Risk Factors Comparison 2024-03-22 to 2023-03-27 Form: 10-K

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The risk factors described below, as well as statements described elsewhere in this Annual Report on Form 10- K, including our audited Consolidated Financial Statements and the related notes and " Management' s Discussion and Analysis of Financial Conditions and Results of Operations ", or in other SEC filings, describe risks that could materially and adversely affect our business, financial condition, and results of operations, which could also cause the trading price of our equity securities to decline. These risks are not the only risks that we face. Our business, financial condition and results of operations could also be affected by additional factors that are not presently known to us or that we currently consider to be immaterial to our operations. Risks Related to our **Financial Position and Capital Needs** ~~Ability to Continue as a Going Concern~~ We **do not currently** have **sufficient** ~~incurred losses since our inception, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future which together with our limited~~ working capital ~~,~~ **to fund our planned operations for the next twelve months** and ~~lack of revenue from product sales~~ **may not be able to continue as a going concern. There is uncertainty regarding our ability to maintain liquidity sufficient to operate our business** , **which** raises substantial doubt about our ~~financial viability~~ -- **ability** ~~and as to whether we will be able~~ to continue as a going concern **. We do not currently have adequate financial resources to fund our forecasted operating costs for at least twelve months from the filing of this Annual Report on Form 10- K. As of December 31, 2023, we had a cash and cash equivalents balance of approximately $ 5. 9 million. As of December 31, 2023, we have incurred a accumulated deficit of $ 76. 3 million. For the year ended December 31, 2023, we reported net losses of $ 12. 5 million. As a result, our existing cash resources are sufficient to meet our anticipated needs into the first half of 2025, even after taking into account our significantly reduced operations, and we would need to raise additional capital in the next several months in order to avoid a wind down and dissolution of our company** . Our auditor' s report on our financial statements for the year ended December 31, ~~2022~~ **2023** , includes an explanatory paragraph related to the existence of substantial doubt about our ability to continue as a going concern. **Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Since inception, we have incurred net losses and negative cash flows from operations.** We ~~are a~~ **may not ever obtain additional financing. Our existing cash and cash equivalents will not be sufficient to enable us to continue the** clinical development **and commercialization of our product candidates for any indications or to in license any other product candidates and develop them. Although the Company is currently exploring various strategic alternatives, these strategic alternatives may not be successful in the next several months prior to its cash position getting to the point that it will need to pursue the winding down and dissolution of the Company. If we do not raise capital in the next several months or engage a strategic partner, we will be forced to cease operations and liquidate our assets and seek bankruptcy protection or engage in a similar process. As such, we cannot conclude that such plans will be effectively implemented within one year after the date that the financial statements included in this Annual Report on Form 10** - ~~stage biopharmaceutical company~~ **K are filed** with ~~a limited~~ **the SEC and there is uncertainty regarding our ability to maintain liquidity sufficient to** ~~operating~~ **operate** ~~history. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have primarily financed~~ our ~~operations through equity financings and~~ **business effectively, which raises substantial doubt about our ability to continue as** a **going concern** ~~grant from CPRIT. We have never been profitable and have incurred operating losses in each year since inception~~ . Our net losses were $ **12. 5 million and $** 31. 6 ~~million and $ 12. 8~~ million for each of the years ended December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022 . Our activities to evaluate and pursue strategic alternatives has not resulted in and may never result in any definitive transaction or enhance shareholder value, and may create a distraction for our management and uncertainty that may adversely affect our operating results and business** . We **have commenced a process to evaluate strategic alternatives in order to enhance stockholder value, including the possibility of an acquisition, merger, reverse merger, other business combination, sales of assets, licensing, or other strategic transactions involving the Company. We have engaged Canaccord Genuity, LLC as our financial advisor to assist us in this process. In connection with the evaluation of strategic alternatives, we have evaluated opportunities to extend our resources and have significantly reduced our headcount. We have devoted significant time and resources to identifying and evaluating strategic transactions and, as of the date of this report, this process has not resulted in any definitive transaction to enhance shareholder value. We have incurred, and may in the future incur, significant costs associated with identifying, evaluating and negotiating potential strategic alternatives, such as legal, financial advisor and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs** will ~~continue~~ **be incurred regardless of whether any such course of action is implemented or transaction is completed, decreasing cash available for use in our business. There can be no assurance that the process** to **evaluate strategic alternatives will result in agreements or transactions. The current market price of our common stock may reflect a market assumption that a transaction will occur, and a failure to complete a transaction could result in a negative investor perceptions and could cause a decline in the market price of our common stock, which could adversely affect our ability to access the equity and financial markets, as well as our ability to explore and enter into different strategic alternatives. Even if we negotiate a definitive agreement, there can be no certainty that any transaction will be completed, be on attractive terms, enhance stockholder value or deliver the anticipated benefits, and successful**

integration or execution of the strategic alternatives will be subject to additional risks. In addition, potential strategic transactions that require ~~substantial~~ **stockholder approval may not be approved by our stockholders. If we do not successfully consummate a strategic transaction or raise capital in the next several months, it will be forced to cease operations, liquidate assets and possibly seek bankruptcy protection or engage in a similar process. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities. If we do not successfully complete a strategic transaction or raise** additional capital ~~to continue our clinical development and potential commercialization activities. Accordingly~~ , we will need to **pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities. There can be no guarantee that the process to identify a strategic transaction will result in a successfully completed transaction. If no strategic transaction is completed and we are unable to** raise ~~substantial~~ additional capital **in the next several months, we will be forced** to **cease operations, liquidate assets and possibly seek bankruptcy protection or engage in a similar process. In that event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution** ~~continue~~ **continues** to **decrease as we** fund our operations **and evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a dissolution, liquidation or winding up of our company** . We ~~cannot~~ **could** be **delisted from Nasdaq** ~~certain that additional funding will be available on acceptable terms~~ , **which would seriously harm the liquidity of** ~~or our stock~~ ~~at all, for a number of reasons, including market conditions,~~ and ~~the pace and results of~~ our **ability** ~~clinical development efforts. Failure~~ to raise capital **. Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders. On September 5, 2023, we were notified (the Notice) by Nasdaq Stock Market, LLC (Nasdaq) that on September 1, 2023, the average closing price of our common stock over the prior 30 consecutive trading days had fallen below $ 1. 00 per share, which is the minimum average closing price required to maintain listing on Nasdaq under Nasdaq Listing Rule 5550 (a) (2) (the Minimum Bid Requirement). Nasdaq' s notice had no immediate effect on the listing or trading of our common stock. Pursuant to Nasdaq Listing Rule 5810 (c) (3) (A), we are provided an initial compliance period of 180 calendar days to regain compliance with the Minimum Bid Requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $ 1. 00 per share for a minimum of 10 consecutive business days prior to the deadline. If we do not achieve compliance with the Minimum Bid Requirement within 180 calendar days, we may be eligible for an additional 180 calendar days to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other Nasdaq initial listing standards, with the exception of the Minimum Bid Requirement, and provide written notice of our intention to cure the minimum bid price deficiency during the second compliance period. On March 5, 2024, we received notice (the " Approval ") from Nasdaq that we have been granted an additional 180- day grace period, or until September 3, 2024, to regain compliance with the Bid Price Rule. To regain compliance with the Bid Price Rule and qualify for continued listing on the Nasdaq Capital Market, the minimum bid price per share of our common stock must be at least $ 1. 00 for at least 10 consecutive business days on or prior to September 3, 2024. If we fail to regain compliance during the additional compliance period, then Nasdaq will notify us of our determination to delist our common stock, at which point we would have an opportunity to appeal the delisting determination to a Nasdaq Listing Qualifications Panel (the " Panel "), but there can be no assurance that the Panel would grant our request for continued listing. As a condition of the Approval imposed by Nasdaq Listing Rule 5810 (c) (3) (a), we notified Nasdaq that we would seek to implement a reverse stock split, if necessary, to regain compliance with the Bid Price Rule. If, for any reason, Nasdaq were to delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders: • liquidity and marketability of our common stock; • our ability to obtain financing for the continuation of our operations; • the number of institutional and general investors that will consider investing in our common stock; • the number of market makers in our common stock; • the availability of information concerning the trading prices and volume of our common stock; and • the number of broker- dealers willing to execute trades in shares of our common stock. In addition, if we cease to be eligible to trade on Nasdaq, we may have to pursue trading on a less recognized or accepted market, such** as ~~and when needed~~ **the over the counter markets** , **our stock may be traded as a " penny stock " which would make transactions in our stock more difficult and cumbersome, and we may be unable to access capital** on favorable terms or at all, **as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to further decline. Certain of our**

warrants to purchase common stock include a right to receive the Black- Scholes value of the unexercised portion of the warrants in the event of a fundamental transaction, which payment could be significant. Certain of our outstanding warrants, including those issued in our merger with Flex Pharma, the February 2020 financing transaction and those issued in connection with our May 2023 financing transaction, provide that, in the event of a " fundamental transaction " that is approved by our board of directors, including, among other things, a merger or consolidation of our company or sale of all or substantially all of our assets, the holders of such warrants have the option to require us to pay to such holders an amount of cash equal to the Black- Scholes value of the warrants. Such amount could be significantly more than the warrant holders would **otherwise receive if they were to exercise their warrants and receive the same consideration as the other holders of common stock, which in turn could reduce the consideration that holders of common stock would be concurrently entitled to receive in such fundamental transaction. Any future equity financing we conduct may require us to issue warrants that** have a ~~negative impact~~ **similar feature. The terms of the warrants could impede our ability to enter into certain transactions or obtain additional financing. The terms of certain of our outstanding warrants to purchase shares of our common stock require us, upon the consummation of any " fundamental transaction " (as defined in the securities), to, among other obligations, cause any successor entity resulting from the fundamental transaction to assume all of our obligations under the warrants and the associated transaction documents. In addition, holders of warrants are entitled to participate in any fundamental transaction** on ~~our financial condition and~~ **an as- converted or as- exercised basis, which could result in the holders of our common stock receiving a lesser portion of the consideration from a fundamental transaction. The terms of the warrants could also impede** our ability to **enter into certain transactions or obtain** ~~continue operations. Further, if we are unable to raise~~ additional ~~capital~~ **financing** in ~~sufficient amounts~~ **the future. Our cost savings plans and the associated headcount reductions may not result in anticipated savings** , ~~when required or on acceptable terms, we also~~ could **result in total costs** ~~be required to (i) delay, limit, reduce or terminate the drug development of our current or future product candidates, or seek collaborators for one or more of our current or future product candidates at an~~ **and expenses** ~~earlier stage than otherwise would be desirable or on terms~~ that are **greater** ~~less favorable~~ than **expected and could disrupt** ~~might otherwise be available; or~~ **our business. On August 5, 2023, we initiated a cost savings plan intended to preserve capital while we assess potential strategic alternatives. On February 22, 2024, we announced that our Board of Directors was implementing a series of additional cost- savings measures designed to extend our expected cash runway into the first half of 2025. These measures will allow us to support the generation of additional clinical data for seclidemstat in the ongoing MD Anderson Cancer Center** (~~ii~~ **MDACC**) **investigator- initiated** ~~significantly curtail our operations, liquidate our assets or seek bankruptcy. The aforementioned factors, which are largely outside of our control, raise substantial doubt about our ability to continue as a going concern within one year from the date of filing of this annual report. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence. We have devoted substantially all our financial resources to identify, acquire, and develop our product candidates, including conducting clinical trials and providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities. The amount of our future net losses will depend, in part, on the rate of our future expenditures and ability to obtain funding through equity or debt financings, strategic collaborations, or grants. Biopharmaceutical product development is a highly speculative and competitive undertaking and involves a substantial degree of risk. We expect losses to increase as we complete~~ Phase 1 **/** ~~development and advance into Phase~~ 2 ~~development of our lead product candidates. It may be several years, if ever, before we complete pivotal clinical trials and have a product candidate approved for commercialization. We expect to invest significant funds into the research and development of our current product candidates to determine the potential to advance these product candidates to regulatory approval. We expect to be required to expend a significant amount of funds before we know if we have a clinically successful product candidate. Even if we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third- party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, because the potential markets in which our product candidates may ultimately receive regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we: • continue the clinical development of our product candidates; • continue efforts to discover new product candidates; • undertake the manufacturing of our product candidates or increase volumes manufactured by third parties; • advance our programs into larger, more expensive clinical trials; • initiate additional pre- clinical, clinical, or other trials or studies for our product candidates; • seek regulatory and marketing approvals and reimbursement for our product candidates; • establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for ourselves; • seek to identify, assess, acquire, and / or develop other product candidates; • make milestone, royalty or other payments under third- party license agreements; • seek to maintain, protect, and expand our intellectual property portfolio; • seek to attract and retain skilled personnel; and • experience any delays or encounters issues with the development and potential for regulatory approval of our clinical candidates such as safety issues,~~ clinical trial **in hematologic cancers** ~~accrual delays, longer follow- up for planned studies, additional major studies, or supportive studies necessary to support marketing approval. Further, the net losses we incur may fluctuate significantly from quarter to quarter~~ and **Salarius'** ~~year to year, such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. Risks Related to the Development of our Product Candidates It may take considerable time and expense to resolve the partial clinical~~

hold that has been placed on our Phase 1 / 2 trial **in** of seclidemstat as a treatment for Ewing sarcoma and FET **. In connection with the cost** - **savings measures** rearranged sarcomas by the FDA , **David Arthur** and no assurance can be given that the FDA will remove the partial clinical hold , in which case our business and prospects will likely suffer material adverse consequences. On October 18, 2022, we announced that per protocol design, we voluntarily paused new patient enrollment in our Phase 1 / 2 trial of seclidemstat as a treatment for Ewing sarcoma and FET- rearranged sarcomas. The pause in new patient enrollment was due to a metastatic FET- rearranged sarcoma patient death, not an Ewing sarcoma patient death that was classified as a suspected unexpected serious adverse reaction (SUSAR). At the time, we also announced that our independent Safety Review Committee for the clinical trial determined that patients currently receiving seclidemstat treatment could continue treatment after consulting with their -- **the Company** physician. During a conference call with the US Food and Drug Administration (FDA) on Tuesday, November 1, 2022, the FDA informed us that the agency agreed with the voluntary enrollment pause and, as an administrative action, the FDA provided verbal notification that the Ewing sarcoma and FET- rearranged sarcoma trial was on partial clinical hold. While on partial clinical hold, FDA informed us that the pause in patient enrollment shall remain in place and patients currently receiving seclidemstat treatment may continue treatment after consulting with their physician. FDA ' s **President** clinical hold procedures provide us with an **and Chief Executive Officer** administrative process to work with the FDA to analyze the available data , **ended his full-** adjust clinical protocols, and make other changes that may be needed in order to restart patient enrollment. It may take a considerable period of time **employment and transitioned to a part- time consultant role** , **effective February 20, 2024. He will continue to serve as Chief Executive Officer and support our ongoing activities. The cost- savings measures also included reducing operating expenses and reducing** the length **cash compensation payable to our non- employee directors beginning in the second quarter** of which is **2024. We may** not **realize** certain at this time , **in** and expense for us to fully - **full** analyze the available data and address the FDA' s concerns. Even if we are able to fully respond to the FDA' s concerns, the FDA may subsequently make additional requests that we would need to fulfill prior to the lifting of the partial clinical hold. It is possible that we will be unable to fully address the FDA' s concerns and as a result the partial clinical hold may never be lifted and we may never be able to enroll new patients in the clinical trial,, which could have a material adverse effect on our - **or** business **in part, the anticipated benefits, savings** and **improvements in our cost structure** prospects. The approach we are taking to discover and develop novel oncology therapeutics using epigenetic enzymes to moderate transcription factors and thereby control abnormal protein expression is unproven and may never lead to marketable products. The scientific discoveries that form - **from** the basis for our **cost savings** efforts **due** to discover and develop our current product candidates are relatively recent. To date, neither we nor any other company has received regulatory approval to market therapeutics using epigenetic enzymes. The scientific evidence to support the feasibility of developing drugs based on these discoveries is both preliminary and limited. The Successful development of therapeutic products will require solving a number of issues. In addition, any product candidates that we develop may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory and pre- clinical trials, and they may interact with human biological systems in unforeseen , ineffective or even harmful ways..... pursuing similar technologies may encounter setbacks and difficulties that regulators and investors may attribute to our product candidates , whether appropriate or not. Clinical trials..... continuation of our clinical trials; • delays in reaching agreement on acceptable terms with..... Delay or failure to obtain, or unexpected costs in obtaining **. For example** , the regulatory approval necessary to bring **we may incur unanticipated charges not currently contemplated as** a potential product candidate **result of the cost savings plans. If we are unable** to **realize the expected operational cost savings from the restructuring** market could decrease our ability to generate sufficient product revenue , and our business, **operating results and** financial condition , results of operations and prospects may be harmed. Our product candidates may cause undesirable side effects or have other properties that could **would** delay or prevent their regulatory approval,....., and additional unexpected adverse events may be **materially** observed. We may experience a high.....- term adverse reactions, and may adversely affect the commercialization of the product,..... difficulties in enrollment. Patient enrollment is affected by several factors, including: •..... monitor patients adequately during and after treatment . We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies. The eligibility criteria of our planned clinical trials may further limit the available eligible trial participants as we expect to require that patients have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical trials. We may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical trials in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our product candidates may be delayed. Even if we enroll a sufficient number of eligible patients to initiate our clinical trials, we may be unable to maintain participation of these patients throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those patients. If we have difficulty enrolling and maintaining the enrollment of a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business. If we experience delays in the completion of, or termination of, any clinical trials of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly. We may face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs which could be greater than our insurance coverage or overall resources. If the use or misuse of our product candidates harms patients,

~~or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals, if any, could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition. The use or misuse of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval exposes us to the risk of potential product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates and approved products, if any. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Patients with the diseases targeted by our product candidates may already be in severe and advanced stages of disease and have both known and unknown significant preexisting and potentially life- threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to our product candidates, the investigation into the circumstance may be time- consuming or inconclusive. These investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations. Although we have product liability insurance, which covers our clinical trials in the United States, for up to $ 2. 0 million per occurrence, up to an aggregate limit of $ 5. 0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer. We will also likely be required to increase our product liability insurance coverage for the advanced clinical trials that we plans to initiate. If we obtain marketing approval for any of our product candidates, we will need to expand our insurance coverage to include the sale of commercial products. There is no way to know if we will be able to continue to obtain product liability coverage and obtain expanded coverage if we requires it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in: • withdrawal of clinical trial volunteers, investigators, patients or trial sites or limitations on approved indications; • the inability to commercialize, or if commercialized, decreased demand for, our product candidates; • if commercialized, product recalls, withdrawals of labeling, marketing or promotional restrictions or the need for product modification; • initiation of investigations by regulators; • loss of revenues; • substantial costs of litigation, including monetary awards to patients or other claimants; • liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourself; • an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all; • the diversion of management' s attention from our business; and • damage to our reputation and the reputation of our products and our technology. Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, financial condition or results of operations. Risks Related to our Financial Condition and Capital Requirements~~ We have never generated any revenue from product sales and may never generate revenue or be profitable. We have no products approved for commercialization and have never generated any revenue. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to: • completing research and development of our product candidates; • obtaining regulatory and marketing approvals for our product candidates; • manufacturing product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved; • marketing, launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor; • gaining market acceptance of our product candidates as treatment options; • addressing any competing products; • protecting and enforcing our intellectual property rights, including patents, trade secrets, and know- how; • negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; • obtaining reimbursement or pricing for our product candidates that supports profitability; and • attracting, hiring, and retaining qualified personnel. Even if one or more of the product candidates that we develop is approved for commercial sale, we ~~anticipate incurring~~ **would need to incur** significant costs associated with commercializing any approved product candidate. Portions of our current pipeline of product candidates have been in- licensed from third parties, which make the commercial sale of such in- licensed products potentially subject to additional royalty and milestone payments to such third parties. We will also have to develop, contract for or acquire manufacturing capabilities to continue development and potential commercialization of our product candidates. We will need to develop or procure our drug product in a commercially feasible manner in order to successfully commercialize any future approved product; if any. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us

to relinquish rights. We **have primarily raised capital through equity financings and** ~~received substantial funding during the year ended December 31, 2022 including reimbursement from CPRIT. Other than the CPRIT funding,~~ these raises caused significant dilution to stockholders who owned our shares of **our** ~~Common~~ **common** ~~Stock~~ **stock** prior to these capital raises. To the extent that we raise additional capital through the sale of equity, convertible debt or other securities convertible into equity the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect rights of our equity holders. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot be assured that we will be able to obtain additional funding when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we **do not successfully complete** ~~are unable to obtain funding on~~ a **strategic transaction** ~~timely basis, we may be required to delay or discontinue one or more of our~~ **or** ~~development programs or~~ **raise additional capital in** the ~~commercialization of any product candidates or~~ **next several months, we will** be ~~unable~~ **forced** to **cease** ~~expand our~~ operations ~~or otherwise capitalize on potential business opportunities~~, ~~which could materially harm~~ **liquidate assets and possibly seek bankruptcy protection** ~~our~~ **or engage in a similar process** ~~business, financial condition, and results of operations~~. We have also historically received funds from state and federal government grants for research and development including CPRIT. The grants have been, and any future government grants and contracts we may receive may be, subject to the risks and contingencies set forth below under the risk factor titled " Reliance on government funding for our programs may add uncertainty to our research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit our ability to take specified actions, increase the costs of commercialization and production of product candidates developed under those programs and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations. " Although we might apply for government contracts and grants in the future, we cannot assure you that we will be successful in obtaining additional grants for any product candidates or programs. Failure to receive additional government grants in the future may substantially harm our business. Risks Related to by several factors,including:• severity of the disease under investigation;• design of the trial protocol;• size of the patient population;• perceived risks and benefits of the product candidate being tested;• willingness or availability of patients to participate in our clinical trials;• proximity and availability of clinical trial sites for prospective patients;• our ability to recruit clinical trial investigators with appropriate competencies and experience;• availability of competing vaccines and / or therapies and related clinical trials;• efforts to facilitate timely enrollment in clinical trials;• our ability to obtain and maintain patient consents;• patient referral practices of physicians;and • ability to monitor patients adequately during and after treatment Regulatory Approval of our Product Candidates and Other Legal Compliance Matters ~~We may seek breakthrough therapy designation by the FDA for one or more of our product candidates, but it might not receive such designation.~~ Even if FDA grants breakthrough therapy designation for one or more of our product candidates, the designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval, and FDA may rescind the designation if it determines the product candidate no longer meets the qualifying criteria for breakthrough therapy. We may seek a breakthrough therapy designation from the FDA for some of our product candidates that reach the regulatory review process. A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug or biological product 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 drugs or biological products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA could also be eligible for accelerated approval. 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. The receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify and are designated as breakthrough therapies, the FDA may later decide that the drugs or biological products no longer meet the conditions for designation and the designation may be rescinded. We have received Fast Track designation for one of our product candidates, but such designation may not actually lead to a faster development or regulatory review or approval process. Additionally, FDA may rescind the designation if it determines the product candidate no longer meets the qualifying criteria for Fast Track. If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. We recently received Fast Track designation for a product candidate. However, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA' s priority review procedures. We cannot guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the necessary regulatory approvals to market our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to

generate revenue will be materially impaired. Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and foreign jurisdictions. Failure to obtain marketing approval for our product candidates will prevent us from commercializing them in those markets. We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither our current product candidates nor any product candidates that we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication of each of our product candidates to establish the product candidates' safety and efficacy for such indications. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, regulatory authorities. The pathway to regulatory approvals is time consuming and unpredictable, involves substantial costs and consumes management time and attention. It is not possible to predict the timing or success of obtaining regulatory approvals with any degree of certainty, and as a result, it is difficult to forecast our future financial results or prospects. Any unexpected development in the regulatory approval process, including delays or denials of regulatory approvals or significant modifications to our product candidates required by our regulators, could materially and adversely affect our business, results of operations and financial condition, and could substantially harm our stock price. To obtain marketing approval, United States laws require: • controlled research and human clinical testing; • establishment of the safety and efficacy of the product for each use sought; • government review and approval of a submission containing, among other things, manufacturing, pre- clinical and clinical data; and • compliance with cGMP regulations. The process of reviewing and approving a drug is time- consuming, unpredictable, and dependent on a variety of factors outside of our control. The FDA and corresponding regulatory authorities in other jurisdictions have a significant amount of discretion in deciding whether or not to approve a marketing application. Our product candidates could fail to receive regulatory approval from the FDA or comparable regulatory authorities outside the United States for several reasons, including: • disagreement with the design or implementation of our clinical trials; • failure to demonstrate that our candidate is safe and effective for the proposed indication; • failure of clinical trial results to meet the level of statistical significance required for approval; • failure to demonstrate that the product candidate' s benefits outweigh its risks; • disagreement with our interpretation of pre- clinical or clinical data; and • inadequacies in the manufacturing facilities or processes of third- party manufacturers. • The FDA or a comparable regulatory authority outside the United States may require us to conduct additional pre- clinical and clinical testing, which may delay or prevent approval and our commercialization plans or cause us to abandon the development program. Further, any approval we receive may be for fewer or more limited indications than we request, may not include labeling claims necessary for successful commercialization of the product candidate, or may be contingent upon our conducting costly post- marketing clinical trials. Any of these scenarios could materially harm the commercial prospects of a product candidate, and our operations will be adversely affected. Even if we obtain regulatory approval for a product, we will remain subject to ongoing regulatory requirements, which may result in significant additional expense and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. If any of our product candidates are approved, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, marketing, advertising, promotion, sampling, record- keeping, conduct of post- marketing clinical trials, and submission of safety, efficacy and other post- approval information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP, regulations and corresponding foreign regulatory manufacturing requirements. 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 NDA or marketing authorization application. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post- marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post- marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things: • issue fines, untitled letters or warning letters; • impose civil or criminal penalties; • suspend or withdraw regulatory approval; • suspend any of our ongoing clinical trials; • refuse to approve pending applications or supplements to approved applications submitted by us; • product seizure or detention or refusal to permit the import or export of products; • impose restrictions on our operations, including closing our contract manufacturers' facilities; or • impose restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls. Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with

ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and our value and our operating results would be adversely affected. Healthcare reform measures may have a material adverse effect on our business, financial condition or results of operations. In the United States, there have been and continue to be a number of initiatives to contain healthcare costs or otherwise change or reform the provision of healthcare products and services to the patient population. For example, in March 2010, the **Affordable Care Act (** ACA **)** was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U. S. pharmaceutical industry. The ACA, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of specified branded prescription drugs, and established a new Medicare Part D coverage gap discount program. Certain provisions of the ACA have been subject to judicial challenges, as well as efforts to modify them or alter their interpretation or implementation. It is unclear how efforts to challenge or modify the ACA or its implementing regulations, or portions thereof, will affect our business. The IRA, which was enacted into law on August 16, 2022, introduces several changes to the Medicare Part D benefit, including a limit on annual out- of- pocket costs and a change in manufacturer liability under the program. The IRA sunsets the current Part D coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA establishes a Medicare Part B inflation rebate scheme effective January 2023 and a Medicare Part D inflation rebate scheme effective October 2022, under which, generally speaking, manufacturers will owe rebates if the price of a Part B or Part D drug increases faster than the pace of inflation. Failure to timely pay a Part B or D inflation rebate is subject to a civil monetary penalty. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologicals without generic or biosimilar competition will be capped by reference to, among other things, a specified non- federal average manufacturer price starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and / or a civil monetary penalty. Congress continues to examine various policy proposals that may result in pressure on the prices of prescription drugs with respect to the government health benefit programs and otherwise. The IRA or other legislative changes could impact the market conditions for our product candidates. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted and we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product candidates, if commercialized, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability, or successfully commercialize our product candidates. We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti- Kickback Statute, the federal False Claims Act, and federal and state transparency laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. These laws, which are described in further detail in Government Regulation and Product Approvals – Other Healthcare Laws include: • the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; • federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government; • HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters; • HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information; • the U. S. federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals (and certain other practitioners as of 2022), as well as ownership and investment interests held in the company by physicians and their immediate family members; and • • state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws that may apply to items or services reimbursed by any third- party payor, including governmental and private payors, laws that require manufacturers to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same scope or application, thus complicating

compliance efforts. Efforts to ensure that our collaborations with third parties, and our business generally, will comply with applicable United States and healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, contractual damages, reputational harm, disgorgement, curtailment or restricting of our operations, any of which could substantially disrupt our operations and diminish our profits and future earnings. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. During the course of our development of our product candidates, we have been funded in part through federal and state grants, including but not limited to the funding we received from CPRIT. If CPRIT terminates the agreement prior to the expiration due to an event of default or if we terminate the agreement, CPRIT may require us to repay some or all of the disbursed grant ~~. In addition to the funding we have received to date, we intend to continue to apply for federal and state grants to receive additional funding in the future~~ . Contracts and grants funded by the U. S. government, state governments and their related agencies include provisions that reflect the government' s substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to: • require repayment of all or a portion of the grant proceeds, in specified cases with interest, in the event we violate specified covenants pertaining to various matters that include a failure to achieve specified milestones or to comply with terms relating to use of grant proceeds, or failure to comply with specified laws; • terminate agreements, in whole or in part, for any reason or no reason; • reduce or modify the government' s obligations under such agreements without the consent of the other party; • claim rights, including intellectual property rights, in products and data developed under such agreements; • audit contract related costs and fees, including allocated indirect costs; • suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations; • impose U. S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements; • impose qualifications for the engagement of manufacturers, suppliers and other contractors as well as other criteria for reimbursements; • suspend or debar the contractor or grantee from doing future business with the government; • control and potentially prohibit the export of products; • pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and • limit the government' s financial liability to amounts appropriated by the U. S. Congress on a fiscal year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period. In addition to those powers set forth above, the government funding we may receive could also impose requirements to make payments based upon sales of our products, if any, in the future. We may not have the right to prohibit the U. S. government from using specified technologies developed by us, and we may not be able to prohibit third- party companies, including our competitors, from using those technologies in providing products and services to the U. S. government. The U. S. government generally takes the position that it has the right to royalty- free use of technologies that are developed under U. S. government contracts. These and other provisions of government grants may also apply to intellectual property we license now or in the future. In addition, government contracts and grants normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example: • specialized accounting systems unique to government contracts and grants; • mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent; • public disclosures of some contract and grant information, which may enable competitors to gain insights into our research program; and • mandatory socioeconomic compliance requirements, including labor standards, non- discrimination and affirmative action programs and environmental compliance requirements. If we fail to maintain compliance with any such requirements that may apply to us now or in the future, we may be subject to potential liability and to termination of our contracts. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs and liabilities that could have a material adverse effect on our business, financial condition or results of operations. Our research and development activities and our third- party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, 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 us and 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. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Risks Related to our Intellectual

Property We may not be successful in obtaining or maintaining necessary rights to our targets, product compounds and processes for our development pipeline through acquisitions and in- licenses. Presently, we have rights to the intellectual property, through licenses from third parties and under patents and patent applications that we own, to modulate only a subset of the known epigenetic enzyme targets. Because our programs may involve a range of targets, including targets that require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in- license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. For example, we have previously ~~and may continue to collaborate~~ **collaborated** with academic institutions worldwide to accelerate our pre- clinical and clinical research or development under written agreements with these institutions. Typically, these institutions provide an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. 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. If we are unable to successfully obtain rights to third- party intellectual property rights, our business, financial condition and prospects for growth could suffer. We intend to rely on patent rights for our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets. We rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products. We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in- licenses may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all 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 from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed. We may not have sufficient patent term protections for our product candidates to effectively protect our business. Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generic medications. In addition, upon issuance in the United States any patent term can be adjusted based on specified delays caused by the applicant (s) or the U. S. Patent and Trademark Office (~~"~~USPTO ~~"~~). Depending on the timing, duration, and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for patent term extension under the Hatch- Waxman Act. Patent term extensions under the Hatch- Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of our product candidates. We will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product may not extend beyond the current patent expiration dates and competitors may obtain approval to

market competing products sooner. As a result, we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations and prospects. If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates, our business and results of operations will be adversely affected. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products, and recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. As is the case with other biotechnology companies, our success is heavily dependent on patents and the ability to enforce and protect these patients. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide- ranging patent reform legislation. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Some of our patent claims may be affected by the recent U. S. Supreme Court decision in Association for Molecular Pathology v. Myriad Genetics. In Myriad, the Supreme Court held that unmodified isolated fragments of genomic sequences, such as the DNA constituting the BRCA1 and BRCA2 genes, are not eligible for patent protection because they constitute a product of nature. The exact boundaries of the Supreme Court' s decision remain unclear as the Supreme Court did not address other types of nucleic acids. On December 16, 2014, the USPTO issued guidance to patent examiners titled 2014 Interim Guidance on Patent Subject Matter Eligibility (Fed. Reg. 79 (241): 74618- 33. These guidelines instruct USPTO examiners on the ramifications of the Prometheus and Myriad rulings and apply the Myriad ruling to natural products and principles including all naturally occurring nucleic acids. In addition, the USPTO continues to provide updates to its guidance and this is a developing area. The recent USPTO guidance could make it impossible for us to pursue similar patent claims in patent applications we may prosecute in the future. Our patent portfolio contains claims of various types and scope, including chemically modified mimics, as well as methods of medical treatment. The presence of varying claims in our patent portfolio significantly reduces, but may not eliminate, our exposure to potential validity challenges under Myriad or future judicial decisions. However, it is not yet clear what, if any, impact this recent Supreme Court decision or future decisions will have on the operation of our business. For our U. S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. On September 16, 2011, the Leahy- Smith America Invents Act (the " Leahy- Smith Act ") was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, did not come into effect until March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition or results of operations. An important change introduced by the Leahy- Smith Act is that, as of March 16, 2013, the United States transitioned to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under such change, a third party that files a patent application in the USPTO after that date, but before we could, may be awarded a patent covering an invention of our even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Among some of the other changes introduced by the Leahy- Smith Act are changes that limit where a patentee may file a patent infringement suit and new procedures providing opportunities for third parties to challenge any issued patent in the USPTO. Included in these new procedures is a process known as Inter Partes Review ("IPR "), which has been generally used by many third parties over the past two years to invalidate patents. The IPR process is not limited to patents filed after the Leahy- Smith Act was enacted, and would therefore be available to a third party seeking to invalidate any of our U. S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our proposed markets. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and

processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seeks to preserve the integrity and confidentiality of our data and trade secrets 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 we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know- how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business, financial condition or results of operations. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. Third- party claims of intellectual property infringement may prevent or delay our development and commercialization efforts. Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the patent rights of third parties. Numerous third- party U. S. and non- U. S. issued patents and pending applications exist in the area of epigenetic enzyme inhibitors and related technologies. We are aware of U. S. and foreign patents and pending patent applications owned by third parties that cover therapeutic uses of epigenetic inhibitors. We are currently monitoring these patents and patent applications. We may in the future pursue available proceedings in the U. S. and foreign patent offices to challenge the validity of these patents and patent applications. In addition, or alternatively, we may consider whether to seek to negotiate a license of rights to technology covered by one or more of such patents and patent applications. If any patents or patent applications cover our product candidates or technologies, we may not be free to manufacture or market our product candidates, as planned, absent such a license, which may not be available to us on commercially reasonable terms, or at all. It is also possible that we have failed to identify relevant third- party patents or applications. For example, applications filed before November 29, 2000 and applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third- party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third- party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Parties making claims against we may obtain injunctive or other equitable relief, which could effectively block our 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 employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. We may not be successful in meeting our obligations under our existing license agreements necessary to maintain our product candidate licenses in effect. In addition, if required in order to commercialize our product candidates, we may be unsuccessful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in- licenses. We currently have rights to the intellectual property, through licenses from third parties and under patents that we do not own, to develop and commercialize our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain in effect these proprietary rights. Any termination of license agreements with third parties with respect to our product candidates would be expected to negatively impact our business prospects. We may be unable to acquire or in- license any compositions, methods of use, processes, or other third- party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to license or acquire third- party intellectual property rights that are necessary for our product candidates, there can be no assurance that they will be available on favorable terms. We collaborate with academic institutions worldwide to identify product candidates, accelerate our research and conduct development. Typically, these institutions have provided us with an option to negotiate an exclusive license to any of the institution' s rights in the patents or other intellectual property resulting

from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue a program that we wish to pursue. If we are unable to successfully obtain and maintain rights to required third- party intellectual property, we may have to abandon development of that product candidate or pay additional amounts to the third- party, and our business and financial condition could suffer. The patent protection and patent prosecution for some of our product candidates is dependent on third parties. While we normally seek and gains the right to fully prosecute the patents relating to our product candidates, there may be times when patents relating to our product candidates are controlled by our licensors. If future licensors fail to appropriately and broadly prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, importing, and selling competing products. In addition, even where we now have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to assuming control over patent prosecution. If we fail to comply with obligations in the agreements under which we licenses intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We are a party to intellectual property licenses and supply agreements that are important to our business and may enter into additional license agreements in the future. Our existing agreements impose, and we expect that future license agreements will impose on us, various diligence, milestone payment, royalty, purchasing, and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, our agreements may be subject to termination by the licensor, in which event we would not be able to develop, manufacture, or market products covered by the license or subject to supply commitments. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Competitors may infringe our patents or the patents of our licensors. If we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / 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, written description, clarity or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. 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 a material adverse effect on the price of our common stock. We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have written agreements and makes every effort to ensure that our employees, consultants, and independent contractors do not use the proprietary information or intellectual property rights of others in their work for us, we may in the future be subject to any claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. 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, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Risks Related to our Reliance on Third Parties We rely on or will rely on third parties to conduct our clinical trials ~~, manufacture our product candidates and perform other services~~ . If these third parties do not successfully perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or **eventually** commercialize our product candidates and our business could be substantially harmed. We have relied upon and ~~plans~~ **plan** to continue to rely upon third- parties such as CROs, hospitals ~~, etc. to conduct, monitor~~ and ~~manage our ongoing~~ clinical ~~programs~~ **investigators to study our product candidates in clinical trials. For example, we have collaborated with MD Anderson to study SP- 2577 in combination with azacitidine for the treatment of patients with myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML)** . We rely on these parties for **the** execution of clinical trials and **we** ~~manages and controls~~ only **manage and control** some aspects of their activities **. With respect to the MD Anderson sponsored investigator initiated trial, we supply seclidemstat in quantities required to conduct the clinical trial, but do not have any control over their development activities or the timing thereof** . We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with all applicable laws, regulations and guidelines, including those required by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of our CROs or vendors fail to comply with applicable laws, regulations and guidelines, the results generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be assured that our CROs and other vendors will meet these requirements, or that upon inspection by any regulatory authority, such regulatory authority will determine that efforts, including any of our clinical trials, comply with applicable requirements. Our failure to comply with these laws, regulations and guidelines may require us to repeat clinical trials, which would be costly and delay the regulatory approval process. If any of our relationships with these third- parties terminate, we may not be able to enter into arrangements with alternative third parties in a timely manner or do so on commercially reasonable terms. In addition, third parties may not prioritize our clinical trials relative to those of other customers and any turnover in personnel or delays in the allocation of third party employees may negatively affect our clinical trials. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical trials may be delayed or terminated and we may not be able to meet our current plans with respect to our product candidates. CROs, in particular, may also involve higher costs than anticipated, which could negatively affect our financial condition and operations. In addition, we do not currently have, nor do we currently plan to establish the capability to manufacture product candidates for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale without the use of third- party manufacturers. We plan to rely on third- party manufacturers and their responsibilities will include purchasing from third- party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval. There are expected to be a limited number of suppliers for the active ingredients and other materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical trials, and, if approved, ultimately for commercial sale. Although we generally do not expect to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the active ingredient or other material components in the manufacture of the product candidate could delay completion of our clinical trials and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations. We expect to rely on third parties to manufacture our clinical product supplies, and we intend to rely on third parties to produce and process our product candidates, if approved, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of government regulators, fail to comply with applicable regulations, fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices. We do not currently have nor ~~does~~ **do** we currently plan to develop the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on outside vendors to manufacture the clinical supplies of our product candidates. We plan to continue relying on third parties to manufacture our product candidates on a commercial scale, if approved. We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates and our current costs to manufacture our drug products is not commercially feasible, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product. In addition, our reliance on third- party manufacturers exposes us to the following additional risks: • We may be unable to identify manufacturers on acceptable terms or at all; • Our third- party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any; • contract manufacturers may not be able to execute our manufacturing procedures appropriately; • Our future third- party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products; • ~~manufacturers~~ **Manufacturers** are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure

strict compliance with cGMPs and other government regulations and corresponding foreign standards. We do not have control over third- party manufacturers' compliance with these regulations and standards; • We may not own, or may have to share, the intellectual property rights to any improvements made by our third- party manufacturers in the manufacturing process for our product candidates; and • Our third- party manufacturers could breach or terminate their agreement with us. Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not appropriately conducted and test data are not reliable, patients could be put at risk of serious harm and could result in product liability suits. The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Third-party manufacturers may not be able to comply with applicable cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed, including clinical holds, fines, injunctions, civil penalties, delays, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot be assured that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. We may be unable to realize the potential benefits of any current or future collaboration. We have entered into strategic collaborations and license agreements with the University of Utah, ~~HLBLS,~~ and CPRIT. While we may seek to enter into future collaborations for the development and commercialization of our product candidates, there can be no assurance that we will be able to do so. Even if we are successful in entering into a collaboration with respect to the development and / or commercialization of one or more product candidates, there is no guarantee that the collaboration will be successful and we may be unable to realize in full or in part the potential benefits of any of our current collaborations. Collaborations may pose a number of risks, including: • collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration, and may not commit sufficient resources to the development, marketing or commercialization of the product or products that are subject to the collaboration; • collaborators may not perform their obligations as expected; • any such collaboration may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to our current product candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to us; • collaborators may cease to devote resources to the development or commercialization of our product candidates if the collaborators view our product candidates as competitive with their own products or product candidates; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time consuming, distracting and expensive; • collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • the collaborations may not result in us achieving revenues to justify such transactions; and • collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate. As a result, a collaboration may not result in the successful development or commercialization of our product candidates. Risks Related to ~~Commercialization of~~ our ~~Product Candidates~~ **Business Operations** We ~~currently have very limited marketing and sales experience. If we~~ are **substantially dependent on** ~~unable to establish sales and marketing capabilities or~~ **our remaining** ~~enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue. Although some of our~~ employees ~~may have marketed, launched,~~ and **consultants to continue** ~~sold other pharmaceutical products in the past while employed at other companies, We have no experience selling and marketing our product candidates and we currently have no marketing or~~ **our** ~~sales organization~~ **operations and facilitate the consideration and consummation of a potential strategic transaction** . ~~To~~ **Our ability to** successfully ~~commercialize any products that may result from our development programs, we will need to find one or more collaborators to commercialize our products or invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult and time consuming. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for success of our products. Factors that may inhibit our efforts to commercialize our products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians; • the lack of adequate numbers of physicians to prescribe any future products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing~~

organization If commercialization collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, particularly in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third- party collaborators, we may be unable to compete **complete a** successfully against these more established companies. We may attempt to form collaborations in the future with respect to our product candidates, but we may not be able to do so, which may cause us to alter our development and commercialization plans. We may attempt to form strategic **transaction** collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our programs that we believe will complement or augment our existing business. We may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. We may not be successful in our efforts to establish such a strategic collaboration for any product candidates and programs on terms that are acceptable to us, or at all. This may be because our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, the competitive or intellectual property landscape may be viewed as too intense or risky, and / or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile. Any delays in identifying suitable collaborators and entering into agreements to develop and / or commercialize our product candidates could delay the development or commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. Absent a strategic collaborator, we would need to undertake development and / or commercialization activities at our own expense. If we elect to fund and undertake development and / or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our product candidates or bring them to market and our business may be materially and adversely affected. If the market opportunities for our product candidates are smaller than we believe they are, we may not meet our future revenue expectations and, assuming approval of a product candidate, our business may suffer. Given the small number of patients who have the diseases that we are targeting, the eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidates. For example, based off data from the National Institute of Health (NIH) and physician collaborators, we believe that there are approximately 500 Ewing sarcoma patients diagnosed annually in the United States. Because the patient populations in the market for our product candidates may be small, we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth, which would negatively affect our revenue and operating results. We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us. The development and commercialization of new drug products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to oncology therapies and the other product candidates that we may seek to develop or commercialize in the future. The list of companies working on some form of cancer treatment is almost limitless with big and small companies working on every aspect of oncology therapies worldwide. If our competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than us, it could result in our competitors establishing a strong market position before we are able to enter the market. Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in pre- clinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. Failure of seclidemstat or other product candidates to effectively compete against established treatment options or in the future with new products currently in development would harm our business, financial condition, results of operations and prospects. The commercial success of any of our current or future product candidates will depend **depends** upon the degree of market acceptance by physicians, patients, third- party payors, and others in **large** the medical community. Even if we obtain the necessary approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our products will depend in part on the health care providers **our ability to retain certain of our remaining personnel** , patients **particularly David J. Arthur** , **our President** and third **Chief Executive Officer, who has recently transitioned to a part** - **time consultant role** party payors accepting our product candidates as medically useful , cost- effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians , patients and third- party payors **Mark J. Rosenblum our Chief Financial Officer** . The degree **loss** of market acceptance of any of our products will depend on a number of factors, including but not limited to: • the efficacy **services** of **either** the product as demonstrated in clinical trials and potential advantages over competing treatments; • the prevalence and severity of the disease and any side effects; • the clinical indications for which approval is granted, including any limitations or warnings contained in a product' s approved labeling; • the convenience and ease of administration; • the cost of treatment; • the willingness of the patients and physicians to accept these **individuals** therapies; • the perceived ratio of risk and benefit of these therapies by physicians and the willingness of physicians to recommend these therapies to patients based on such risks and benefits; • the marketing, sales and distribution support for the product; • the publicity concerning our products or competing products and treatments; and • the pricing and availability of third- party insurance coverage and reimbursement. Even if a product displays a favorable efficacy and safety profile upon approval, market acceptance of the product remains uncertain. Efforts to educate the medical community and third- party payors on the benefits of the products may require

significant investment and resources and may never be successful. If our products fail to achieve an adequate level of acceptance by physicians, patients, third- party payors, and other health care providers, we will not be able to generate sufficient revenue to become or remain profitable. We may not be successful in any efforts to identify, license, discover, develop, or commercialize additional product candidates. Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing product candidates, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop, or commercialize additional product candidates. Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products. Furthermore, until such time as we are able to build a broader product candidate pipeline, if ever, any adverse developments with respect to our current product candidates would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of product candidates. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following: • Our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates; • We may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates; • our product candidates may not succeed in pre- clinical or clinical testing; • our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; • competitors may develop alternatives that render our product candidates obsolete or less attractive; • product candidates we develop may be covered by third parties' patents or other exclusive rights; • the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop; • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and • a product candidate may not be accepted as safe and effective by patients, the medical community, or third- party payors. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business, financial condition or results of operations and could potentially cause us **harm our ability** to cease **continue our** operations . Failure to obtain or maintain adequate reimbursement or insurance coverage for products when approved to market, if any, could limit our ability to market those products and decrease our ability to generate revenue. The pricing, coverage, and reimbursement of our approved products, if any, must be sufficient to support our commercial efforts and other development programs and the availability and adequacy of coverage and reimbursement by third- party payors, including governmental and private insurers, are essential for most patients to be able to afford expensive treatments. Sales of our approved products, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of our approved products, if any, will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or government payors and private payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free or we may not be able to successfully commercialize our products. In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by Centers for Medicare and Medicaid Services, (" CMS "), an **and evaluate** agency within the U. S. Department of Health and Human Services **pursue strategic alternatives** , as CMS decides whether and to what extent a new drug will **well** be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates such as **fulfill** our **reporting obligations** and what reimbursement codes our product candidates may receive if approved. Outside the United States, international operations are generally subject to extensive governmental price controls and other price- restrictive regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products, if any. Accordingly, in markets outside the United States, the potential revenue may be insufficient to generate commercially reasonable revenue and profits. Moreover, increasing efforts by governmental and private payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a **public** result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs has and is expected to continue to increase in the future. As a result, profitability of our products, if any, may be more difficult to achieve even if they receive regulatory approval. Risks Related to our Business Operations Our future success depends in part on our ability to retain our president and chief executive officer and our executive vice president of finance and chief financial officer, and to attract, retain, and motivate other qualified personnel. We are a small company with a limited number of employees performing multiple tasks each. We are highly dependent on David J. Arthur, our president and chief executive officer, and Mark J. Rosenblum, our executive vice president of finance and chief financial officer, the loss of service from either may adversely impact the achievement of our objectives. Although Mr.

~~Arthur' s employment agreement contains a non- compete provision for a period of one year following the termination of his employment agreement, he could leave our employment at any time, as he is an " at- will " employee. Recruiting and retaining other qualified employees, consultants, and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. Additionally, this shortage of highly qualified personnel is particularly acute in the area where we are located. As a result, competition for personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in development and commercialization of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of Mr. Arthur or Mr. Rosenblum may impede the progress of our research, development, and commercialization objectives and would negatively impact our ability to succeed in our product development strategy. We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations. As of March 8, 2023, we had 12 full- time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal, and other resources. Our management may need to divert a disproportionate amount of its attention away from its day- to- day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth~~ . Risks Related to Our Common Stock ~~The terms of the warrants could impede our ability to enter into certain transactions or obtain additional financing. The terms of the warrants require us, upon the consummation of any " fundamental transaction " (as defined in the securities), to, among other obligations, cause any successor entity resulting from the fundamental transaction to assume all of our obligations under the warrants and the associated transaction documents. In addition, holders of warrants are entitled to participate in any fundamental transaction on an as- converted or as- exercised basis, which could result in the holders of our common stock receiving a lesser portion of the consideration from a fundamental transaction. The terms of the warrants could also impede our ability to enter into certain transactions or obtain additional financing in the future.~~ Future sales of a significant number of our shares of common stock in the public markets, or the perception that such sales could occur, could depress the market price of our shares of our common stock or cause our stock price to decline. Sales of a substantial number of our shares of common stock in the public markets, or the perception that such sales could occur, including from the exercise of warrants or sales of common stock issuable thereunder, could cause the market price of our shares of common stock to decline and impair our ability to raise capital through the sale of additional equity securities. A substantial number of shares of common stock are being offered by this prospectus. We cannot predict the number of these shares that might be sold nor the effect that future sales of our shares of common stock, including shares issuable upon the exercise of warrants, would have on the market price of our shares of common stock. We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock. At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, we have no intention of paying any such dividends in the foreseeable future. Any return to investors is expected to come, if at all, only from potential increases in the price of our common stock. General Risks Failure in our information technology and storage systems could significantly disrupt the operation of our business and / or lead to potential large liabilities. Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology systems. Information technology systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back- up measures, some of our and our vendors' servers are potentially vulnerable to physical or electronic break- ins, including cyber- attacks, computer viruses and similar disruptive problems. These events could lead to the unauthorized access, disclosure and use of non- public information which in turn could lead to operational difficulties and liabilities. A security breach or privacy violation that leads to disclosure of consumer, customer, supplier, partner or employee information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state and foreign breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our computer systems are compromised, we could be subject to fines, damages, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. Despite precautionary measures to prevent unanticipated problems that could affect our information technology systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business. In addition, a data security breach could distract management or other key personnel from performing their primary operational duties. The interpretation and application of consumer and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. Among other things, foreign privacy laws impose significant obligations on U. S. companies to protect the personal information of foreign citizens. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices, which could have a material adverse

effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.