT Platform Platforms** or the **APXiMAB Platform**, which could have a material adverse effect on our business, financial condition, results of operations and prospects - We may not be successful in our efforts to use and expand the FACT Platform or the APXiMAB Platform to continue to build a pipeline of product candidates and develop marketable products. Our business depends not only on our ability to successfully

develop, obtain regulatory licensure for, and commercialize our product candidates, but to continue to generate new product candidates through our FACT Platform and APXiMAB Platform. Even if we are successful in continuing to build our pipeline and further progress the development of our current product candidates, any additional product candidates may not be suitable for clinical development, including as a result of harmful side effects, manufacturing issues, limited potency or other characteristics that indicate that they are unlikely to be products that will succeed in clinical development, receive marketing licensure or achieve market acceptance. If we cannot validate our technology platform by successfully commercializing product candidates, we may not be able to obtain product, licensing or collaboration revenue in future periods, which would adversely affect our business, financial condition, results of operations and prospects. We are parties to and may in the future enter into additional agreements with third parties under which those parties have or will be granted a license to develop product candidates discovered using our APXiMAB platform Platform. If any such programs are not successful or if disputes arise related to such programs, we may not realize the full commercial benefits from such programs. Our APXiMAB platform Platform has enabled the discovery of several product candidates with potential utility in multiple therapeutic areas and has resulted in five several programs that have been licensed to third parties, including larger global biopharmaceutical companies and mid- sized regional or China- focused companies. Our likely counterparties for future licensing and collaboration arrangements include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. Such arrangements generally allow the licensing parties to control the amount and timing of resources that they dedicate to the development or potential commercialization of any product candidates they develop from the technology we have licensed to them, subject to any territorial or field of use restrictions in the license. In addition, Apexigen had partnered with ESBA Tech AG, which was acquired by Aleon and later Novartis to provide rabbit monoclonal antibodies in order to develop product candidates for certain diseases. Apexigen typically negotiated milestone payments and royalty fees from the licensees that will require various levels of success with their product candidate development program in order for us to generate revenue from them. Our ability to generate revenue from these licensing arrangements will depend on our counterparties' abilities to successfully develop and commercialize the product candidates they are developing. We cannot predict the success of any licensing program that we enter into or whether such program will lead to any meaningful milestone or royalty revenue to us. Licensing programs involving third- party development of product candidates derived from our licensed technology pose the following risks to us: • counterparties generally have significant discretion, if not total control, in determining the efforts and resources that they will apply to these development efforts; • counterparties may not properly or adequately obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our intellectual property or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property- related proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property; • counterparties may own or co- own with us intellectual property covering their product candidates, and, in such cases, we typically will not have the exclusive right to commercialize such intellectual property or their product candidates based on the terms of the licensing agreement; • we may need the cooperation of these counterparties to enforce or defend any intellectual property we contribute to the program; • counterparties typically will control the interactions with regulatory authorities related to their product candidates, which may impact our ability to obtain and maintain regulatory approval of our own product candidates; • disputes may arise between the counterparties and us that result in the delay or termination of the research, development, or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources; • counterparties may decide to not pursue development and commercialization of any product candidates that are derived from our licensed technology, or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the counterparties' strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities, or counterparties may elect to fund or commercialize a competing product; • counterparties could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • counterparties may not commit sufficient resources to the marketing and distribution of their product candidates, resulting in lower royalties to us; • counterparties may grant sublicensees to our technology or undergo a change of control, and the sublicensees or new owners may decide to pursue a strategy with respect to the program which is not in our best interest; • counterparties may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know- how, or intellectual property of the counterparty relating to our technology in relation to the terms of the licensing agreement; • if these counterparties do not satisfy their obligations under our agreements with them, or if they terminate our licensing agreements with them, we may be adversely impacted; and • licensing agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. Beovu ® is a drug product developed by Novartis covered under the ESBA Tech Agreement. Novartis obtained approval for Beovu for use in neovascular (wet) age- related macular degeneration and as a treatment of visual impairment due to diabetic macular edema; Novartis continues to develop Beovu for other indications. Under the terms of the ESBA Tech agreement, Novartis is obligated to pay us a very low single- digit royalty on worldwide net sales of Beovu. However, Novartis has disputed its obligation to pay royalties to us under the agreement and continues to pay such royalties under protest. As a result, we have determined that any sales- based royalties received from Novartis for Beovu are currently fully constrained, and we have recorded the royalty proceeds as deferred revenue on our consolidated balance sheet, with the amounts totaling \$ 7.7 million as of December 31, 2023. If the dispute with Novartis regarding their royalty obligations is not settled favorably through negotiation or if the parties escalate the dispute through arbitration or litigation, there is no guarantee that we will recognize such historic and future royalty revenue in part or at all, we may be required to return the cash received to date for the constrained royalty payments, we may not receive future payments, and we may incur substantial costs and distraction of management related to such dispute. While

this dispute continues, the Beovu royalty rights will be impaired which will limit our ability to exercise ownership over or monetize this royalty stream, all of which could have an adverse effect on our business, financial condition, and results of operations. Many of the risks relating to product development, intellectual property, regulatory approval, and commercialization described in this “Risk Factors” section also apply to the activities of our licensees and any negative impact on these counterparties and their product development programs may adversely affect us. We may expend our resources to pursue particular product candidates and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success. As a result of our limited financial and managerial resources, we must make strategic decisions as to which targets and product candidates to pursue and may forego or delay pursuit of opportunities with other targets or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Failure to properly assess potential product candidates could result in our focus on product candidates with low market potential, which would harm our business, financial condition, results of operations and prospects. Our spending on current and future research, product candidates and discovery programs for specific targets or indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. ~~If we reach commercialization for any of our product candidates and the market opportunities for any product candidate that we develop are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.~~ The potentially addressable patient population for our current programs or future product candidates may be limited and the number of patients who have the cancers we are targeting may turn out to be lower than expected. Potentially addressable patient populations for our product candidates are only estimates. These estimates could prove to be incorrect, and the estimated number of potential patients in the United States and elsewhere could be lower than expected. It may also be that such patients may not be otherwise amenable to treatment with our product candidates, or patients could become increasingly difficult to identify and access, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects. Our estimated addressable markets and market opportunities for our product candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot be assured of its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may prove not to be accurate. Although we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this Annual Report on Form 10-K. If this third-party or internally generated data prove to be inaccurate or if we make errors in our assumptions based on that data, our actual market may be more limited than we estimate it to be. In addition, these inaccuracies or errors may cause us to misallocate capital and other critical business resources, which could harm our business. The market may not be receptive to **micvotabart pelidotin** some or any of our product candidates because they are ~~it is~~ based on our novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of ~~this product candidates-~~ **candidate**. Even if regulatory licensure is obtained for ~~a-~~ **our** product candidate, we may not **gain sufficient market acceptance among physicians, patients, healthcare payors** generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether **others in the product medical community. Micvotabart pelidotin** is otherwise accepted in the market. Some product candidates that we are developing are based on the FACT Platform, which is a new technology and therapeutic approach. Our future success depends on the successful development of this novel therapeutic approach. Additionally, the regulatory licensure process for ~~a novel product candidates-~~ **candidate** such as ours can be more expensive and take longer than for other, better-known or extensively-studied product candidates. No regulatory authority has granted licensure for any therapeutic using the FACT Platform. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, ~~and we cannot predict whether the FACT Platform will result in the development and marketing licensure of any products.~~ Any development problems we experience in the future related to ~~any of our programs-~~ **program** may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Advancing our products creates significant challenges for us, including educating medical personnel regarding the potential potency and safety benefits, as well as the challenges, of incorporating our product ~~candidates-~~ **candidate**, if approved, into treatment regimens and establishing the sales and marketing capabilities to gain market acceptance, if approved. Any of these factors may prevent us from commercializing ~~any of our product candidates-~~ **candidate** we may develop on a timely or profitable basis, if at all. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt a product or ~~our~~ treatment based on the FACT Platform and technologies, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product ~~candidates-~~ **candidate** developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on, among other factors: • the timing of our receipt of any marketing and commercialization licensures; • the terms of any licensures and the countries in which licensures are obtained; • the safety, purity, and potency of our product ~~candidates-~~ **candidate**; • the prevalence and severity of any adverse side effects associated with our product ~~candidates-~~ **candidate**; • the limitations or warnings contained in any labeling approved by the FDA, or other comparable foreign regulatory authorities; • the relative convenience and ease of administration of our product ~~candidates-~~ **candidate**; • the willingness of patients to accept any new methods of administration; • the success of our physician education programs; • the availability of adequate government and third-party payer reimbursement; • the pricing of our products, particularly as compared to alternative

treatments; and • the availability of alternative effective treatments for the disease indications our product candidates—**candidate are is** intended to treat and the relative risks, benefits and costs of those treatments. If any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects. We are early in our development efforts. Our lead product candidates—**candidate** , **micvotabart pelidotin** PYX-201, **is** PYX-106 and PYX-107, are in the early stages of clinical development. The results of preclinical studies and early —stage clinical trials may not be predictive of future results in later studies or trials. Initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later- stage clinical trials. The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early —stage clinical trials that are continuing may not be predictive of the results of the later —stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed on in later stage clinical trials. In particular, the small number of patients in our ~~planned early-Phase 1 clinical trials—~~ **trial** may make the ~~results—~~ **result** of these ~~this trials—~~ **trial** less predictive of the outcome of later clinical trials .~~For example, even if successful, the results of our clinical trials of our product candidates PYX-201, PYX-106 and PYX-107 and other product candidates may not be predictive of the results of further clinical trials of these product candidates or any of our other product candidates.~~ Moreover, preclinical and clinical data often are susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless have failed to obtain marketing licensure of their products. Our clinical trials may not ultimately be successful or support further clinical development of **micvotabart pelidotin** any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving encouraging results in earlier studies. Any such setbacks in our clinical development could materially harm our business, results of operations, financial condition and prospects. **If Additionally, from time to time, we or may publish interim, top-line or our preliminary data from collaborators experience delays or difficulties in the enrollment of patients in our clinical trials , these** . Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced or published. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary, top-line or interim data and final data could significantly harm our reputation and business prospects. If we experience delays or difficulties in the enrollment of patients in our clinical trials, our timelines for submitting applications for and receiving necessary marketing authorizations, if any, could be delayed or prevented. We may not be able to continue clinical trials for our product candidates—**candidate** if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials, as required by the FDA or ~~similar~~ **other comparable foreign** regulatory authorities ~~outside of the United States.~~ While we believe that we will be able to enroll a sufficient number of patients into each of these clinical trials, we cannot predict with certainty how difficult it will be to enroll patients for trials in these rare indications. Our ability to identify ~~and sites who will~~ enroll eligible patients for clinical trials may turn out to be limited or we may be slower in enrolling these trials than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates—**candidate** and, as a result, patients who would otherwise be eligible for our clinical trials may instead elect to enroll in clinical trials of our competitors' product candidates. Patient enrollment in clinical trials is also affected by other factors including: • the severity of the disease under investigation; • the size and nature of the patient population; • the eligibility criteria for the trial in question; • the competing clinical trials or approved therapies which present an attractive alternative to patients and their physicians; • the perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies; • the efforts to facilitate timely enrollment in clinical trials; • the patient referral practices of physicians; • the burden on patients due to the scope and invasiveness of required procedures under clinical trial protocols, some of which may be inconvenient and / or uncomfortable; • the ability to monitor patients adequately during and after treatment; • the proximity and availability of clinical trial sites for prospective patients; • the risk that **a high number of patients fail during screening or** enrolled patients will drop out or die before completion of the trial; • patients failing to complete a clinical trial or returning for post- treatment follow- up; and • our ability to manufacture the requisite materials for a patient and clinical trial. Our ~~or our collaborators~~ inability to **timely** enroll a sufficient number of patients for our clinical trials, ~~based on our inability to do so on a timely basis~~ **the above factors or others** , ~~would could~~ result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates—**candidate** , which would cause the value of our company to decline and limit our ability to obtain additional financing. Our product candidates—**candidate** may cause undesirable and unforeseen side effects or have other properties impacting safety that could halt ~~their its~~ clinical development, delay or prevent ~~their its~~ regulatory licensure, limit ~~their its~~ commercial potential or result in significant negative consequences. Undesirable side effects caused by our product candidates—**candidate** could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory licensure or approval by the FDA or other regulatory authorities. As is the case with oncology drugs, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny licensure or approval of our product candidates—**candidate** for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. Further, clinical trials by their nature utilize a sample of the potential

patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product ~~candidates~~ **candidate** may only be uncovered with a significantly larger number of patients exposed to the product candidate. In the event that ~~any of our product candidates~~ **candidate** ~~receive~~ **receives** regulatory licensure or approval and we or others ~~later~~ identify undesirable side effects ~~caused by one of our products~~, any of the following adverse events could occur, which could result in ~~the loss of significant~~ **negative consequences** ~~revenue to us and materially and adversely affect our results of operations and business~~:

- regulatory authorities may withdraw their licensure or approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline. From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings and may be associated with payments from collaborators. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones may vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, our revenue may be lower than expected, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline. We ~~may~~ face **significant** competition from **other oncology- focused biotechnology and pharmaceutical** entities, **and that have developed or our operating results will suffer if** ~~we develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we~~ **fail to compete** ~~do or their technologies are more effective~~ **effectively**, ~~our ability to develop and successfully commercialize product candidates may be adversely affected~~. The development and commercialization of therapeutic biological products is highly competitive. We compete with a variety of multinational biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product ~~candidates~~ **candidate**. Competitive therapeutic treatments include those that have already been approved or licensed and accepted by the medical community and any new treatments that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may try to develop product candidates. The biotechnology and pharmaceutical industries, including the oncology subsector, are characterized by rapidly evolving technologies, intense competition ~~and~~ a strong defense of intellectual property and proprietary technologies. Any product ~~candidates~~ **candidate** that we successfully commercialize may ~~not~~ be competitive with currently marketed therapies and any new therapies commercialized in the future. We are aware of several companies that are developing cancer immunotherapies and ADCs. Many of these companies are well- capitalized and, in contrast to us, have significant clinical experience, and may include our existing or future collaborators. In addition, these companies compete with us in recruiting scientific and managerial talent and the patient pool available for participation in clinical trials **which could negatively impact our ability to execute our business plan**. Our success will partially depend on our ability to develop and protect therapeutics that are more safe, pure, and potent than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products that are safer, more effective, or less expensive than the therapeutics we develop are commercialized. If our product ~~candidates~~ **candidate** ~~are~~ **is** licensed, ~~they~~ **it** will compete with a range of therapeutic treatments that are either in development or currently marketed. Many companies are active across various stages of development in the oncology subsector and are marketing and developing products that employ similar ADC and immunotherapy approaches. As of ~~October~~ **February 2023-2025**, there were approximately ~~304~~ **650** ADCs in clinical or preclinical development worldwide, of which the vast majority are being developed for the treatment of various cancer indications. Additionally, there are several large and small companies working on various immunotherapy approaches for treatment of cancer. Multiple companies are also involved in the development of ADC therapeutics and immunotherapies, including, but not limited to, AbbVie Inc., Abcure, Inc., ADC Therapeutics SA, Alligator Bioscience AB, Astellas Pharma, Inc., AstraZeneca plc, Celldex Therapeutics, Inc., Daiichi Sankyo Company, Ltd., Eucure Biopharma, a subsidiary of Biocytogen, ~~Hoffmann-La Roche AG~~, Genentech, Inc., Gilead Sciences, Inc, GlaxoSmithKline, plc, Lyvgen Biopharma, Nextcure, Inc., Pfizer, Philogen S. p. A., **Merck Sharpe Dohme (MSD)** and Rakuten Medical, Inc. ~~We~~ **Our** preclinical ADC and immunotherapy candidates may face substantial competition from alternative therapeutic modalities, such as CAR-T therapies, bispecific antibodies, and small molecules that are being developed for the same cancer types that we are targeting with our pipeline candidates. These approaches could prove to be more effective, safer, or convey other advantages over any products resulting from our technology. In addition, we also face competition on specific targets, including the target of our **micvotabart pelidotin** PYX-201 candidate, EDB ~~FN~~, from Philogen S. p. A., ~~and as well as the~~ **other emerging agents in key indications of interest including R / M HNSCC. Merus’ s EGFR and LGR5 target targeting of our PYX biclonic, petosemtamab, and Bicara’ s EGFR / TGF** -106 product candidate **beta targeting bifunctional** . BSI-060T **ficerafusp alfa (BCA101)** , from Nextcure, Inc. In addition, each of Alligator Bioscience AB, Celldex Therapeutics, Inc., Lyvgen Biopharma, Eucure Biopharma, a subsidiary of Biocytogen, Hoffmann-La Roche AG, and AbbVie Inc. are **notable competitors** developing CD40- based antibody product candidates for solid tumor oncology indications that are in **targeting patient populations of interest to**

micvotabart pelidotin and pose a potentially significant threat to our clinical development strategy. Other competitors may also include agents targeting specific segments such as HPV HNSCC, namely Hookipa's and PDS Biotech's vaccines and agents such as Nanobiotix's radioenhancer that may be used earlier in the treatment sequence. Furthermore, there are also some ADCs such as Sacituzumab govitecan, Gilead's TROP-2 ADC, Pfizer's Nectin-4 targeting ADC, enfortumab vedotin, and AZ's AZD9592, a dual targeting ADC against EGFR and cMET that are in clinical development in HNSCC and have shown preliminary clinical efficacy in early stage trials, typically in combination therapies. Other companies and institutions also have CD40-based product candidates in development. Additionally, there is a wide array of activity in the development of immunotherapies for oncology which may be competitive with our preclinical discovery programs. Furthermore, if any of our product candidates are approved in oncology indications such as lung, hematological and other cancers, they may compete with existing approaches to treating cancer including surgery, radiation, and drug therapy, including conventional chemotherapy, biological products, and targeted drug small molecule therapies. Many of our competitors have significantly greater scientific, research and development capabilities, as well as greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. **Competitive products may make any products we develop obsolete owing to treatment paradigm shifts or noncompetitive, reducing the addressable market before we recover the expense of developing and commercializing our product candidate. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. We believe that our ability to successfully compete to obtain licensure for any product candidate, we will depend face competition based on many different factors, including among the other things:**

- safety, purity and potency of our ability to develop and protect therapeutics that are more effective and safer than competing products;
- our ability to innovate with rapidly evolving technologies;
- the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration;
- the timing and scope of regulatory licenses for these products;
- the availability and cost of manufacturing, marketing and sales capabilities, price;
- of our product candidate and whether coverage and adequate levels of reimbursement are available under health insurance plans;
- coverage and patent position.

Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or our ability to utilize marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. Our biological product candidates for which we intend to seek licensure may face competition sooner than anticipated. The Affordable Care Act, or ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated licensure pathway pathways for biological products that; and • the length of time we are granted market biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our product candidates - candidate. There is a risk that any product candidates we may develop that are is licensed as a biological product under a **Biologics License Application (BLA)** would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider any product candidates we may develop to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation, including litigation challenging the constitutionality of the ACA. For example, in December 2018, a federal district court ruled that the ACA, without the "individual mandate" penalty (which was repealed by the U. S. Congress as part of the Tax Cuts and Jobs Act), is unconstitutional in its entirety. In December 2019, the U. S. Court of Appeals for the 5th Circuit upheld the district court ruling that the individual mandate provisions are unconstitutional and remanded the case back to the district court for further analysis of whether such provisions could be severed from the remainder of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the case without specifically ruling on the constitutionality of the ACA. There may, however, be other efforts to challenge, repeal, or replace the ACA in the future. We continue to evaluate the effect that the ACA and its possible repeal and replacement has (or may have) on our business and exclusivity under the BPCIA. It is uncertain the extent to which any such changes may impact our business or financial condition. Our business entails a significant risk of product liability, and if we are unable to obtain sufficient insurance coverage, such failure could have a material and adverse effect on our business, financial condition, results of operations and prospects. We expect to be exposed to significant product liability risks inherent in the development, testing and manufacturing of our product candidates - candidate and products, if approved. Product liability claims could delay or prevent completion of product candidate development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our third-party manufacturer's manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, including limitations on the approved indications for which our product candidates - candidate may be used or suspension or withdrawal of licenses. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion

of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. In addition, we may be subject to liability based on the actions of our existing or future collaborators in connection with their development of products using the FACT Platform or the APXiMAB Platform. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Regulatory Licensure or Approval and Other Legal Compliance Matters

The regulatory licensure and approval processes of the FDA and other comparable **foreign** regulatory authorities are lengthy, time-consuming and inherently unpredictable and, if we are ~~ultimately~~ unable to obtain marketing licensure or approval for our product ~~candidates-~~ **candidate**, our business will be substantially harmed. The time required to obtain approval or licensure by the FDA and other comparable **foreign** regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval and licensure policies, regulations or the type and amount of clinical data necessary to gain approval or licensure may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained marketing approval or licensure for any product candidate, and it is possible that ~~none of our existing product~~ **candidate, or any product** ~~candidates-, or any product candidates~~ we may seek to develop in the future, will ~~ever-never~~ obtain marketing approval or licensure. Our product ~~candidates-~~ **candidate** could fail to receive marketing licensure in the ~~United States~~ **U. S.** for many reasons, including the following:

- the FDA may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that ~~a the~~ product candidate is safe, pure, and potent;
- results of clinical trials may not meet the level of statistical significance required by the FDA for licensure;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- data collected from clinical trials of our product ~~candidates-~~ **candidate** may not be sufficient to support the submission of a BLA to the FDA or other submission or to obtain marketing licensure in the ~~United States~~ **U. S.**;
- the FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third ~~-party~~ manufacturers with which we contract for clinical and commercial supplies; and
- the licensure policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for licensure.

This lengthy licensure process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory licensure to market ~~any of our product~~ ~~candidates-~~ **candidate**, which would significantly harm our business, results of operations, financial condition and prospects. The FDA has substantial discretion in the licensure process and determining when or whether regulatory licensure will be obtained for ~~any of our product~~ ~~candidates-~~ **candidate**. Even if we believe the **preliminary** data collected from clinical trials of our product ~~candidates-~~ **candidate** ~~are-is~~ promising, such **preliminary** data may not be sufficient to support licensure by the FDA. In addition, even if we were to obtain licensure, regulatory authorities may approve ~~any of our product~~ ~~candidates-~~ **candidate** for fewer or more limited indications than we request, ~~may not approve the price we intend to charge for our products-~~, may grant a license contingent on the performance of costly post-marketing clinical trials, or may approve or license a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product ~~candidates-~~ **candidate**. Even if we ~~obtain FDA receive regulatory~~ licensure for ~~any of our product~~ ~~candidates-~~ **candidate** in the United States, we **will be subject to ongoing regulatory obligations and continued regulatory review** may never obtain approval or licensure for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety, purity, potency and efficacy. Licensure by the FDA in the United States does not ensure approval or licensure by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval or licensure in one jurisdiction may **result in significant** negatively impact our ability to obtain approval or licensure elsewhere. In addition **additional expense**, and we clinical trials conducted in one country may not be **subject** accepted by regulatory authorities in other countries, and regulatory approval or licensure in one country does not guarantee regulatory approval or licensure in any other country. Approval or licensure processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval or licensure could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to **penalties if** country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved or licensed for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval or licensure in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals or licensures, or if regulatory approvals or licensures in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. Even if we receive regulatory licensure of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to **penalties if we fail to comply with regulatory requirements** or experience unanticipated problems with our product ~~candidates-~~ **candidate**. If ~~any of our product~~ ~~candidates-~~ **candidate** ~~are-is~~ licensed or approved by regulatory authorities, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, track and trace, serialization, post-market adverse event reporting, and submission of safety, purity, potency, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. **In addition, we will be subject to continued compliance with Current Good Manufacturing Practices, or cGMP, and GCP requirements for any clinical trials that we conduct**

post-licensure. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA or other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory licenses that we receive for our product candidates may be subject to limitations on the approved indications for which the product may be marketed or to the conditions of licensure, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety, purity, and potency of the product candidate. The FDA may also require a REMS program as a condition of licensure of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Comparable foreign regulatory authorities will **continue** may also have programs similar to REMS **monitor closely the safety profile of any product even after approval**. If In addition, if the FDA or a comparable foreign regulatory authority **authorities** licenses or **become aware of new safety information after approval** our of a product candidates- **candidate**, we will have to comply with **they may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategies (REMS), if not already established in pre-approval, or similar strategy, impose significant restrictions on its indicated uses or marketing, or impose ongoing requirements including submissions of safety and other for potentially costly postapproval studies or post-marketing market surveillance** information and reports and registration. Clinical trials of our product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receive marketing licensure and we, or others, discover that the biological product is less effective than previously believed or causes undesirable side effects that were not previously identified, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw their licensure of the biological product or seize the biological product; • we, or any future collaborators, may be required to recall the biological product, change the way the biological product is administered or conduct additional clinical trials; • additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular biological product; • we, or any future collaborators, may be required to create a medication guide outlining the risks of the previously unidentified side effects for distribution to patients; • we, or any future collaborators, could be sued and held liable for harm caused to patients; • the biological product may become less competitive in the marketplace; and Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price. The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety, purity, or potency of the product, including the adoption and implementation of REMS. The FDA and other agencies, including the United States Department of Justice, or DOJ, closely regulate and monitor the post-licensure marketing and promotion of biological products to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products only for the approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. We, and any collaborators, must comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing licensure. Promotional communications with respect to prescription biological products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we, and any collaborators, will not be able to promote any products we develop for indications or uses for which the biological product is not licensed. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. The policies of the FDA and of comparable foreign regulatory authorities may **conduct periodic inspections** change and additional government regulations may be enacted that could prevent, limit or **for** delay regulatory licensure of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing licensure that we may have obtained and we may not achieve or sustain profitability. In addition, later discovery of previously unknown side effects or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements **and standards. Later discovery of previously unknown problems with our product candidate**, may yield various results- **result in consequences** including, **among other things**: • restrictions on such products, manufacturers or manufacturing processes; • restrictions and warnings on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post-marketing studies or clinical trials; • warning letters or untitled letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to

approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing licenses; • suspension of any ongoing clinical trials; • damage to relationships with any potential collaborators; • unfavorable press coverage and damage to our reputation; • refusal to permit the import or export of our products; • product seizure; • injunctions or the imposition of civil or criminal penalties; or • litigation involving patients using our products. The FDA and similar foreign authorities may impose consent decrees or withdraw licensure if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; • fines, warning letters or holds on clinical trials; • refusal by the FDA and similar comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of licenses; • product seizure or detention or refusal to permit the import or export of our product candidates- **candidate**; and • injunctions or the imposition of civil or criminal penalties. **We Non-compliance with European Union, or EU, requirements regarding safety monitoring or pharmacoepidemiology, and any collaborators, must comply** with requirements related to **concerning advertising and promotion for our product candidate for which we or the they development of obtain marketing licensure. Promotional communications with respect to prescription biological products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we, and any collaborators, will not be able to promote any products we develop for or uses for which the biological product is not licensed. The FDA and the other pediatric population (as explained further below), also can result in agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant financial penalties liability. However, and non-physicians may, in their independent medical judgment, prescribe legally available products for off-compliance with pediatric requirements may prevent label uses. The FDA does not regulatory regulate the behavior of physicians in approvals from being granted. Similarly, failure to comply with the their choice EU and United Kingdom, or UK, requirements regarding the protection of treatments personal information can lead to significant penalties and sanctions. A If we decide to seek additional Breakthrough Therapy designation Designation and / or Fast Track Designation by the FDA, even if granted for any of our product candidates- **candidate**, may not lead to a faster development or regulatory review or licensure process and it does not increase the likelihood that our product candidates- **candidate** will receive marketing licensure. We may seek additional Breakthrough Therapy Designation and / or Fast Track Designation for our product candidate. For example, in February 2025, the FDA granted Fast Track Designation for use of micvotabart pelidotin in the treatment of adult patients with R / M HNSCC whose disease has progressed following treatment with platinum-based chemotherapy and an anti- PD- (L) 1 antibody. The FDA may withdraw the Fast Track Designation if the clinical development program no longer meets the criteria for Fast Track Designation. There is no assurance that the FDA will grant these designation designations to any of for our product candidates and some or our current all of our- or future product candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs or biological products, to treat a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the drug or biological products may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, **increased** interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as Breakthrough Therapies by the FDA may also be eligible for other expedited approval programs, including **accelerated Accelerated approval Approval and Priority Review**, if they meet regulatory requirements for those other programs. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or licensure compared to candidate products considered for licensure under non-expedited FDA review procedures and does not assure ultimate licensure by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product no longer meets the conditions for qualification. For example, in June 2022, the FDA published a draft guidance document outlining considerations for the FDA in rescinding Breakthrough Therapy designation for products that no longer meet the requirements for that designation. Thus, even though we intend to seek Breakthrough Therapy designation for some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive Breakthrough Therapy designation. Fast Track designation by the FDA, even if granted for other current or future product candidates, may not lead to a faster development or regulatory review, licensure process and does not increase the likelihood that our product candidates will receive marketing licensure. We may seek Fast Track designation for one or more of our future product candidates. If a drug or biological product is intended for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for our product candidates, but there is no assurance that the FDA will grant this designation to any of our proposed product candidates. Marketing applications submitted by sponsors of products in Fast Track development may qualify for priority **Priority** review**

Review under the policies and procedures offered by the FDA, but the Fast Track ~~designation~~ **Designation** does not assure any such qualification ~~or ultimate marketing licensure by the FDA~~. The FDA **may withdraw any** ~~has broad discretion whether or not to grant Fast Track designation~~ **Designation**, ~~so~~ **at any time. In any even event if we believe, the receipt of a** **Breakthrough Therapy** particular product candidate is eligible for this designation **Designation and / or**, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track ~~designation~~ **Designation**, ~~we~~ **for a product candidate** may not ~~experience~~ **result in** a faster development process, review or licensure compared to ~~conventional~~ **standard review and do not assure ultimate licensure by the** FDA procedures or pathways and receiving a Fast Track designation does not provide assurance of ultimate FDA licensure. In addition, **even if our product candidate qualifies as a Breakthrough Therapy, the FDA may later decide that the product no longer meets the conditions for qualification. Additionally**, the FDA may withdraw Fast Track ~~designation~~ **Designation** if it believes that the designation is no longer supported by data from our clinical development program. The FDA may withdraw any Fast Track ~~designation~~ **Designation** at any time. If we decide to seek Orphan Drug Designation for any of our current or future product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for supplemental market exclusivity. We may seek Orphan Drug Designation for one or more of our current or future product candidates. For example, in May 2023, the FDA granted Orphan Drug Designation, ~~or~~ **for micvotabart pelidotin ODD, for PYX-201** in pancreatic cancer. Also, the FDA granted ~~ODD~~ **Orphan Drug Designation** for PYX-107 in the treatment of soft tissue carcinoma, esophageal and GEJ cancers. Regulatory authorities in some jurisdictions, including the ~~United States~~ **U. S.** and Europe, may designate drugs or biological products for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the ~~United States~~ **U. S.**, or a patient population greater than 200,000 in the ~~United States~~ **U. S.** when there is no reasonable expectation that the cost of developing and making available the drug in the ~~United States~~ **U. S.** will be recovered from sales in the ~~United States~~ **U. S.** for that drug or biological product. In the ~~United States~~ **U. S.**, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants Orphan Drug Designation, the identity of the drug or biological product and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and licensure process. If a product that has Orphan Drug Designation subsequently receives the first FDA approval or licensure for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA or BLA, to market the same drug or biological product for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the biological product was designated. As a result, even if ~~one of our product candidates~~ **candidate** receives orphan exclusivity, the FDA can still approve or license other drugs or biological products that have a different active ingredient for use in treating the same indication or disease. Further, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product. We may seek Orphan Drug Designation for our product ~~candidates~~ **candidate** in additional orphan indications in which there is a medically plausible basis for the use of ~~these~~ **this** product ~~candidates~~ **candidate**. Even if we obtain Orphan Drug Designation, exclusive marketing rights in the ~~United States~~ **U. S.** may be limited if we seek licensure for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we, through our manufacturer, are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek Orphan Drug Designation for other product candidates, we may never receive these designations. The U. S. Congress is also considering updates to the orphan drug provisions of the **Federal Food, Drug, and Cosmetic Act (FDCA)** in response to a ~~recent~~ **2021** 11th Circuit decision. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects. Accelerated ~~approval~~ **Approval** by the FDA, even if granted, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product ~~candidates~~ **candidate** will receive marketing licensure. If ~~not granted~~ we are unable to obtain licensure of our products through the Accelerated Approval Program in the ~~United States~~, we may be required to conduct additional nonclinical and clinical studies and trials beyond those that we currently contemplate, ~~which could increase the expense of obtaining, reduce the likelihood of obtaining and / or delay the timing of obtaining, necessary marketing licensure~~. Even if we receive accelerated approval from the FDA through the Accelerated Approval Program, if our confirmatory post-marketing trial does not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated **Accelerated approval Approval**. We plan to seek accelerated **Accelerated approval Approval** of **micvotabart pelidotin PYX-201 and PYX-106** and may seek approval of future product candidates using through the FDA's accelerated **Accelerated approval Approval** pathway **Program**. For any licensure to market a biological product, we must provide the FDA and **comparable** foreign regulatory ~~agencies~~ **authorities** with clinical data that adequately demonstrate the safety, purity, and potency of the product for the indication applied for in the NDA or BLA or other respective regulatory filings. The Accelerated Approval Program is one of several approaches used by the FDA to make prescription drugs or biological products more rapidly available for the treatment of serious or life-threatening diseases. Section 506 (c) of the FDCA provides that the FDA may grant accelerated **Accelerated approval Approval** to "a product for a serious or life-threatening condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or

other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.” Licensure through the Accelerated Approval Program is subject, however, to the requirement that a sponsor perform adequate and well controlled post- marketing clinical trials to verify and describe the drug’s clinical benefit, where there is uncertainty as to the relationship of the surrogate endpoint to the clinical benefit, or of the observed clinical endpoint to ultimate outcome. Typically, clinical benefit is verified when post- marketing clinical trials show that the biological products provide a clinically meaningful positive therapeutic effect, that is, an effect on how a patient feels, functions, or survives. If required, these confirmatory trials must be ~~completed with due diligence and~~ **underway prior to Accelerated Approval**, pursuant to the Food and Drug Omnibus Reform Act of 2022 (~~or FDORA~~) enacted in 2022 ~~and~~, ~~may require that such studies be underway~~ **under prior to FDA’s draft guidance on “ Accelerated approval Approval and Considerations for Determining Whether a Confirmatory Trial is Underway ” made available in January 2025**. If such confirmatory post- marketing trials fail to confirm the product’s clinical profile or risks and benefits, the FDA may withdraw ~~accelerated Accelerated approval Approval~~ of the product. The FDA has broad discretion with regard to licensure through the Accelerated Approval Program ~~and~~ even if we believe that the Accelerated Approval Program is appropriate for one of our products, we cannot assure you that the FDA will ultimately agree. The FDA may also change its policies with respect over Accelerated Approval over time. For example, in March 2023, the FDA announced the availability of draft guidance on “ Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics, ” in which the Agency outlined, and invited public comment on, its “ preferred approach ” of randomized controlled trials, including those that provide for longer term follow- up that could fulfill a ~~post- postmarketing~~ **marketing** requirement to verify clinical benefit. ~~The~~ ~~in that~~ draft guidance, **while not finalized, included statements where** the FDA acknowledged that historically, single- arm trial designs and response endpoints have most commonly been used in oncology, but noted that such trials have limitations. Furthermore, even if we do obtain licensure through the Accelerated Approval Program, we may not experience a faster development process, review, or licensure compared to conventional FDA procedures. Even if the FDA reviews a BLA seeking ~~accelerated Accelerated approval Approval~~, there can be no assurance that licensure will be granted on a timely basis, or at all. The FDA may disagree that the design of, or results from, our studies support ~~accelerated Accelerated approval Approval~~. Additionally, the FDA could require us to conduct further studies or trials prior to granting licensure of any type, including by determining that licensure through the Accelerated Approval Program is not appropriate and that our clinical trials may not be used to support licensure through the conventional pathway. We might not be able to fulfill the FDA’s requirements in a timely manner, which would cause delays, or licensure might not be granted because our submission is deemed incomplete by the FDA. There also can be no assurance that after subsequent FDA feedback we will continue to pursue licensure through the Accelerated Approval Program. A failure to obtain licensure through the Accelerated Approval Program could result in a longer time period to obtain licensure of our products, could increase the cost of our products’ development, could delay our ability to commercialize our products and could significantly harm our financial position and competitive position in the marketplace. Even if we receive licensure for one of our products through the Accelerated Approval Program, we will be subject to rigorous post- marketing requirements, including the completion of one or more confirmatory post- marketing trials as the FDA may require, to verify the clinical benefit of the product, and submission to the FDA of all promotional materials prior to their dissemination. These requirements could adversely impact the timing of the commercial launch of the product. Even if we do receive ~~accelerated Accelerated approval Approval~~, we may not experience a faster development or regulatory review or licensure process. Further, receiving ~~accelerated Accelerated approval Approval~~ does not provide assurance of ultimate full FDA licensure. The FDA could seek to withdraw ~~accelerated Accelerated approval Approval~~ for multiple reasons, including if we fail to conduct any required confirmatory post- marketing trial with due diligence, our confirmatory post- marketing trial does not confirm the predicted clinical benefit, other evidence shows that the product is not safe, pure, or potent under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading. **Further description of the expedited withdrawal process was released by the FDA in the recent draft guidance Expedited Program for Serious Conditions – Accelerated Approval of Drugs and Biologics (December 2024). Moreover, Congress is considering potential changes to the Accelerated Approval Program that could impact our ability to obtain Accelerated Approval, or increase the burdens associated with post- marketing requirements in the event we do obtain Accelerated Approval. In particular, the FDA must specify certain conditions for required postapproval studies for products that receive Accelerated Approval, which may include enrollment targets and milestones, including the target date for study completion, by the time the drug is approved. The FDA may also require postapproval studies to be underway at the time of Accelerated Approval or within a specified time period following Accelerated Approval for such drugs, and must explain any instances where it does not require such studies. FDA’s January 2025 draft guidance on Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway, while not finalized, suggests that FDA generally intends to consider a confirmatory trial to be" underway" prior to Accelerated Approval if (1) the trial has a target completion date that is consistent with diligent and timely conduct of the trial, considering the nature of the trial’s design and objectives, (2) the sponsor’s progress and plans for postapproval conduct of the trial provide sufficient assurance to expect timely completion of the trial, and (3) enrollment of the confirmatory trial has been initiated.** Any delay in obtaining, or inability to obtain, licensure through the Accelerated Approval Program, or any issues in maintaining approval granted under the Accelerated Approval Program, would delay or prevent commercialization of our products, and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects. If foreign regulatory authorities approve biosimilar versions of ~~any of our product candidates~~ ~~candidate~~ that receive marketing approval, or such authorities do not grant our product ~~candidate~~ appropriate periods of data or market exclusivity before approving generic versions of our product ~~candidate~~, the sales of our product ~~candidate~~ could be adversely affected. In the EU and the UK, innovative medicinal products are authorized based on a full marketing

authorization application and conditional authorization (as opposed to an application for marketing authorization that relies on data in the marketing authorization dossier for another, previously approved medicinal product). Applications for marketing authorization for innovative medicinal products must contain, inter alia, the results of pharmaceutical tests, preclinical tests and clinical trials conducted with the medicinal product for which marketing authorization is sought ~~(and where applicable the results of the pediatric studies unless a waiver or a deferral has been obtained — as described further below)~~. A marketing authorization can be obtained via the centralized procedure or the national procedure. The centralized procedure results in a single marketing authorization, issued by the European Commission (based on the opinion of the EMA), which is valid across the entire European Economic Area ~~(, or EEA)~~ which comprises the EU, Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are (i) derived from biotechnology processes, such as genetic engineering; (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV / AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases; (iii) designated orphan medicines; and (iv) advanced- therapy medicines, such as gene therapy, somatic cell therapy or tissue- engineered medicines. The centralized procedure may at the request of the applicant also be used in certain other cases. The centralized procedure would be mandatory for the product ~~candidates-~~ **candidate** we are developing. Where an applicant for a marketing authorization submits a full dossier containing its own pharmaceutical, preclinical tests and clinical trials data, and where the application does not fall within the ‘ global marketing authorization’ of an existing medicinal product, reference product candidates may receive eight years of data exclusivity and an additional two years of market exclusivity, upon grant of the marketing authorization. If granted, during the data exclusivity period, applicants for approval of biosimilars cannot rely on data contained in the marketing authorization dossier submitted for the already authorized, or reference product candidate, to support their application. The market exclusivity period prevents a successful biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial marketing authorization of the reference product in the EU, but a biosimilar marketing authorization application can be submitted during this time. The overall 10- year market exclusivity period can further be extended by one more year if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, even if a compound is considered to be a new active substance and the innovator is able to gain the period of data and market exclusivity, provided that no other intellectual property or regulatory exclusivities apply, another unrelated company could also apply for a marketing authorization and market another competing medicinal product for the same therapeutic indication if such company obtained its own marketing authorization based on a separate marketing authorization application based on a full self- standing scientific data package supporting the application. In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical testing or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological products. There are currently no such guidelines for complex biological products such as gene or cell therapy medicinal products, and so in the short term it is unlikely that biosimilars of those products will be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time. In the EU, ~~marketing authorization applications for new medicinal products must include the results of clinical trials conducted in pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA’ s Pediatric Committee, or PDCO. The PDCO can grant waivers or deferrals to these requirements in certain circumstances (for example, a waiver may be obtained if the condition only occurs in adult populations). Where required, pediatric studies must cover all sub- sets of the pediatric population for both existing and new indications, pharmacological forms and route of administrations. Limited further exclusions apply, including in relation to biosimilar applications. Certain incentives may be available for completion of pediatric studies. For example, once the marketing authorization is obtained in all countries in the European Union, or EU Member States, and study results are included in the product information, even when negative, the product is eligible for a six- months supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two- year extension of the orphan market exclusivity is granted. In the EU, the criteria for designating an “ orphan medicinal product ” are similar in principle to those in the United States U. S.~~ A medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition (2) either (a) such condition affects no more than five in 10, 000 persons in the EU when the application is made or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The application for Orphan Drug Designation must be submitted before the marketing authorization application. Orphan Drug Designations entitle a party to financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to 10 years of market exclusivity. During the 10- year market exclusivity period, the EMA cannot accept another marketing authorization application, or grant a marketing authorization or accept an application to extend an existing marketing authorization, for the same therapeutic indication, in respect of a similar medicinal product. ~~An orphan medicinal product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.~~ Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The ten- year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for Orphan Drug Designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. At any time, a marketing authorization may be granted to a similar

product for the same indication if: 1. the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; 2. the holder of the marketing authorization for the original orphan medicinal product has given his consent to the second applicant; or 3. the holder of the marketing authorization for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product. Although the UK has left the EU, its regulatory legal framework provides for similar periods of protection (namely regulatory data exclusivity, marketing protection and market exclusivity). Competition that our product ~~candidates-~~ **candidate** may face from biosimilar versions of our product ~~candidates-~~ **candidate** could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in ~~those-~~ **the** product ~~candidates-~~ **candidate**. Our future revenues, profitability and cash flows could also be materially and adversely affected and our ability to obtain a return on the investments we have made in ~~those-~~ **this** product ~~candidates-~~ **candidate** may be substantially limited if our product ~~candidates-~~ **candidate**, if and when approved, are not afforded the appropriate ~~periods-~~ **period** of non- patent exclusivity. **Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidate outside the U. S. and the sales of our product candidate could be adversely affected. In order to market and sell our product candidate in other jurisdictions, we must obtain separate marketing approvals for those jurisdictions and comply with their numerous and varying regulatory requirements. We may not obtain foreign regulatory approvals on a timely basis, or at all. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U. S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U. S., product reimbursement approvals must be secured before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidate in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country. Our failure to obtain approval of our product candidate by foreign regulatory authorities may negatively impact the commercial prospects of such product candidate and our business prospects could decline.** The failure to obtain required regulatory clearances or approvals for any companion diagnostic tests that we may pursue may prevent or delay approval of ~~any of our product candidates-~~ **candidate**. Moreover, the commercial success of ~~a any of our product candidates-~~ **candidate** that ~~require-~~ **requires** a companion diagnostic will be tied to the receipt of any required regulatory clearances or approvals and the continued availability of such tests. **We may seek to identify patient subsets within a disease category that may derive selective and meaningful benefit from the product candidate we are developing. Through collaborations or license agreements, companion diagnostics may help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidate, if approved.** In connection with the clinical development of our product ~~candidates-~~ **candidate** for certain indications, we may work with collaborators to develop or obtain access to companion diagnostic tests to identify appropriate patients for our product ~~candidates-~~ **candidate**. We may rely on third parties for the development, testing and manufacturing of these companion diagnostics, the application for and receipt of any required regulatory clearances or approvals, and the commercial supply of these companion diagnostics. **Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as a medical device and may require separate regulatory authorization prior to commercialization.** The FDA and foreign regulatory authorities regulate companion diagnostics as medical devices that will likely be subject to clinical trials in conjunction with the clinical trials for product candidates, and which will require separate regulatory clearance or approval prior to commercialization. This process could include additional meetings with health authorities, such as a pre-submission meeting and the requirement to submit an investigational device exemption (~~-, or-~~ **IDE**). In the case of a companion diagnostic that is designated as “ significant risk device,” approval of an IDE by the FDA and an ~~Institutional Review Board, or~~ **Institutional Review Board, or** IRB ~~is~~ is required before such diagnostic is used in conjunction with the clinical trials for a corresponding product candidate. We or our third ~~-~~ party collaborators may fail to obtain the required regulatory clearances or approvals, which could prevent or delay approval of our product candidates. In addition, the commercial success of ~~any of our product candidates-~~ **candidate** that requires a companion diagnostic will be tied to and dependent upon the receipt of required regulatory clearances or approvals and the continued ability of such third parties to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies. ~~If we are required to in the future and if we are unable to successfully develop companion diagnostic tests for our product candidates that require such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates. We may be required by the FDA to develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. We have no prior experience with medical device or diagnostic test development. If we choose to develop and seek FDA clearance or approval for companion diagnostic tests on our own, we will require additional personnel with medical device knowledge and expertise. We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that require such tests. These third parties may be laboratories that develop companion diagnostic tests. Recently, FDA published a proposed rule announcing its intention to regulate laboratory- developed tests (LDTs) as medical devices subject to existing device regulatory requirements. If these parties are unable to successfully develop companion diagnostics for these therapeutic product candidates, meet FDA regulatory requirements, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. Any~~

failure to successfully develop this companion diagnostic may cause or contribute to delayed enrollment of this trial and may prevent us from initiating or completing further clinical trials to support marketing approval for our product candidates. As a result, our business, results of operations and financial condition could be materially harmed. Our relationships with customers, physicians and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply or have not fully complied with these laws, we could face substantial penalties. Healthcare providers, physicians and third-party payors in the United States, U.S., and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing licensure. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, drug wholesalers / distributors, pharmacy benefit managers, and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, develop, sell, market and distribute our product candidates, if we obtain marketing licensure. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business or financial arrangements. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. 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 governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties; damages; fines; disgorgement; imprisonment; or exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid; additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws; contractual damages; reputational harm; and / or the curtailment or restructuring of our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusion from government-funded healthcare programs. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace. The successful commercialization of our product candidate, if we obtain marketing licensure, or any other product candidates in the United States and elsewhere will depend in that we develop, may become subject to unfavorable pricing regulations or third-party payors on the extent to which coverage or reimbursement practices, which third-party payors, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our business ability to market those products and decrease our ability to generate revenue. Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory licensure. In the United States and in other countries, our ability to successfully commercialize our product candidate will depend, in part, on the extent to which coverage and adequate reimbursement for any products for which we obtain marketing authorization will be available from third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government health care programs (e.g., Medicare, Medicaid or TRICARE), managed care providers, private health insurers, health maintenance organizations and other organizations is essential. In the U.S., no uniform policy for coverage most patients to be able to afford medical services and reimbursement for pharmaceutical products such as our product candidates exists among third party payors. Third-party payors decide which medications they will pay for and establish reimbursement levels; therefore, our ability to successfully commercialize our product candidates will depend, in part, on the extent to which coverage and adequate reimbursement for any our products, product candidate for which we obtain marketing authorization will be available from third-party payors. In the United States, no uniform policy for coverage and reimbursement for pharmaceutical products exists among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval processes apart from Medicare coverage and reimbursement determinations. Therefore, coverage and reimbursement for products for which we may obtain marketing authorization could differ significantly from payor to payor. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product. Payors consider a number of factors when determining whether to cover a new product, including, for example, whether the 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. Third-party payors may also limit coverage to specific products on an approved list, or

formulary, which might not include all of the FDA- approved products for a particular indication **if they are granted Accelerated Approval. Failure to obtain or maintain coverage and adequate reimbursement for our product candidate, if approved, could limit our ability to market the products and decrease our ability to generate revenue.** Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A decision by a third-party payor not to cover or not to separately reimburse for any products for which we may obtain marketing authorization could reduce physician utilization of such products. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement in the United States will be available for our current or future product candidates or for any procedures using our current product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Limitation on coverage and reimbursement may impact the demand or for future product candidates, or the price of, and our ability to successfully commercialize any reimbursement product candidate that we develop. may become available may not be adequate or For may be decreased or eliminated in the future. Moreover, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, increasing efforts by third-party payors in the United States U. S. and abroad to cap or reduce healthcare costs may cause payor organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates- candidate. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of our products, in addition to the costs required to obtain FDA or comparable marketing authorizations or approvals. Additionally, we may also need to provide permissible discounts to purchasers, private health plans or government healthcare programs. Our product candidates- candidate may nonetheless not be considered medically necessary or cost- effective. If third-party payors do not consider a product to be cost- effective compared to other available therapies, they may not cover the product after marketing authorization or approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates- candidate. Lastly- The regulations that govern marketing approvals, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. In some foreign countries, the proposed pricing for a drug must be approved before the drug may be lawfully marketed. The requirements governing drug In many countries, the pricing review period begins after marketing vary widely from country to country. For- or example, EU Member States can restrict the range of medicinal products- product licensing for which their national health insurance systems provide reimbursement and they can control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these Member States may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. An EU Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Approaches between EU Member States are diverging. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines is granted negotiated with the Economic Committee for Health Products. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates- candidate. Historically, products launched in the EU do not follow price structures of the United States and generally prices in the EU tend to be significantly lower than- that prices in the United States are sufficient to recoup our investment. Enacted and future healthcare legislation may increase the difficulty and cost for us to progress our clinical programs and obtain marketing licensure or approval of and commercialize our product candidates- candidate and may affect the prices we may set. In the United States U. S. and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect results of our future operations. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, the Inflation Reduction Act (IRA), which was signed into law on August 16, 2022, allows Medicare to: beginning in 2026, establish a " maximum fair price " for a fixed number of pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with the Centers for Medicare and Medicaid Services (CMS); and, beginning in 2023, penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation, among other reforms. CMS has recently taken steps to implement the IRA, including: • On June 30, 2023, issuing guidance detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the " maximum fair price " provision that would become effective in 2026; • On August 29, 2023, announcing the initial list of 10 drugs subject to price negotiations (including one product for oncologic indications); • On November 17, 2023, releasing guidance outlining further details in implementing the Medicare Part D Discount Program; and • On December 14, 2023, updating a list of 48 Medicare Part B products that had adjusted coinsurance rates based on the inflationary rebate provisions of the IRA for the time period of January 1, 2024 to March 31, 2024. It is unclear how future regulatory actions to implement the IRA, as well as the

outcome of pending litigation against the IRA, may affect our products and future profitability. See Part I, Item 1, Government Regulation – ~~Other Healthcare Laws~~ **and Data Privacy Regulation** – Healthcare Reform of this Annual Report on Form 10-K for additional detail on recent healthcare reform efforts that could affect our operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which state and federal governments cover particular healthcare products and services and could limit the amounts that federal and state governments will pay for healthcare items and services. This could result in reduced demand for any product candidate we develop or could result in additional pricing pressures. In markets outside of the ~~United States~~ **U. S.**, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. The price control regulations outside of the ~~United States~~ **U. S.** can have a significant impact on the profitability of a given market, and further uncertainty is introduced if and when these laws change. ~~For example, in Canada, price control legislation for patented medicines is currently undergoing significant changes that may have significant effects on profitability for companies selling products in Canada.~~ We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the ~~United States~~ **U. S.** or any other jurisdiction. If we, or any third parties we may engage, are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we, or these third parties, are not able to maintain regulatory compliance, our product ~~candidates~~ **candidate** may lose any regulatory licensure or approval that may have been obtained and we may not achieve or sustain profitability. **The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities. On June 28, 2024, the U. S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) “ must exercise their independent judgment ” and “ may not defer to an agency interpretation of the law simply because a statute is ambiguous. ” The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the Department of Health and Human Services (HHS), CMS, FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny. In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles, including, for example, the current presidential administration’ s commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA and CMS. Efforts by the current administration to limit federal agency budgets or personnel may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidate or obtain regulatory approval for our product candidate. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.** Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, operations, and financial condition. ~~In The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the~~ **ordinary course of business, we** ~~collect~~ **collect, receive, store, process, generate**, use, disclosure, transfer, **disclose** security and processing of personal information, **make accessible** such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, **protect** which may create uncertainty in our business, **secure** affect our or our service providers’ ability to operate in certain jurisdictions or to collect, store **dispose of**, transfer use **transmit**, and share, **or collectively, process, personal data and**, result in liability or impose additional compliance or other costs on us **sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third party data, business plans, transactions, clinical trial data and financial information or collectively, sensitive data**. Any failure or perceived failure by us to comply with federal, state or foreign laws or self- regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. ~~As our operations and business grow~~ **In the U. S.**, **federal, state, and local governments have enacted numerous** we may become subject to or affected by new or additional data **privacy and security laws, including data breach notification laws, personal data privacy laws, consumer** protection laws (e and regulations and face increased scrutiny or attention from regulatory authorities. ~~In g., Section 5 of the Federal Trade Commission Act), and the other~~ **United States similar laws (e. g. , wiretapping laws).** ~~most~~ **Most** healthcare providers, including certain research institutions from which we may obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (**HIPAA**), as amended by the Health Information Technology for Economic and Clinical Health Act (**HITECH**), which we collectively refer to as **HIPAA**. We are not currently acting as a covered entity (**health plans, health care clearinghouses and certain health care providers**) or business associate (**individuals or entities that create, receive, maintain or transmit individually identifiable health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors**) under HIPAA and therefore are not directly regulated under HIPAA. However, any person may be prosecuted under HIPAA’ s criminal provisions either directly or under aiding- and- abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA- covered healthcare provider or research institution that has disclosed individually identifiable health information in a manner that is not authorized or permitted under HIPAA. In addition, in the future, we may maintain sensitive personal information, including health- related information, that we receive throughout the clinical trial

process, in the course of our research collaborations and / or directly from individuals (or their healthcare providers) who may enroll in patient assistance programs if we choose to implement these types of programs. As a result, we may be subject to data privacy and security laws protection such information, including state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. ~~Other federal and state laws establish additional requirements for protecting the privacy and security of personal information, including health information. In addition the past few years, certain numerous U. S. states have proposed or enacted legislation health- specific or comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data.~~ For instance ~~example~~, Washington 's state recently passed the "My Health My Data "Act ; which will regulate ~~regulates~~ "consumer health data," which ~~includes~~ is defined as "personal information that is linked or reasonably linked to a consumer and that identifies a consumer' s past, present, or future physical or mental health. " ~~The "However, the~~ My Health My Data "Act provides exemptions for personal data used or shared in research, including data subject to 45 C. F. R. Parts 46, 50, and 56. Nevada also recently enacted a consumer health data privacy bill, and additional states may adopt health- specific privacy laws that could impact our business activities depending on how they are interpreted. The Federal Trade Commission, or the FTC, and many state attorney generals are interpreting existing federal and state consumer protection laws to impose evolving standards for the collection, use, dissemination and security of health- related and other ~~Another example~~ personal information. Privacy laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. Violating individuals' privacy rights, publishing false or misleading information about security practices, or failing to take appropriate steps to keep individuals' personal information secure may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. Additionally, the FTC recently published an advance notice of proposed rule making on "commercial surveillance " and data security, and is seeking comment on whether it should implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (2) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive. Federal regulators, state attorneys general and plaintiffs' attorneys have been and will likely continue to be active in this space, and if we do not comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions. Further, the California Consumer Privacy Act of 2018 (~~or the CCPA~~), went into effect in January ~~as amended by the California Privacy Rights Act of~~ 2020 (CPRA), which ~~collectively CCPA~~, creates individual data privacy rights for consumers and operational requirements for companies, including placing increased privacy and security obligations on entities handling certain personal information of consumers or households ~~. These ; imposes additional data protection obligations on covered businesses, including additional consumer rights processes; limitations on data uses; new audit requirements could increase our compliance costs for higher risk data; and potential liability opt outs for certain uses of sensitive data.~~ The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, ~~as well as a private right of action for data breaches~~, that is expected to increase data breach litigation. While there is currently an ~~and~~ exception for protected health information maintained by a business associate or covered entity as well as an exception for clinical trial data, as currently written, the CCPA may impact certain of our business activities. Further, the California Privacy Rights Act, or CPRA, was passed in California in 2020 and modifies the CCPA. The CCPA (as modified by the CPRA) imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates ~~created~~ a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement ~~. The majority of the provisions went into effect on January 1, 2023, and~~ ~~litigation~~ additional compliance investment and potential business process changes may be required. Similar laws have been adopted ~~in other states~~ or proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging. While these ~~new laws may~~ ~~generally~~ include exemptions for health- related data such as clinical trial data, they add layers of complexity to compliance in the U. S. market, and could increase our compliance costs and adversely affect our business. In the event ~~that~~ we are subject to or affected by HIPAA, the CCPA (~~as modified by the CPRA~~), or other privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. ~~In addition~~ ~~Additionally,~~ the FTC and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the collection, use, dissemination and security of health- related and other personal information and in particular health information. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Consumer protection laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. If such information that we publish is considered untrue, we may be subject to government claims of unfair or deceptive trade practices, which could lead to significant liabilities and consequences. Furthermore, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 of the FTC Act. The FTC has also been active with respect to enforcement of its Health Breach Notification Rule and in scrutinizing the use and disclosure of sensitive personal information. The FTC finalized changes to the Health Breach Notification Rule in April 2024. Additionally, the FTC published an advance notice of proposed rulemaking in 2022 on commercial surveillance and data security, and may implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (1) collect, aggregate, protect, use, analyze, and

retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive in the coming years. Outside the U. S., an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union ~~’s~~ **EU General Data Protection Regulation (EU GDPR)** ~~and the United Kingdom’s GDPR (UK GDPR)~~, **collectively GDPR**, imposes ~~impose~~ strict requirements for the processing of personal data (i. e., data which identifies an individual or from which an individual is identifiable). The UK has implemented the EU GDPR into its national law by virtue of Section 3 of the European Union (Withdrawal) Act 2018 (known as the UK GDPR, and, together with the EU GDPR, the GDPR), which sits alongside the UK Data Protection Act 2018. The GDPR imposes a number of compliance obligations on controllers including inter alia: (i) accountability and transparency requirements, which require controllers to demonstrate and record compliance with the GDPR and to provide more detailed information to data subjects regarding processing; (ii) requirements to process personal data lawfully, including specific requirements for obtaining valid consent where consent is the lawful basis for processing; (iii) obligations to consider data protection as any new products or services are developed and designed, including to limit the amount of personal data processed; (iv) obligations to implement appropriate technical and organizational security measures to safeguard personal data and to report certain personal data breaches to the relevant supervisory authority without undue delay (and, in any event, no later than 72 hours, where feasible) and affected individuals where the personal data breach is likely to result in a high risk to their rights and freedoms; (v) obligations to comply with data protection rights of data subjects, including a right of access to and rectification of personal data, a right to obtain restriction of processing or to withdraw consent to processing, or to object to processing of personal data and a right to ask for a copy of personal data to be provided to a third party in a useable format and a right to erasure of personal data in certain circumstances; and (vi) additional requirements around the processing of special categories of personal data (including health data and genetic data). **The** In addition, the EU-GDPD also prohibits transfers of personal data subject to the EU-GDPD to countries outside of the EEA, unless such transfers are made to a country deemed to have adequate data privacy laws by the European Commission or specific safeguards have been implemented in accordance with the EU-GDPD or a derogation under the EU-GDPD can be relied on. The Court of Justice of the European Union issued a decision in July 2020 invalidating the EU-U. S. Privacy Shield framework as a data transfer mechanism (Schrems II) and imposing further restrictions on the use of EU standard contractual clauses, or EU SCCs, including a requirement for companies to carry out a transfer impact assessment, or TIA. A TIA, among other things, assesses laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under the EU SCCs will need to be implemented to ensure an “essentially equivalent” level of data protection to that afforded in the EU. The UK GDPR imposes similar restrictions on transfers of personal data from the **their UK jurisdiction to other** jurisdictions that the UK does not consider adequate. This may have implications for our cross-border data flows and may result in compliance costs. Further, on October 7, 2022, the U. S. President introduced an Executive Order to facilitate a new Trans-Atlantic Data Privacy Framework, or DPF, which will act as a successor to the invalidated Privacy Shield. On July 10, 2023, the European Commission adopted its Final Implementing Decision granting the U. S. adequacy, or Adequacy Decision, for EU-US transfers of personal data for entities self-certified to the DPF. Entities relying on EU SCCs for transfers to the U. S. are also able to rely on the analysis in the Adequacy Decision as support for their TIA regarding the equivalence of U. S. national security safeguards and redress. It should also be noted that the UK Government has published its own form of EU SCCs, known as the International Data Transfer Agreement and International Data Transfer Addendum to the new EU SCCs. The UK Information Commissioner’s Office has also published its own version of the TIA and revised guidance on international transfers, although entities may choose to adopt either the EU or UK style TIA. Further, on September 21, 2023, the UK Secretary of State for Science, Innovation and Technology established a UK-US data bridge (i. e., a UK equivalent of the Adequacy Decision) and adopted UK regulations to implement the UK-US data bridge, or UK Adequacy Regulations. Personal data may now be transferred from the UK under the UK-US data bridge through the UK extension to the DPF to organizations self-certified under the UK extensions to the DPF. Companies subject to the EU-GDPD may be subject to robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million (under the EU GDPR) or £ 17. 5 million (under the UK GDPR) or **up to** 4 % of the annual global turnover of the **preceding year for the** noncompliant company, whichever is greater. ~~In addition, the EU-GDPD confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the EU-GDPD.~~ Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations. If we or our third-party manufacturers and suppliers 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 an adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We **cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and / or liabilities under applicable laws and regulations. We** generally contract with third parties for the disposal of these materials and wastes **and**. ~~We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and~~

development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Upon an event of this nature, we may be held liable for any resulting damages and such liability could exceed our resources and **federal, state or federal** or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. **Further, environmental** **Environmental** laws and regulations are complex, change frequently and have tended to become more stringent. ~~We cannot predict the impact of any changes of this nature and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with .current~~ **Current** or future environmental, health and safety laws and regulations. ~~These current~~ or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations ~~also~~ may result in substantial fines, penalties or other sanctions. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. ~~We do not carry specific biological waste or hazardous waste insurance coverage, workers' compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination. We are subject to U. S. and certain foreign export and import controls , sanctions, embargoes, anti- corruption laws and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business. We are subject to~~ **various federal, state, and foreign government** export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department's Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act of 2001 and other state and national anti-bribery and anti- money laundering laws in the **U. S. and** countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the ~~United States~~ **U. S.**, to sell our products abroad once we enter a commercialization phase and / or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We may also have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of these activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. **The biopharmaceutical and medical device industries are subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities. On June 28, 2024, the U. S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) " must exercise their independent judgment " and " may not defer to an agency interpretation of the law simply because a statute is ambiguous. " The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by HHS, CMS, FDA and other agencies with significant oversight of the biopharmaceutical and medical device industries. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny. In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles. For example, the current presidential administration's commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA, and CMS. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidate or obtain regulatory approval for our product candidate.** Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business If we fail to attract and retain qualified senior management and key scientific **and medical** personnel, our business may be materially and adversely affected. Our success depends in part on our continued ability to attract, retain and motivate highly qualified management **and**, clinical and scientific personnel. We are highly dependent upon members of our senior management, including Lara Sullivan, M. D., our President and Chief Executive Officer, and Pamela Connealy, our Chief Financial Officer and Chief Operating Officer, as well as our senior scientists, **senior medical personnel** and other members of our senior management team. The loss of ~~services one or more of any our executive officers, senior scientists, senior medical personnel and other members~~ of these individuals **our senior management team** could delay or prevent the successful development of our product pipeline, the initiation and completion of our clinical trials or the commercialization of ~~our product candidates~~ **candidate** or any future product candidates. Competition for qualified personnel in the pharmaceutical, biopharmaceutical and biotechnology field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We ~~will~~ **may** need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on

acceptable terms, or at all. In addition, 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. **As our employees, consultants and collaborators may engage in misconduct or other improper activities** product candidates advance into clinical trials, **including insider trading** we may experience difficulties in managing our growth and **non** expanding our operations. As of March 20, 2024, we had 50 full-time **compliance with regulatory standards and requirements. We are exposed to the risk that our** employees, **consultants, distributors, and collaborators may engage in fraudulent or** development and commercialization plans and strategies develop **illegal activity. Misconduct by these parties could include intentional, reckless** and as we continue to operate as a public company, we expect to expand our **or negligent conduct or disclosure of unauthorized activities to us that violates the regulations of the FDA, U. S. regulators and non- U. S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators. We have adopted a code of conduct applicable to all of our employee-employees** base for managerial, operational-officers, financial-directors, including consultants, but it is not **always possible to identify and deter misconduct by our employees** and other **third** resources. In addition, we have limited experience in product development. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners- **parties**, suppliers and other- **the** organizations. Our ability to manage our operations- **precautions we take** and future growth will require us to **detect** integrate products and **prevent this activity** technology from the Merger and continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be **effective in controlling unknown** able to implement improvements to our- **or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of** management information and control systems in **defending ourselves against an any of these claims** efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our- **or investigations** growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects. We currently have no marketing, sales, or distribution infrastructure and **both** we intend to either establish **establishing this** a sales and marketing infrastructure or **outsource-outsourcing** this function to a third party. Either of these commercialization strategies carries substantial risks to us. We currently have no marketing, sales, and **or** distribution capabilities because all our product candidates- **candidate** are **is** still in preclinical or clinical development. If any of our product candidates- **candidate** complete **completes** clinical development and are **is** approved, we intend to either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates- **candidate** in a legally compliant manner, or to outsource this function to a third party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks, including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborators' business strategy. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, 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, which would have a material adverse effect on our business, financial condition, and results of operations. Our **internal computer information technology** systems, or those of any of our existing or future CROs, manufacturers, other contractors, consultants, or collaborators, may **be compromised** fail or suffer security or data privacy breaches or other unauthorized or improper access to, **use of or destruction of our proprietary and confidential data, employee data or personal data**, which could result in additional costs, significant liabilities, harm to our reputation and material disruption of our operations. In the ordinary course of our business, we collect, process, and store proprietary, confidential, and sensitive information, including personal information (including health information), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties. Despite the implementation of security measures, our **internal computer information technology and infrastructure**, and those of our current and any future CROs, manufacturers, other contractors, consultants, existing or future collaborators and other third-party service providers are vulnerable to damage from various methods, including cybersecurity attacks, breaches, **intentional or accidental mistakes or errors, malfeasance**, or other technological failures, which can include, among other things, computer viruses, unauthorized access attempts, including third parties gaining access to systems using stolen or inferred credentials, ransomware attacks, denial- of- service attacks, phishing attempts, service disruptions, natural disasters, fire, terrorism, war and telecommunication and electrical failures. As the cyber- threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate

preventative measures. We may also experience security breaches that may remain undetected for an extended period. While we have implemented security measures designed to protect against security breaches, there can be no assurance that our security measures or those of our service providers, partners and other third parties, will be effective in protecting against all security breaches and material adverse effects on our business that may arise from such breaches. The recovery systems, security protocols, network protection mechanisms and other security measures that we (and our third parties) have integrated into our platform, systems, networks and physical facilities, which are designed to protect against, detect and minimize security breaches, may not be adequate to prevent or detect service interruption, system failure, or data loss. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information, it could result in a material disruption of our product candidate development programs, program and our business operations including without limitation, disruptions of our drug development programs, delays in our regulatory approval efforts, regulatory investigations or enforcement actions, litigation, indemnity obligations, negative publicity, and financial loss and significant liabilities. In addition, system failures could cause the loss, theft, exposure, or unauthorized access or use of valuable clinical trial data as a result of accidents, errors or malfeasance by our employees, independent contractors or others working with us or on our behalf or otherwise disrupt our clinical activities and be expensive and time-consuming to remedy. Some of the federal, state and foreign government legal requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed, ongoing or future clinical trials involving our product candidates, candidate could result in delays in our regulatory licensure efforts and significantly increase our costs to recover or reproduce the lost data. Any breach of our computer systems may result in a loss of data or compromised data integrity across many of our programs in various stages of development. We may be required to expend resources, modify our business activities and practices, or modify our operations, including our development program activities, or information technology in an effort to comply with applicable data protection laws, privacy policies and data protection obligations. While we have implemented security measures designed to prevent a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates, candidate could be delayed and we could be subject to significant fines or penalties for any noncompliance with certain state, federal or international privacy and security laws. Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles, in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. In addition, such insurance We or the third parties upon whom we depend may not be available to adversely affected by earthquakes, wildfires or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us in from a serious disaster. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other -- the future natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on economically reasonable terms, our or at ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or 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 may prove inadequate 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 could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development and discovery programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects. Our business is subject to economic, political, regulatory and other risks associated with conducting business internationally. We may seek regulatory approval or licensure of our product candidates, candidate outside of the United States. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals or licenses, including, but not limited to: • differing regulatory requirements and reimbursement regimes in foreign countries; • unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in

another country; • difficulties staffing and managing foreign operations; • workforce uncertainty in countries where labor unrest is more common than in the United States; • potential liability under the FCPA or comparable foreign regulations; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States U. S.; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geo-political actions, including war and terrorism. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations. Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns 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--- **perform** 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 **U. S. Securities and Exchange Commission (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 drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U. S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. 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, 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. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Risks Related to Our Dependence on Third Parties If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses. We are a party to license agreements with Pfizer, Biosion, and the University of Chicago, pursuant to which we in- license patents and technology for certain of our product candidates, pursuant to which we may license patents and technology for future product candidates. Our current license agreements and our collaboration agreement impose, and any future license agreements or collaboration agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement and / or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor' s rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. We **have already entered into collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop.** We may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future. If any of these collaborations, strategic alliances or **additional** licensing arrangements are not successful, we may not be able to capitalize on the market potential of ~~those~~ **the** product candidates **candidate**. We may in the future form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our **current or future** product candidates ~~and any future product candidates that we may develop~~. Any of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. **We** ~~In addition, we~~ face significant competition in seeking appropriate strategic partners, **and** the negotiation process for these sorts of transactions is time-consuming, complex and expensive. Moreover, 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, potency, purity and efficacy and obtain marketing approval. Additionally, our existing partners may decide to acquire or partner with other companies developing oncology therapeutics, which may have an adverse impact on our business prospects, financial condition and results of operations. Further, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of those transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business prospects, financial condition and results of operations. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies the entry into the transaction in the first place. Any delays in entering into new collaborations or strategic partnership agreements related to our

product candidates could delay the development and commercialization of our product ~~candidates-~~ **candidate** in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations. We rely on third parties to manufacture our product ~~candidates-~~ **candidate**. Any failure by a third party manufacturer to produce acceptable raw materials or product ~~candidates-~~ **candidate** for us or to obtain authorization from the FDA or comparable foreign regulatory authorities relating thereto may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory licensure or approvals or commercialize approved products. **We do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or distribute preclinical, clinical or commercial quantities of drug substance or drug product, including our existing product candidate. We** rely on third ~~party~~ contract manufacturers to manufacture our preclinical **and clinical** trial product supplies. **We expect** ~~and clinical product supplies, and if we receive authorization to~~ **continue to** market our product candidates, we will rely on such ~~third party~~ manufacturers **if we receive regulatory licensure** for commercial supplies ~~our product candidate~~. We do not ~~own~~ **have complete control over the ability of or our operate third party manufacturers to maintain adequate** manufacturing facilities for producing such supplies **capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel**. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices, whether as a result of inflationary pressures or otherwise. In particular, any replacement of any of our manufacturers could require significant effort and expense because there may be a limited number of qualified replacements and could take a significant amount of time to complete. The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as **Current Good Manufacturing Practice (cGMPs- cGMP)**. In the event that any of our manufacturers fail to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the 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 reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product ~~candidates-~~ **candidate** 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 our product ~~candidates-~~ **candidate**. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop ~~our~~ product ~~candidates-~~ **candidate** in a timely manner or within budget. We expect to continue to rely on third party manufacturers if we receive regulatory licensure for ~~any our~~ product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third party manufacturing for ~~our~~ product ~~candidates-~~ **candidate**, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product ~~candidates-~~ **candidate** successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMP or similar foreign requirements could adversely affect our business in a number of ways, including: ~~an~~ inability to initiate or continue clinical trials of ~~the~~ product ~~candidates-~~ **candidate** under development; ~~delay in~~ submitting regulatory applications, or receiving regulatory licenses, for ~~the~~ product ~~candidates-~~ **candidate**; ~~loss of the cooperation of an existing or future collaborator;~~ ~~subjecting~~ third party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities; ~~requirements to cease distribution or to recall batches of our product~~ ~~candidates-~~ **candidate**; and ~~the inability to commercialize a product candidate, and an inability to meet commercial demands for such products.~~ We may be unable to establish agreements with third party CDMOs, or to do so on acceptable terms. Even if we are able to establish agreements with CDMOs, reliance on them entails additional risks, including: ~~reliance on the CDMO for regulatory, compliance and quality assurance;~~ ~~the possible breach of the manufacturing agreement by the CDMO;~~ ~~the possible misappropriation of our proprietary information, including our trade secrets and know-how;~~ and ~~the possible termination or nonrenewal of the agreement by the CDMO at a time that is costly or inconvenient for us.~~ We have only limited technology transfer agreements in place with respect to our product ~~candidates-~~ **candidate**, and these arrangements do not extend to commercial supply and, in some instances, to clinical supply. We acquire many key materials on a purchase order basis. As a result, we do not have long- term committed arrangements with respect to our product ~~candidates-~~ **candidate** and other materials. If we receive marketing licensure for ~~any of our product~~ ~~candidates-~~ **candidate**, we will need to establish an agreement for commercial manufacture with a third party. The CDMOs we retain may not be able to comply with cGMP regulations or ~~similar~~ **comparable foreign** regulatory requirements ~~outside of the United States~~. Our failure, or the failure of our CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of license, license revocation, seizures or recalls of ~~our~~ product ~~candidates-~~ **candidate** or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. The facilities used by our contract manufacturers to manufacture our product ~~candidates-~~ **candidate** must be approved by the FDA or the EU Member States in coordination with the EMA pursuant to inspections that will be conducted after we submit our BLA to the FDA or our marketing authorization application to the EMA. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing. Third ~~party~~ manufacturers may not be able to comply with cGMP regulations or ~~similar~~ **comparable foreign** regulatory requirements ~~outside of the United States~~. If our

contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory bodies, they will not be able to secure and / or maintain marketing licensure for their manufacturing facilities. In addition, we do not have complete control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EU Member States and the EMA or other comparable regulatory authorities do not approve these facilities for the manufacture of our product candidates- **candidate** or if they withdraw any such licensure in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing licensure for or market our product candidates- **candidate**, if approved or licensed. Our failure, or the failure of our third -party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of licensure, license revocation, seizures or recalls of products or **our** product candidates- **candidate**, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates- **candidate** and harm our business and results of operations. Our product candidates- **candidate** and any products that we may develop may compete with other product candidates and products for access to suitable 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 delay clinical development or marketing licensure. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current CDMOs cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates- **candidate**, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer. Our current and anticipated future dependence upon others for the manufacture of our product candidates- **candidate** or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing licensure on a timely and competitive basis. A portion of our manufacturing of our product candidates- **candidate** takes place in China, through third -party manufacturers. A significant disruption in the operation of those manufacturers could materially adversely affect our business, financial condition and results of operations. We currently contract manufacturing operations to third parties, and large quantities of our product candidates- **candidate** are **is** manufactured by these third parties globally, including in China. Any disruption in production or inability of our manufacturers to produce adequate quantities to meet our needs could impair our ability to operate our business on a day- to- day basis and to continue our development of our product candidates- **candidate**. **Foreign and** Furthermore, since certain of **Chinese biotechnology companies and CDMOs, may become subject to U. S. legislation, including these-- the manufacturers legislation pending in Congress called the BIOSECURE Act. The Act could impose trade restrictions, sanctions, and other regulatory requirements by the U. S. government, which could restrict or even prohibit our ability to work with such entities. If we are located in China- restricted or prohibited from working with our current CDMOs**, we are exposed to the possibility **may incur added costs or reduction** of product **the** supply **disruption and increased costs in the event of** **material available to us** changes in the policies of the U. S. or Chinese governments- **delays political unrest or unstable economic conditions in China. the procurement For- or supply of such material or adverse effects** example, a trade dispute between the U. S. and China could lead to tariffs on **our ability to the** chemical intermediates we use that are manufactured- **manufacture in China our product candidate**. Any of these matters could materially and adversely affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding our product candidates- **candidate** used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. Our CDMOs may be unable to successfully scale- up manufacturing of our product candidates- **candidate** in sufficient quality and quantity, which would delay or prevent us from developing our product candidates- **candidate** and commercializing approved products, if any. In order to conduct clinical trials of our product candidates- **candidate**, we will need to manufacture **them- it** in large quantities. Quality issues may arise during scale- up activities. Our reliance on a limited number of CDMOs, the complexity of drug manufacturing and the difficulty of scaling up a manufacturing process could cause the delay of clinical trials, regulatory submissions, required licensure, or commercialization of our product candidates- **candidate**, cause us to incur higher costs and prevent us from commercializing our product candidates- **candidate** successfully. Furthermore, if our CDMOs fail to deliver the required commercial quality and quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement CDMOs capable of production in a timely manner at a substantially equivalent cost, then testing and clinical trials of **that- our** product candidate may be delayed or infeasible, and regulatory licensure or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain sufficient raw and intermediate materials on a timely basis or if we experience other manufacturing or supply difficulties, our business may be adversely affected. The manufacture of **certain of** our product candidates- **candidate** requires the timely delivery of sufficient amounts of raw and intermediate materials. We work closely with our suppliers to ensure the continuity of supply but cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier. While we believe that alternative sources of supply exist where we rely on sole supplier relationships, there can be no assurance that we will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our product candidates- **candidate** in a timely or cost- effective manner. We expect to rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for completing such trials. We will rely on third -party CROs to conduct clinical trials for our biological product candidates- **candidate**. We currently do not plan to conduct any clinical trials independently. Agreements with these CROs might terminate for a variety of reasons, including for their failure to

perform. Entry into alternative arrangements, if necessary, could significantly delay our product development activities. Our reliance on these CROs for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols in the applicable IND. Moreover, the FDA requires compliance with standards, commonly referred to as GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If these CROs 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 licenses for our product candidates- **candidate** and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates- **candidate**. Risks Related to Our Intellectual Property If we are unable to obtain **or and maintain patent protection** --- **protect for our intellectual property in and to** our product candidates, **we may or** if the scope of the patent protection obtained is not sufficiently broad, **be able to compete effectively in or our** if our markets. **We rely upon a combination of** patents are insufficient to protect our product candidates for an adequate amount of time, or if we are unable to obtain adequate protection for our proprietary know- how, **we may not be able to compete effectively in our** markets. We rely upon a combination of patents, proprietary know- how, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and discovery programs. Our success depends in large part on our ability to obtain and maintain patent **and protection in the other** United States **intellectual property rights in the U. S.** and other countries with respect to our current and any future product candidates. We **and seek to protect our- or licensors** **have filed** proprietary position by, among other methods, licensing and filing patent applications in the United States **U. S.** and abroad **related directed** to our current **product candidates in and- an effort to establish intellectual property positions for** their compositions of matter as well as uses in the treatment of diseases. Our intellectual property includes patents and patent applications that we own, as well as those we in- license, including in- licensed patents that we manage directly and those that remain managed by our licensors. We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, **patent protection for our** product candidates and discovery programs in every country or territory in which we may sell our products, if approved. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also rely on trade secrets, know- how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We in- license and file patent applications directed to our product candidates in an effort to establish intellectual property positions directed to their compositions of matter as well as uses of these product candidates in the treatment of diseases. Our intellectual property includes patents and patent applications that we own, as well as patents and patent applications that we in- license. For example, our license agreements with Pfizer and Biosion grant us exclusive rights to certain patents and patent applications relating to our product candidates. We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. In addition, we cannot be sure that any of our pending patent applications will issue, or that, if issued, they have or will issue in a form that will be **in a form** advantageous to us. The United States Patent and Trademark Office (**or the USPTO**), international patent offices, or judicial bodies may deny, or significantly narrow claims made under our patent applications and our issued patents may be successfully challenged, may be designed around, or may otherwise be of insufficient scope to provide us with protection for our commercial products. It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover **We may be subject to a third party submission of prior art to the USPTO, or other patent offices, in our pending patent applications. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing. In addition to the above,** patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO may be significantly narrowed **by the time they issue, or claims** may not issue at all. The claims of our issued patents or patent applications when issued may not cover our current or future product candidates, or even if such patents provide coverage, the coverage obtained may not provide any competitive advantage. The patent applications that we own, or in- license, may fail to result in issued patents with claims that cover our current or **any** future product candidates in the United States **U. S.** or in other foreign countries. **There is no assurance that, or we may be required to disclaim** all of the potentially relevant prior art relating to our **or** patents and **a portion of the remaining** patent **term to secure issuance** applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our current or any future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of **any current and future** product candidates **that we may develop**. Further, if we encounter delays in regulatory licensure or approvals, the period of time during which we could market a product candidate under patent protection could be reduced. If the patent applications we own or have in- licensed with respect to our product candidates and discovery programs fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current or any future product candidates, it could dissuade companies from collaborating with us to develop and commercialize product candidates and future drugs and threaten our ability to commercialize future drugs. Any such outcome could have a negative effect on our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States **U. S.** For example, European patent law restricts the patentability of methods of treatment of the

human body more than ~~United States~~ **U. S.** law does. Furthermore, other parties may have developed or may develop technologies that may be related to, or competitive with, our technologies, and such parties may have filed, or may file, patent applications, or may have received, or may receive, patents, claiming inventions that may overlap or conflict with those claimed in our patent applications or issued patents, and that we may rely upon to establish exclusivity for our products in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the ~~United States~~ **U. S.** and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. **It is also possible that in our evaluation of third party intellectual property, we failed to identify relevant patents or applications. We cannot guarantee that any of our patent searches or analyses, including but not limited to 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 our current and future products.** As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drugs, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the ~~United States~~ **U. S.** and other countries may diminish the value of our patents or narrow the scope of our patent protection. ~~We may be subject to a third-party submission of prior art to the USPTO, or other patent offices, in our pending patent applications. Such a submission may preclude the granting of any of our pending patent applications, or may result in patents granting with narrow claims, which could limit our ability to stop others from using or commercializing similar or identical technology and products.~~ The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patent rights may be challenged in the courts or patent offices in the ~~United States~~ **U. S.** and abroad. For example, we may become involved in opposition, derivation, reexamination, inter partes review, post-grant review, or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding, or in litigation, could reduce the scope of our patent claims, result in our patent rights being held invalid, in whole or in part, or unenforceable, or limit the duration of the patent protection of our technology and products, and allow third parties to commercialize our technology or products and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our current or any future product candidates. Moreover, patents have a limited lifespan. In the ~~United States~~ **U. S. and internationally**, a patent generally expires 20 years after the earliest filing date of a non-provisional patent application. Various extensions may **or may not** be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or ~~any~~ future product candidates, we may be open to competition from generic and / or biosimilar versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent rights may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours. **We may also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.** Even if our patent rights are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned patent rights by developing similar or alternative technologies or products in a non-infringing manner. For example, a third-party may develop a competitive product that provides benefits similar to one or more of our product candidates, but that has a different composition that falls outside the scope of our patent protection. If the protection provided by our patent rights with respect to our product candidates is not sufficiently broad to impede such competition, or if the breadth, strength or term (including any extensions or adjustments) of protection provided by our patent rights with respect to our product candidates or any future product candidates is successfully challenged, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. ~~Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates or any future product candidates under patent protection would be reduced.~~ Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and / or patent applications will have to be paid to the USPTO and various government patent agencies outside of the ~~United States~~ **U. S.** over the lifetime of our owned and licensed patents and / or applications and any patent rights we may own or license in the future. We rely on a combination of in-house employees, **reputable law firms**, service providers, and our licensors to pay these fees. ~~The USPTO and various non-U. S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ a combination of in-house employees, reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property.~~ 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. If we or our licensors fail to maintain the

patents and patent applications covering our products or technologies, we may not be able to stop a competitor from marketing products that are the same as, or similar to, our product candidates, which would have a material adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance 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. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business. In addition, if we fail to apply for, or are unsuccessful in our application for, applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. In addition, if we are responsible for patent prosecution and maintenance of patent rights in- licensed to us, any of the foregoing could expose us to liability to the applicable patent owner. **Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.** Given the amount of time required for the development, testing and regulatory review of new product candidates such as PYX-201 and PYX-106, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, provided that the patent is not enforceable for more than 14 years from the date of licensure, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case. Intellectual property rights do not necessarily address all potential threats to our business. 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. The following examples are illustrative: • others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or license; • we or our licensors might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license; • we or our licensors 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 license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges; • our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • we may not be successful in enforcing our patents against potential infringers or recovering meaningful damages; and • the patents of others may have an adverse effect on our business. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business. **Third parties may initiate legal proceedings against us** Our commercial success depends, in part, upon our **or our licensors or** ability and the ability of others with whom we may collaborate **collaborators alleging that we** to develop, manufacture, market and sell our **or our licensors** current and any future product candidates and use our **or collaborators are** proprietary technologies without infringing the proprietary rights and intellectual property of third **their** parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights **or**. We may in the future become party to, **challenge the validity or scope of or our** be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, including **in oppositions, interference interferences** proceedings, **reexaminations, post grant review and inter partes review reviews, derivation or other similar proceedings** before the USPTO. **U. S.** In addition, there are third party patents and, if issued as patents, patent applications, relating to: the engineering of antibodies, including with respect to CD40 and Fe domains; and methods for treating cancers, including those expressing siglec-15; that may be construed to cover our product candidates or methods of using our product candidates, including PYX-107 and PYX-106, respectively. The third parties that control these patents may allege that our product candidates, including PYX-107 and PYX-106, infringe these patents. Parties making infringement, misappropriation, or other **domestic intellectual** property claims against us may obtain injunctive or other equitable relief, which could effectively block our **or foreign** ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction **jurisdictions .** could hold that these **These** third party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not

infringe patents that may be granted in the future. Other companies and research institutions have filed, and may file in the future, patent applications related to antibodies or antibody-drug conjugates and their therapeutic use. Some of these patent applications have already been allowed or issued, and others may issue in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, **expensive and time-consuming and adversarial in these proceedings** may **have the ability to dedicate substantially greater resources to prosecuting** be applications now pending which may later result in issued patents that may be infringed by the **these** manufacture, use **legal actions than we or our** sale of **licensors or collaborators can. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing** our product candidates. ~~Regardless of when filed, or we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes our product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the therapeutic or product candidate that is the subject of the actual or threatened suit. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all. Our business could be harmed if in litigation the prevailing party does not offer us or our licensors or collaborators a license, and such a license may not be on commercially reasonable terms. The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If **Even if** we are unable to successfully **or our licensors or collaborators** obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate(s), which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could **may** be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us **or**, and it 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 **our product candidate-licensors or collaborators**. 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 or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could materially harm our business. **Even if we are successful in defending against such claims, litigation can be expensive and time consuming and would divert management's attention from our core 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.** We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. **Certain Many** of our employees, consultants or advisors **were previously, or** are currently, ~~or were previously~~, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals have used or disclosed **confidential information or** intellectual property, including trade secrets, **or** other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and ~~be a distraction~~ **distract** to management. **We** In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents, **or** patent applications, as a result of the work they performed on our behalf. Although 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 such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach our ~~University of Chicago, Pfizer, or Biosion~~ license agreements **agreement** or~~

any of the other agreements under which we acquired, or will acquire, intellectual property rights covering our product candidates, we could lose the ability to continue the development and commercialization of the related product candidates (s). The licensing of intellectual property is of critical importance to our business and to our current and future product candidates, and we **may expect to** enter into additional such agreements in the future. In particular, the rights to the intellectual property covering **micvotabart pelidotin** **PYX-201** are in- licensed from Pfizer ~~and the rights to the intellectual property covering our product candidate PYX-106 are in- licensed from Biosion. We may acquire the rights to the intellectual property covering future product candidates from other third- party licensors.~~ If we fail to meet our obligations under any of our in- license agreements, including the amended and restated license agreement with Pfizer, dated October 6, 2022 ~~, as further amended, or the Biosion License Agreement,~~ as further amended, then the licensor may terminate the license agreement. If one of our material in- license agreements is terminated, we will lose the right to continue to develop and commercialize the product candidate (s) covered by such in- license agreement. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under our in- license agreements, we may not be able to do so in a timely manner, at an acceptable cost or at all. We may **be become** involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time- consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid ~~or,~~ is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in **such any litigation or defense** proceedings could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing. The initiation of a claim against a third party might also cause the third party to bring counter claims against us, such as claims asserting that our patent rights are invalid or unenforceable. In patent litigation in the **United States-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, non- enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent, withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post- grant proceedings such as ex parte reexaminations, inter partes review, or post- grant review, or oppositions or similar proceedings outside the **United States-U. S.**, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the **United States-U. S.** Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. 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 this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock. 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. 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. Changes in U. S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates. The **United States-U. S.** has recently enacted and implemented wide ranging patent reform legislation. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available **or weakening the rights of patent owners** in certain circumstances ~~or weakening the rights of patent owners in certain~~ situations. In addition to increasing uncertainty ~~with regard~~ **regarding** to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own, have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future. **For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties, or limit the enforceability of patents against third parties, including government agencies or government contractors.** We may not be able to protect our intellectual property rights throughout the world,

which could negatively impact our business. Filing, prosecuting and defending patents covering our current and any future product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States-U. S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims, or other intellectual property rights may not be effective or sufficient to prevent them from so competing. **Additionally, some foreign countries do not protect intellectual property rights to the same extent as the federal laws of the U. S. and we may encounter problem protecting and defending our intellectual properties rights in such countries, which could negatively affect our business. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties, or limit the enforceability of patents against third parties, including government agencies or government contractors.** If we are unable to protect the confidentiality of our trade secrets, our business and competitive position ~~would~~ **may** be harmed. In addition to seeking patent and trademark protection for our product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States-U. S. are less willing or unwilling to protect trade secrets. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive **and**, time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Since we rely on third parties to help us discover, develop, manufacture or commercialize our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing or commercialization of our current or any future product candidates, we must, at times, share trade secrets with them. ~~We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements.~~ We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States-U. S. are sometimes less willing to protect trade secrets. ~~Any trademarks we may~~

obtain may be infringed or successfully challenged, resulting in harm to our business. We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our current or any future product candidate. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. In addition, any proprietary name we propose to use with our current or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Risks Related to Our Common Stock Our operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. We expect our operating results may be subject to annual and quarterly fluctuations. Our net loss and other operating results may be affected by numerous factors, including: • results of preclinical studies, IND submissions, clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners; • variations in the level of expense related to the ongoing development of the FACT Platform, the APXiMAB Platform, our product candidates or future development programs; • our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements; • any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved; • additions and departures of key personnel; • strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy; • if any of our product candidates receive regulatory licensure, the terms of such licensure and market acceptance and demand for such product candidates; • regulatory developments affecting our product candidates or those of our competitors; and • changes in general market and economic conditions. If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. Our stock price is volatile, and you could lose all or part of your investment. Our stock price is highly volatile. As a result of this volatility, investors may not be able to sell their common stock at or above the price they purchased their common stock. The market price for our common stock may be influenced by many factors, including the other risks described in this section of the Annual Report on Form 10-K titled “Risk Factors” as well as and the following: • results of our preclinical studies, IND submissions and clinical trials, ~~if any,~~ of our product candidates **candidate**, or those of our competitors or our existing or future collaborators; • regulatory or legal developments in the U. S. and other countries, ~~especially changes in laws or regulations applicable to our products~~; • the success of competitive products or technologies; • introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements; • **regulatory** actions ~~taken by regulatory agencies~~ with respect to our products, ~~our product candidates-~~ **candidate**, preclinical studies, clinical trials, manufacturing process or sales and marketing terms **or that of our competitors**; • actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us; ~~• the success of our efforts to acquire or in-license additional technologies, products or product candidates~~; • developments concerning any future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners; • market conditions in the pharmaceutical and biotechnology sectors; • announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments; • developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products; • our ability or inability to raise additional capital and the terms on which we raise it, **including announcement and expectation of additional financing efforts**; • the recruitment or departure of key personnel; • changes in the structure of healthcare payment systems; • actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally; • our failure or the failure of our competitors to meet analysts’ projections or guidance that we or our competitors may give to the market; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • **announcement and expectation of additional financing efforts**; • speculation in the press or investment community; • trading volume of our common stock; • sales of our common stock by us, our insiders or our other stockholders; • the concentrated ownership of our common stock; • changes in accounting principles; **and • general economic, industry and market conditions, including, but not limited to,** terrorist acts, acts of war ~~or,~~ periods of widespread civil unrest ~~;~~ ~~• the impact of any natural disasters or,~~ public health emergencies and other calamities ~~;~~ ~~and • general economic, industry and market conditions~~. In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. The future issuance of equity or of debt securities that are convertible into equity will dilute our share capital. We will need to raise additional capital in the future. To the extent we raise additional capital through the issuance of equity or convertible debt securities in the future, there will be dilution to our existing investors and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders’ rights. Future issuances of our common stock or other equity securities, or the

perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. We may choose to raise additional capital through the issuance of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock. If securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading research or reports regarding us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us, our business or our market. If no or few securities or industry analysts commence or maintain coverage of us, the trading price for our stock would be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our product ~~candidates~~ **candidate**, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline . **Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, bank failures, increases in inflation rates and uncertainty about economic stability. Any such volatility and disruptions may have adverse consequences for us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Inflation can adversely affect us by increasing our costs, including personnel costs. Any significant increases in inflation and related increases in interest rates could have a material adverse effect on our business, results of operations and financial condition** . Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval and their interests may conflict with your interests as an owner of our common stock. As of March ~~20-17~~ **2024-2025**, our executive officers and directors, together with holders of five percent or more of our outstanding common stock and their respective affiliates, beneficially own approximately ~~44-39~~ **73** % of our outstanding common stock. As a result, these stockholders, if acting together, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with interests of our other stockholders. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate . ~~Shares issued upon the exercise of stock options and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and /or lock-up agreements, as well as Rules 144 and 701 under the Securities Act.~~ We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to **us emerging growth companies and smaller reporting companies** may make our common stock less attractive to investors. We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering (~~or IPO~~), (b) in which we have total annual gross revenue of at least \$ 1. 235 billion or (c) 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 exceeded \$ 700 million as of the prior June 30th and (ii) the date on which we have issued more than \$ 1. 0 billion in non- convertible debt during the prior three- year period. An emerging growth company may take advantage of specified reduced reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include: • being permitted to present only two years of audited financial statements and only two years of related management' s discussion and analysis of financial condition and results of operations in this Annual Report on Form 10- K; • not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, or the Sarbanes- Oxley Act; • an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotations; • reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and • exemptions from the requirement to hold a nonbinding advisory vote on executive compensation and to obtain stockholder approval of any golden parachute payments not previously approved. We have elected to take advantage of certain reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our investors may be different from the information you might receive from other public reporting companies that are not emerging growth companies in which you hold equity interests. The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt

new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. We are also a “smaller reporting company,” and will continue to be a smaller reporting company as long as (i) the market value of our shares held by non-affiliates is less than \$ 250 million or (ii) our annual revenue was less than \$ 100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$ 700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company with less than \$ 100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. Anti-takeover provisions in our charter documents and under Delaware law would make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in the amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders be called only by the chairman of our board of directors, our chief executive officer, or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- a requirement that directors may only be removed “for cause” and only with 66 2 / 3 % voting stock of our stockholders;
- a requirement that only the board of directors may change the number of directors and fill vacancies on the board;
- division of our board of directors into three classes, serving staggered terms of three years each; and
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders. We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management has and will be required to devote substantial time to new compliance initiatives and corporate governance practices. Additionally, if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. As a public company, we have incurred and, particularly after we are no longer an emerging growth company or a smaller reporting company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors or our board committees or as executive officers. These rules and regulations are also often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. In addition, as a public company, we incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company or a smaller reporting company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. Our internal control over financial reporting will not prevent or detect all errors and all fraud. If we are not able to comply with the requirements of Section 404 of

the Sarbanes- Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the **SEC-U. S Securities and Exchange Commission**. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the facts that judgments in decision- making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain. We may be subject to securities litigation, which is expensive and could divert our management’ s attention. In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. In addition, securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements. Even if the lawsuits are without merit, defending against these claims could result in substantial costs and divert management time and resources. We may be a target for securities and shareholder lawsuits in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management’ s attention from other business concerns. Our certificate of incorporation and bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, another state court located within the State of Delaware, or the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on our behalf under Delaware law, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or bylaws, (4) any other action asserting a claim that is governed by the internal affairs doctrine or (5) any other action asserting an “ internal corporate claim, ” as defined in Section 115 of the Delaware General Corporation Law. This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the U. S. federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act 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. Our amended and restated bylaws further provide that the federal district courts of the **United States of America-U. S.** will be the exclusive forum to the fullest extent permitted by law, for resolving any complaint asserting a cause of action arising under the Securities Act or the Exchange Act. 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, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation and amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation and amended and restated bylaws described above. Our ability to use net operating loss carryforwards and other tax attributes may be subject to limitations. We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. ~~To the extent that we continue to generate taxable losses, unused~~ **Unused** losses will carry forward to offset future taxable income, if any, subject to certain limitations (including the limitations described below) until such unused losses expire ~~(if at all)~~. As of December 31, ~~2023~~ **2024**, our federal and state net operating losses (NOLs) in the ~~United States-U. S.~~ were \$ ~~56.63~~ **4.1** million (\$ ~~268.300~~ **5.7** million before tax) and \$ ~~11.15~~ **2.1** million (\$ ~~167.229~~ **4.6** million before tax), respectively. The federal **NOL** net operating loss carryforwards in the ~~United States-U. S. after tax year 2017~~ can be carried forward indefinitely but may be subject to annual usage limitations to the extent certain substantial changes our ownership occur. The federal ~~net operating loss~~ **NOL and the state NOL** carryforward ~~carryforwards~~ relating to tax years prior to 2017 of ~~the Company will~~ \$ ~~5.9~~ **5.9** million (\$ ~~28.3~~ **28.3** million before tax), acquired with Apexigen, begin to expire in 2033 ~~and~~. The state net operating loss carryforwards begin expiring in 2035, respectively. In addition, as of December 31, 2023, the Company had \$ ~~7.8~~ **7.8** million and \$ ~~3.6~~ **3.6** million of federal and state credit carryovers which ~~of the Company will~~ begin to expire in 2030. These loss and credit carryforwards are subject to review and possible

adjustment by the relevant taxing authorities. Our NOL and credit carryforwards are subject to review and possible adjustment by the IRS, and state tax authorities. Under Section 382 of the Internal Revenue Code of 1986, as amended, ~~or the Code,~~ our federal NOL and credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership of our company, **which**. ~~An “ownership change” pursuant to Section 382 of the Code~~ generally occurs if one or more stockholders, or groups of stockholders, who own at least 5 % of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period. ~~Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with our IPO.~~ Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from our IPO or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. In addition, we may experience ownership changes in the future due to subsequent shifts in our stock, some of which are outside of our control. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.