

Risk Factors Comparison 2025-03-21 to 2024-03-22 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 **the Merger** **The Merger may be completed even though certain events occur prior to Merger Closing that materially and adversely affect Salarius. The Merger Agreement provides that either Salarius or Decoy can refuse to complete the Merger if there is a material adverse change affecting the other party between January 10, 2025, the date of the Merger Agreement, and the Merger Closing. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on Salarius or Decoy, including:**

- general business or economic conditions affecting the industry in which Salarius or Decoy or their subsidiaries, as applicable, operate;
- acts of war, armed hostilities or terrorism, acts of God or comparable events, epidemic, pandemic or disease outbreak (including the COVID- 19 virus) or any worsening of the foregoing, or any declaration of martial law, quarantine or similar directive, policy or guidance or law or other action by any governmental body in response thereto;
- changes in financial, banking or securities markets;
- any change in, or any compliance with or action taken for the purpose of complying with, any law or generally accepted accounting principles (“ GAAP ”) (or interpretations of any law or GAAP);
- changes resulting from the announcement of the Merger Agreement or the pendency of the transactions contemplated by the Merger Agreement; or
- changes resulting from the taking of any action required to be taken under the Merger Agreement.

If adverse changes occur and Salarius and Decoy still complete the Merger, the market price of the combined company’s common stock may suffer. This in turn may reduce the value of the Merger to the stockholders of Salarius. The Exchange Ratio set forth in the Merger Agreement is adjustable based on the Parent Cash Amount and the Company Cash Amount, each of which will be impacted by, among other things, unexpected expenses that could be experienced by Salarius or Decoy during the pre- Merger Closing period, which could result in Salarius stockholders owning significantly less of the combined company than currently estimated. The Exchange Ratio formula in the Merger Agreement is subject to adjustment based on the Parent Cash Amount and Company Cash Amount on the anticipated Merger Closing Date (each as defined in the Merger Agreement). For example, if the Parent Cash Amount is \$ 0 and the Company Cash Amount is \$ 2. 0 million, stockholders of Salarius would own approximately 14. 1 % of the fully diluted common stock, and stockholders of Decoy would own, or hold rights to acquire, approximately 85. 9 % of Salarius common stock, in each case calculated on a fully- diluted basis for in- the- money options and warrants (and in each case, prior to taking into account any dilution from the Qualified Financing). The calculation of the Exchange Ratio under the Merger Agreement and post- Merger Closing ownership of Salarius stockholders are subject to adjustment based on an assumed value of Salarius at Merger Closing based on the Parent Cash Amount and Company Cash Amount as of the anticipated Merger Closing Date. To the extent the Parent Cash Amount falls below \$ 0, Salarius’ assumed value would be reduced or increased by \$ 100, 000 for every \$ 100, 000 below the threshold. To the extent the Company Cash Amount falls below \$ 2. 0 million, Decoy’s assumed value would be reduced by \$ 100, 000 for every \$ 100, 000 below the threshold. Based on Salarius’ current estimates, Salarius anticipates delivering a Parent Cash Amount of approximately \$ 0; however, the final Parent Cash Amount will not be calculated until the anticipated Merger Closing Date, and may vary significantly depending on, among other things, Salarius’ ability to control and correctly estimate its operating expenses, and if the amount is significantly less, Salarius stockholders would experience additional dilution, subject to a floor of 10 % of the combined company, regardless of the Parent Cash Amount on the anticipated Merger Closing Date. Further, these ownership percentages do not give effect to the shares of Salarius common stock that will be issued to investors in the Qualified Financing prior to the Merger Closing, and do not account for any additional shares of Salarius common stock that may be issued to investors following the effective time of the Merger. As a result, current stockholders of Salarius will own less of the combined company than currently contemplated. Stockholders of the combined company may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger and the Qualified Financing. If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, Salarius stockholders and Decoy stockholders will have experienced substantial dilution of their ownership interests in their respective companies. The Qualified Financing will cause substantial dilution to Salarius and Decoy stockholders which may result in such stockholders not receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Qualified Financing. During the pendency of the Merger, Salarius may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect its business. Covenants in the Merger Agreement impede the ability of Salarius and Decoy to make acquisitions, subject to certain exceptions relating to fiduciary duties, as set forth below, or to complete other transactions that are not in the ordinary course of business pending completion

of the Merger. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during such period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, initiating, encouraging or entering into certain extraordinary transactions, such as a merger, sale of assets, or other business combination outside the ordinary course of business with any third party, subject to certain exceptions relating to fiduciary duties. Any such transactions could be favorable to such party's stockholders. Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement. The terms of the Merger Agreement prohibit each of Salarius and Decoy from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to lead to a superior takeover proposal and that failure to cooperate with the proponent of the proposal would be reasonably likely to be inconsistent with the applicable board's fiduciary duties. Any such transactions could be favorable to such party's stockholders. In addition, if Salarius terminates the Merger Agreement under certain circumstances, including terminating because of a decision of Salarius to enter into definitive agreement with respect to a superior offer, Salarius would be required to pay a termination fee of \$ 300, 000 to Decoy. This termination fee described above may discourage third parties from submitting alternative takeover proposals to Salarius stockholders. Pursuant to the terms of the Merger Agreement, Salarius is required to recommend that its stockholders approve the conversion of all outstanding shares of its Series A Preferred Stock into shares of its Common Stock. Salarius cannot guarantee that its stockholders will approve this matter, and if they fail to do so its operations may be materially harmed. Under the terms of the Merger Agreement, Salarius agreed following the consummation of the Merger to use reasonable best efforts to call and hold a meeting of Salarius stockholders to obtain the requisite approval for the conversion of all outstanding shares of Series A Preferred Stock issued in the Merger into shares of Salarius Common Stock, as required by the Nasdaq listing rules, as soon as practicable after the Merger Closing of the Merger and, if such approval is not obtained at that meeting, to seek to obtain such approval at an annual or special stockholders meeting to be held at least every four months thereafter until such approval is obtained, which would be time- consuming and costly and could significantly negatively affect Salarius' projected cash position. Because the lack of a public market for Decoy's capital stock makes it difficult to evaluate the value of Decoy's capital stock, the stockholders of Decoy may receive shares of Salarius common stock in the Merger that have a value that is greater than, the fair market value of Decoy's capital stock. The outstanding capital stock of Decoy is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Decoy. Because the percentage of Salarius common stock to be issued to Decoy's stockholders was determined based on negotiations between the parties, it is possible that Salarius may pay more than the aggregate fair market value for Decoy. The combined company may become involved in securities class action litigation that could divert management's attention and harm the combined company's business and insurance coverage may not be sufficient to cover all costs and damages. In the past, securities class action or shareholder derivative litigation often follows certain significant business transactions, such as the sale of a business division or announcement of a merger. The combined company may become involved in this type of litigation in the future. Litigation is often expensive and diverts management's attention and resources, which could adversely affect the combined organization's business. The Merger Agreement between Salarius and Decoy may be terminated in accordance with its terms and the Merger may not be completed. The Merger Agreement is subject to a number of conditions which must be fulfilled in order to complete the Merger. Those conditions include, among other things: (i) the lack of a Material Adverse Effect on the respective businesses of Salarius and Decoy; (ii) the continued listing of Salarius' Common Stock on The Nasdaq Capital Market (" Nasdaq ") through the Merger Closing; (iii) the absence of any order, injunction, decree or other legal restraint preventing the consummation of the Merger or any of the other transactions contemplated by the Merger Agreement or making the completion of the Merger or any of the other transactions contemplated by the Merger Agreement illegal; (iv) completion of the Qualified Financing and (v) the accuracy of the respective parties' representations and warranties contained in the Merger Agreement (subject to certain customary qualifications) and compliance by Salarius and Decoy with its respective agreements and covenants contained in the Merger Agreement. These conditions to the Merger Closing may not be fulfilled in a timely manner or at all, and, accordingly, the Merger may not be completed. In addition, the parties can mutually decide to terminate the Merger Agreement at any time, or Salarius or Decoy may elect to terminate the Merger Agreement in certain other circumstances. Salarius may not be able to effect the Merger pursuant to the Merger Agreement, and failure to complete the Merger would negatively impact Salarius' stock price and materially adversely impact the future business and financial results of the Salarius. In connection with the Merger Agreement, Salarius has incurred substantial costs planning and negotiating the transaction. These costs include, but are not limited to, costs associated with employing and retaining third- party advisors who performed the financial, auditing, and legal services required before Salarius was able to enter into the Merger Agreement and which will continue as Salarius seeks to complete the transaction. If, for whatever reason, including those set forth above, the transactions contemplated by the Merger Agreement fail to close, Salarius' will be responsible for these costs, which could adversely affect Salarius liquidity and financial results. In addition, Salarius' stock price may decline significantly if the Merger is not completed. The market price of Salarius' common stock following the Merger may decline as a result of the Merger. The market price of Salarius' common stock may decline as a result of the Merger for a number of reasons, including if: • investors react negatively to the prospects of the combined company's product candidates, business and financial condition following the Merger; • the effect of the Merger on the combined company's business and prospects is not consistent with the expectations of financial or

industry analysts; or • the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts. Saliarius and Decoy securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the Merger Closing as compared to their current ownership and voting interest in the respective companies. If the proposed Merger is completed, the current securityholders of Saliarius and Decoy will own a smaller percentage of the combined company than their ownership in their respective companies prior to the Merger. Accordingly, the issuance of shares of Saliarius common stock to Decoy's stockholders in the Merger will reduce significantly the relative voting power of each share of Saliarius common stock held by its current stockholders and will reduce the relative voting power of each share of Decoy common stock held by its current stockholders. Consequently, Saliarius' stockholders as a group and Decoy's stockholders as a group will have less influence over the management and policies of the combined company after the Merger than prior to the Merger. Consequently, securityholders of both Saliarius and Decoy will be able to exercise less influence over the management and policies of the combined company following the Merger Closing than they currently exercise over the management and policies of their respective companies. The combined company will need to raise additional capital by issuing securities or debt or through licensing or other strategic arrangements, which may cause dilution to the combined company's stockholders or restrict the combined company's operations or impact its proprietary rights. The combined company may be required to raise additional funds sooner than currently planned. If either or both of Saliarius or Decoy hold less cash at the time of the Merger Closing than the parties currently expect, the combined company will need to raise additional capital sooner than expected. Additional financing may not be available to the combined company when it needs it or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such an issuance may cause significant dilution to the combined company's stockholders' ownership and the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of the combined company's technologies or product candidates and proprietary rights, or grant licenses on terms that are not favorable to the combined company. Furthermore, provisions in the agreements for the Qualified Financing may deter or prevent the combined company from raising additional capital to fund the company as and when needed. Restrictive covenants and other provisions in the Qualified Financing documents could deter or prevent the combined company from raising additional capital as and when needed. The combined company's failure to raise capital as and when needed would have a negative effect on its financial condition and its ability to develop and commercialize its pipeline and otherwise pursue the combined company's business strategy and the combined company may be unable to continue as a going concern.

Risks Related to our Financial Position and Capital Needs We do not currently have sufficient working capital completed, Saliarius may not be able to otherwise source adequate liquidity to fund its our planned operations for the next twelve months, meet its obligations, and may not be able to continue as a going concern. Saliarius' board of directors may decide to pursue a dissolution and liquidation of Saliarius. In such an event, there there can be no assurances as to the amount or timing of available cash left, if any, to distribute to its stockholders after paying its debts and other obligations and setting aside funds for reserves. While Saliarius has entered into the Merger Agreement with Decoy, the Merger Closing may be delayed or may not occur at all and there can be no assurance that the Merger will deliver the anticipated benefits Saliarius expects or enhance stockholder value. If the Merger is not completed and the Merger Agreement is terminated under uncertainty ---- certain regarding our ability circumstances, Saliarius may be required to maintain liquidity sufficient to operate our business pay Decoy a termination fee of \$ 300, 000. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, Saliarius will have incurred significant fees and expenses, which raises substantial doubt about must be paid whether our- or not the Merger is completed ability to continue as a going concern. We do Saliarius does not currently have adequate financial resources to fund our-its forecasted operating costs for at least twelve months from the filing of this Annual report. As of December 31, 2024, Saliarius' cash and cash equivalents totaled \$ 2. 4 million, which were held in bank deposit accounts and a money market account. As of December 31, 2024, Saliarius has incurred an accumulated deficit of \$ 81. 9 million. For the twelve months ended December 31, 2024, Saliarius reported net losses of \$ 5. 5 million. As of December 31, 2024, Saliarius' cash and cash equivalents totaled \$ 2. 4 million, which were held in bank deposit accounts and a money market account. As a result, Saliarius believes its existing cash resources are sufficient to meet its anticipated needs into the later part of the second quarter of 2025. If for any reason the Merger does not close, Saliarius would need to raise additional capital to continue to fund the further development of its product candidates and its operations thereafter. Saliarius has based its cash sufficiency estimates on its current business plan and its assumptions may prove to be wrong. Saliarius could utilize its available capital resources sooner than it currently expects, and it could need additional funding sooner than currently anticipated. Additionally, the process of advancing early stage product candidates and testing product candidates in clinical trials is costly, and the timing of progress in these clinical trials is uncertain. Even if Saliarius raises sufficient funds and decides to continue the development of its product candidates, its ability to successfully transition to profitability will be dependent upon achieving a level of product sales adequate to support its cost structure. Saliarius cannot assure you that it will ever be profitable or generate positive cash flow from operating activities. Failure to secure any necessary financing in a timely manner and on favorable terms or the failure of the proposed Merger to be consummated in a timely manner would require Saliarius to further delay or abandon any potential future clinical

development plans. If, for any reason, the Merger does not close, the Salarius board of directors may elect to, among other things, attempt to complete another strategic transaction like the Merger, attempt to sell or otherwise dispose of the various assets of Salarius, resume its research and development activities and continue to operate the business of Salarius. Any of these alternatives would be costly and time-consuming and would require that Salarius obtain additional funding. Salarius expects that it would be difficult to secure financing in a timely manner, on favorable terms or at all. Salarius can make no assurances that it would be able to obtain additional financing or find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement or that any such alternatives are possible or would be successful, if pursued. To the extent that Salarius seeks and is able to raise additional capital through the sale of equity or convertible debt securities, Salarius' stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as a common stockholder. Debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting Salarius' ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Salarius raises funds through strategic transactions or marketing, distribution, or licensing arrangements with third parties, Salarius may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to it. Even if Salarius is able to pursue such alternatives, the failure to complete the Merger may result in negative publicity and / or a negative impression of Salarius in the investment community, could significantly harm the market price of Salarius common stock and may affect Salarius' relationship with employees and other partners in the business community. If the Salarius board of directors were to decide to dissolve and liquidate Salarius' assets, Salarius would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left, if any, to distribute to stockholders after paying its debts and other obligations and setting aside funds for reserves. In addition, Salarius may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, the Salarius 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, Salarius' stockholders would likely lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of Salarius. Salarius does not believe that its current expenses are indicative of the costs it may incur in the future in connection with the development and commercialization of any product candidate if it consummates the Merger or raises additional capital to continue its operations. Salarius' future funding requirements will depend on many factors, including: • its ability to consummate the Merger with Decoy; • the scope, rate of progress and cost of its preclinical and clinical trials for any product candidate in its future pipeline and results of future clinical trials; • the cost and timing of regulatory filings and approvals for any product candidates that successfully complete clinical trials; • the timing and nature of any strategic transactions that Salarius undertakes, including potential partnerships; • the effect of competing technological and market developments; • the cost incurred in responding to actions by activist stockholders; and • the cost of filing, prosecuting, defending and enforcing its intellectual property rights. In addition, the amounts available under Salarius' shelf registration statement on Form S-3 will be significantly limited as long as Salarius' public float remains below \$ 75 million, which, given its currently depressed stock price, limits its ability to obtain meaningful funding through a shelf registration statement at this time, although Salarius could still raise funds through a registration statement on Form S-1 or through private placements. As such, there is uncertainty regarding Salarius' ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt about its ability to continue as a going concern. Salarius' common stock may be subject to delisting from Nasdaq, which would seriously harm the liquidity of our stock and our ability to raise capital or complete a strategic transaction. Salarius' common stock is currently listed on the Nasdaq Capital Market ("Nasdaq"). To maintain its listing on Nasdaq, Salarius is required to maintain: (i) a minimum bid price of \$ 1.00 per share; (ii) a market value of publicly held securities of \$ 1 million; (iii) a certain number of round lot stockholders; and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least \$ 500,000, a market value of listed securities of at least \$ 35 million or a stockholders' equity of at least \$ 2.5 million (the "Stockholders' Equity Requirement"). Nasdaq has the authority to delist Salarius' common stock if Salarius fails to maintain these minimum requirements. In addition, Nasdaq may delist Salarius if, based on Nasdaq's review of Salarius' operations and pursuant to Nasdaq Listing Rule 5101, Nasdaq believes that Salarius is a "public shell" and that the continued listing of its securities is no longer warranted. Salarius has no current plans to delist its shares of common stock from Nasdaq. However, following the decision to close the clinical development of seclidemstat for Ewing sarcoma, Salarius may be treated as a public shell under Nasdaq rules. Although Nasdaq evaluates whether a listed company is a public shell company based on a facts and circumstances determination, a Nasdaq-listed company with no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets is generally considered to be a public shell company. Listed companies determined to be public shell companies by Nasdaq may be subject to delisting proceedings or additional and more stringent listing criteria. On August 9, 2024, Salarius reported in its Quarterly Report on Form 10-K As-Q that as of December 31, 2023, its stockholders' equity was we had a cash and cash equivalents balance of approximately \$ 5.9 million. As of December 31, 2023, we have incurred an 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, 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 **disclosed** operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Since inception, we have incurred net losses and negative cash flows from operations. We 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 **Quarterly** 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-K are filed with the SEC and there **Q, subsequent to June 30, 2024, Salarius sold 564, 730 shares of is its common stock for gross proceeds of approximately** uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. Our net losses were \$ **12-1. 5 million pursuant to that certain At** and \$ **31. 6 million for each of the years ended** **Market Offering Agreement, dated as of February 5, 2021, with Ladenburg Thalmann & Co. Inc. (the "ATM Financing Transaction"). On August 13, 2024, Salarius reported via Current Report on Form 8-K that Salarius regained compliance with the Stockholders' Equity Requirement after giving effect to the ATM Financing Transaction. Notwithstanding the foregoing, Nasdaq indicated that it would continue to monitor Salarius' ongoing compliance with the Stockholders' Equity Requirement and, if at the time of a future periodic report Salarius does not evidence compliance, Salarius' common stock may be subject to delisting. As of** December 31, 2023 **2024** and December 31, **we had (i) 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 **total** 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 **stockholders'** 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 **equity**, LLC as our financial advisor to assist us in this process. In connection with the evaluation of strategic alternatives **approximately \$ 1. 5 million**, **(ii) we have evaluated opportunities not had net income in any period during this fiscal year or either of the to two extend last fiscal years and (iii) the market value of** our resources and have significantly reduced our headcount **listed securities is below \$ 35 million**. We have devoted significant time **As a result, Salarius is not in compliance with the Stockholders' Equity Requirement** and resources **expects** to identifying and evaluating strategic transactions and **receive a delisting notice from Nasdaq. In addition**, as of **March 19** the date of this report, **2025** 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 **the closing** related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will 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 **Salarius'** common stock **was \$ 0. 8615 per share. If Salarius'** 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 **trades**, 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 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 **thirty** 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, 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 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 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 could be delisted from Nasdaq, which would seriously harm the liquidity of our stock and our ability 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 business days had fallen below the \$ 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 requirement, Nasdaq will send a delisting determination to the company. If the delisting determination is sent within one year of our common Salarius' most recent reverse stock split in June 2024, must meet or exceed \$ 1.00 per share for a minimum of 10 consecutive business days prior to the then Salarius will deadline. If we do not achieve compliance with the Minimum Bid Requirement within 180 calendar days, we may be eligible for an any additional 180 calendar days to regain compliance period. To qualify, we would be required to address 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 and will be subject to immediate delisting. Under these circumstances, Salarius can appeal the delisting determination to a Hearings Panel, during which time any suspension or delisting action will be stayed. Salarius is actively monitoring the second market value of its publicly held securities, its stockholders' equity and trading prices and will consider any and all options available to it to maintain compliance period. On March 5, 2024 however, we received notice that Salarius will be able to maintain compliance and meet Nasdaq's continued listing requirements. If Salarius' common stock is delisted from Nasdaq, whether because Nasdaq determines Salarius is a "public shell" or Salarius fails to maintain compliance with the continued listed requirements, or otherwise, Salarius' securities may qualify for trading over-the-counter (the "Approval-OTC") from, in the United States on a market colloquially referred to as the "Pink Sheets." Securities quoted on OTC are generally subject to lesser requirements than securities listed for trading on a U.S. national stock exchange, such as Nasdaq that we have been granted, including reduced corporate governance and public reporting standards additional 180-day grace period, or until September 3, 2024, to regain compliance with the Bid Price Rule. If To regain compliance with the Bid Price Rule and qualify for continued listing on the Nasdaq should delist Salarius' Capital Market, the minimum bid price per share of our common stock from trading, a reduction in some must be at least \$ 1.00 for or at least 10 consecutive business days all of the following may occur, each of which could have a material adverse effect on holders or prior to September 3, 2024. If we fail to regain compliance during the additional compliance period, then Nasdaq will notify us of Salarius' 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: • the liquidity and marketability of our the common stock; • our ability to obtain financing for the continuation market price of our operations the common stock; • the number of institutional and general investors that will consider investing in our the common stock; • the number of investors market makers in our general that will consider investing in the common stock; • the availability number of information concerning market makers in the trading prices and volume of our common stock; the availability of information concerning the trading prices and • volume of the common stock; and the number of broker-dealers willing to execute trades in the shares of our common stock. In addition to the foregoing, there are certain consequences under the Securities Act of 1933, as amended (the "Securities Act"), of being a public shell company, including the unavailability of Rule 144 thereunder for the resale of restricted securities and the inability to utilize Form S-8 for the registration of employee benefit plan securities. 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 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 Salarius is substantially dependent on its remaining employees and consultants to facilitate the consummation of our warrants the Merger. As of March 12, 2025, Salarius had only to two full purchase common stock include a right to receive the Black-time employees 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 and one consultant acting 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 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 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. Our cost savings plans and the associated headcount reductions may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt 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 (MDACC) investigator-initiated Phase 1/2 clinical trial in hematologic cancers and Salarius’ Phase 1/2 trial in Ewing sarcoma. In connection with the cost-savings measures, David Arthur, the Company’s President and Chief Executive Officer, Salarius’ ability to successfully complete the Merger depends in large part on its ability to retain certain remaining personnel. Despite Salarius’ efforts to retain these employees, one or more may terminate their employment or consulting arrangement with Salarius on short notice. The loss of the services of certain employees could potentially harm Salarius’ ability to consummate the Merger, to run its day-time employment and transitioned to a part-time consultant role day business operations, effective February 20, 2024. He will continue to serve as Chief Executive Officer and support our ongoing activities well as to fulfill its reporting obligations as a public company. The pendency of the Merger could have cost-savings measures also included reducing operating expenses and an adverse effect reducing the cash compensation payable to our non-employee directors beginning in the second quarter trading price of Salarius’ common stock 2024. We may not realize, in full or in part, the anticipated benefits, savings and its business improvements in our cost structure from our cost savings efforts due to unforeseen difficulties, delays or unexpected costs. For example, we may incur unanticipated charges not currently contemplated as a result of the cost savings plans. If we are unable to realize the expected operational cost savings from the restructuring, our operating results and financial condition and prospects. The pendency of the Merger would could disrupt Salarius’ business in many ways, including: • the attention of its remaining management and employees may be materially directed toward the completion of the Merger and related matters and may be diverted from Salarius’ day-to-day business operations; and • third parties may seek to terminate or renegotiate their relationships with Salarius as a result of the Merger, whether pursuant to the terms of their existing agreements with Salarius or otherwise. Should they occur, any of these matters could adversely affected-- affect the trading price of Salarius’ common stock or harm its business, financial condition and prospects. We have Salarius has never generated any revenue from product sales and may never generate revenue or be profitable. We have Salarius has no products approved for commercialization and have has never generated any revenue. Our Salarius’ ability to generate revenue and achieve profitability depends on our Salarius’ 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 its product candidates. We do Salarius does not anticipate generating revenue from product sales for the foreseeable future. Our Salarius’ ability to generate future revenue from product sales depends heavily on our Salarius’ success in many areas, including but not limited to: • completing research and development of our its product candidates; • obtaining regulatory and marketing approvals for our its 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 Salarius’ product candidates, if approved; • marketing, launching and commercializing product candidates for which we Salarius obtain obtains regulatory and marketing approval, either directly or with a collaborator or distributor; • gaining market acceptance of our Salarius’ product candidates as treatment options; • addressing any competing products; • protecting and enforcing our Salarius’ intellectual property rights, including patents, trade secrets, and know-how; • negotiating favorable terms in any collaboration, licensing, or other arrangements into which we Salarius may enter; • obtaining reimbursement or pricing for our Salarius’ product candidates that supports profitability; and • attracting, hiring, and retaining qualified personnel. Even if one or more of the product candidates that we Salarius develop develops is approved for commercial sale, we Salarius would need to incur significant costs associated with commercializing any approved product candidate. Portions of our Salarius’ 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 Salarius will also have to develop, contract for or acquire manufacturing capabilities to continue development and potential commercialization of our Salarius’ product candidates. We Salarius will need to develop or procure our its drug product in a commercially feasible manner in order to successfully commercialize any future approved product ;, if any. Additionally, if we are Salarius is not able to generate revenue from the sale of any approved products, we Salarius 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 these raises caused significant dilution to stockholders who owned our shares of our common 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 a strategic transaction or raise 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. 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 the Development of our Salarius' Product Candidates

The approach we have Salarius has taken 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 have formed the basis for our Salarius' efforts to discover and develop our Salarius' product candidates are relatively recent. 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 Salarius decide decides to develop further 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. For instance, our Salarius' clinical and pre-clinical data to date is not validated and we have Salarius has no way of knowing if after validation our Salarius' clinical trial data will be complete and consistent. If we do Salarius does not successfully develop and commercialize product candidates based upon this technological approach, we Salarius may not become profitable and the value of our Salarius' capital stock may further decline. Further, our Salarius' focus on epigenetic enzyme technology for developing product candidates as opposed to multiple, more proven technologies for drug development has increased the risk associated with our Salarius' business. We are Salarius is not able to identify and successfully implement an alternative product development strategy due to our Salarius' previous investments in current product candidates. In addition, work by other companies pursuing similar technologies may encounter setbacks and difficulties that regulators and investors may attribute to our Salarius' product candidates, whether appropriate or not. Clinical trials are costly, time consuming and inherently risky, and may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities. Clinical development is expensive, time consuming and involves significant risk. If we Salarius decide decides to move forward with our Salarius' clinical trials, we Salarius cannot guarantee that they will be conducted as planned or completed on schedule, if at all. We Salarius currently do does not have the funds to advance our Salarius' planned clinical trials. A failure of one or more of these clinical trials can occur at any stage of development. Salarius' Events that may prevent successful or timely completion of clinical development include but are not limited to:

- the inability to generate satisfactory pre-clinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of our clinical trials;
- delays in reaching agreement on acceptable terms with clinical research organizations, (CROs), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required IRB approval at each clinical trial site;
- failure to permit the conduct of a clinical trial by regulatory authorities, after review of an investigational new drug or equivalent foreign application or amendment;
- delays and inability in recruiting qualified patients in our clinical trials;
- imposition of a clinical hold by regulatory agencies for any reason, including safety concerns raised by other clinical trials of similar product candidates that may reflect an unacceptable risk with the patient population, technology platform, product stability or after an inspection of clinical operations or trial sites;
- failure by clinical sites or CROs or other third parties to adhere to clinical trial requirements;
- failure by our clinical sites, CROs or other third parties to perform in accordance with contractual obligations or the regulatory requirements of the FDA, or applicable foreign regulatory guidelines;
- patients dropping out of our clinical trials;
- withdrawal of clinical trial sites from our clinical trials, including as a result of changing standards of care or the ineligibility of a site to participate;
- delays or failure in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- adverse events or tolerability or animal toxicology issues significant enough for the FDA or other regulatory agencies to put any or all clinical trials on hold;
- occurrence of adverse events associated with our product candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of the clinical trials of our product candidates;
- negative or inconclusive results from our clinical trials which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in other ongoing or planned indications for a product candidate;
- the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge by jurisdiction;
- evolution in the standard of care that require amendments to ongoing clinical trials and / or the conduct of additional preclinical studies or clinical trials;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; and
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture

of sufficient quantities of our product candidates for use in clinical trials. Any inability to successfully complete clinical development and obtain regulatory approval for our product candidates that we move forward with could result in additional costs or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional pre-clinical trials or the results obtained from such new formulation may not be consistent with previous results obtained. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our IND or similar application outside the United States or the conduct of the trial. Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial. We cannot give any assurance that we will be able to resolve any future clinical holds imposed by the FDA or other regulatory authorities outside of the United States, or any delay caused by manufacturing failures or other factors described above or any other factors, on a timely basis or at all. If we are not able to successfully initiate and complete clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates. Even if our clinical trials are successfully completed, the results may not support approval of our product candidates under the laws and regulations of the FDA or other regulatory authorities outside the United States. The clinical trial process may fail to demonstrate that our product candidates are both safe and effective for their intended uses. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of our product candidates. This, in turn, would significantly adversely affect our business prospects. Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any. Undesirable side effects caused by our **Salarius** product candidates could cause us **Salarius**, an IRB or ethics committee, or regulatory authorities to **continue the clinical hold status**, interrupt, delay, or terminate clinical trials or even if approved, result in a restrictive label or delay regulatory approval by the FDA or comparable foreign authorities and potential product liability claims. In addition, to date our product candidates have been studied in only a very limited number of patients. Our understanding of the relationship between our product candidates and these events, as well as our understanding of adverse events reported in future clinical trials of other product candidates, may change, and additional unexpected adverse events may be observed. There is no guarantee that severe side effects will not be identified through ongoing clinical trials of our product candidates. Undesirable side effects and negative results for other indications may negatively impact the development and potential for approval of our product candidates for their proposed indications. In addition, the side effect profile of pharmaceutical drugs cannot be fully established based on preapproval clinical trials involving a limited number of patients. Routine review and analysis of post-marketing safety surveillance and clinical trials will provide additional information, for example, potential evidence of rare, population-specific or long-term adverse reactions, and may adversely affect the commercialization of the product, and even lead to the suspension or revocation of product marketing authorization. Specifically, as a result of concerns regarding the potential teratogenic and abortifacient effects of SP-2577, pregnant women were excluded from the conducted studies. If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including but not limited to: • our clinical trials may be put on hold, such as the partial clinical hold that was previously placed on our Phase 1/2 trial of seclidemstat as a treatment for Ewing sarcoma and FET-rearranged sarcomas; • we may be unable to obtain regulatory approval for our product candidates; • regulatory authorities may withdraw approvals of such products; • regulatory authorities may require additional warnings on the label; • We may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and / or other elements to assure safe use; • We could be sued and held liable for harm caused to patients; and • its reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm or cause the complete failure of our business, results of operations, and prospects. Some of our product candidates may produce results in pre-clinical or clinical settings for indications other than those for which we contemplate conducting development activities or seeking FDA approval, and we cannot give any assurance that our clinical trials will generate data for any of our product candidates sufficient to receive regulatory approval in our planned indications, which will be required before they can be commercialized. None of our product candidates have advanced into a pivotal clinical trial and such an occurrence may never occur. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier pre-clinical and clinical trials may not be predictive of future clinical trial results. Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical trials and early clinical trials of our **Salarius** product candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials. Our **Salarius** clinical trials to date have been conducted on a small number of patients in limited numbers of clinical sites for a limited number of indications. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses. We **Salarius** cannot assure whether any clinical trials we **Salarius** or **The University of**

Texas MD Anderson **Cancer Center (“ MDACC ”)** may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to receive regulatory approval or market **our Salarius’** drug candidates. Difficulty in enrolling patients is a common hurdle faced by early stage biotechnology companies and could, and often does, delay or prevent clinical trials of product candidates. Identifying and qualifying patients to participate in clinical trials of **our Salarius’** product candidates is essential to **our Salarius’** existence. The timing of **our Salarius’** clinical trials depends in part on the rate at which **we Salarius** or investigators can recruit patients to participate in clinical trials of **our Salarius’** product candidates, and **we Salarius** and **our Salarius’** investigators may experience delays in **our Salarius’** clinical trials if **we Salarius** or they encounter difficulties in enrollment. **Salarius** Patient enrollment is affected 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. 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 will be delayed. Even if we or investigators enroll a sufficient number of eligible patients to initiate our clinical trials, we or they 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 or investigators have difficulty enrolling and maintaining the enrollment of a sufficient number of patients to conduct clinical trials, we won’t receive the necessary data from the clinical trial which would have a material adverse effect on our business. We may face potential product liability, and, if successful claims are brought against **us Salarius**, **we Salarius** may incur substantial liability and costs which could be greater than **our Salarius’** insurance coverage or overall resources. If the use or misuse of **our Salarius’** product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to **our Salarius’** product candidates, **our Salarius’** regulatory approvals, if any, could be revoked or otherwise negatively impacted and **we Salarius** could be subject to costly and damaging product liability claims. If **we are Salarius is** unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, **our Salarius’** insurance coverage, a material liability claim could adversely affect **our Salarius’** financial condition. The use or misuse of **our Salarius’** product candidates in clinical trials and the sale of any products for which **we Salarius** may obtain marketing approval exposes **us Salarius** to the risk of potential product liability claims. Product liability claims might be brought against **us Salarius** by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with **our Salarius’** product candidates and approved products, if any. There is a risk that **our Salarius’** 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 **AEs** 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. 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 Regulatory Approval of **our Salarius’** Product Candidates and Other Legal Compliance Matters Even if FDA grants breakthrough therapy designation for one or more of **our Salarius’** 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 Salarius’** 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 Salarius** may seek a breakthrough therapy designation from the FDA for some of **our Salarius’** 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 Salarius believe believes** one of **our Salarius’** 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 Salarius’** 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 Salarius has** received **Fast fast**

Track-track designation for one of our product candidates **SP- 2577 as a potential treatment for a rare pediatric disease in Ewing's Sarcoma**, 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-fast Track-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-fast Track-track** designation. **Salarius** We recently received **Fast-fast Track-track** designation for **SP- 2577 as a product candidate-potential treatment for a rare pediatric disease in Ewing's Sarcoma**. However, **Fast-fast Track-track** designation does not ensure that we **Salarius** will receive marketing approval or that approval will be granted within any particular time frame. We **Salarius** may not experience a faster development or regulatory review or approval process with **Fast-fast Track-track** designation compared to conventional FDA procedures. In addition, the FDA may withdraw **Fast-fast Track-track** designation if it believes that the designation is no longer supported by data from our **Salarius'** clinical development program. **Fast Track-track** designation alone does not guarantee qualification for the FDA's priority review procedures. We **Salarius** cannot guarantee how long it will take regulatory agencies to review our **Salarius'** applications for product candidates, and we **Salarius** may fail to obtain the necessary regulatory approvals to market our **Salarius'** product candidates. If we are **Salarius** is not able to obtain required regulatory approvals, we **Salarius** will not be able to commercialize our **Salarius'** product candidates and our **Salarius'** ability to generate revenue will be materially impaired. Our **Salarius'** 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 **Salarius'** product candidates will prevent us **Salarius** from commercializing them in those markets. We have **Salarius** has not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither our **Salarius'** current product candidates nor any product candidates that we **Salarius** may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us **Salarius** to commence product sales. **Reliance on government funding** Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication **Salarius' programs may add uncertainty to Salarius' research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit Salarius' ability to take specified actions, increase the costs of each commercialization and production of our product candidates to establish developed under the those programs and subject Salarius to potential financial penalties, which could materially and adversely affect Salarius' business, financial condition and results of operations. During the course of Salarius' development of Salarius' product candidates -safety and efficacy for such indications. Securing marketing approval also requires the submission of information about the product manufacturing process to, Salarius 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 has 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 **Salarius** received from **the Cancer Prevention and Research Institute of Texas (“ CPRIT ”)**. If **Salarius does not comply with the terms of the grant**, CPRIT terminates the agreement prior to the expiration due to an event of default or if we terminate the agreement, CPRIT may require us **Salarius** to repay some or all of the disbursed grant. 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 Salarius' Intellectual Property We Salarius may not be successful in obtaining or maintaining necessary rights to our Salarius' targets, product compounds and processes for our Salarius' development pipeline through acquisitions and in-licenses. Presently, we have Salarius has rights to the intellectual property, through licenses from third parties and under patents and patent applications that we Salarius own-owns , to modulate only a subset of the known epigenetic enzyme targets. Because our Salarius' programs may involve a range of targets, including targets that require the use of proprietary rights held by third parties, the growth of our Salarius' business may depend in part on our Salarius' ability to acquire, in- license or use these proprietary rights. In addition, our Salarius' product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We Salarius 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 Salarius 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 Salarius may consider attractive. These established companies may have a competitive advantage over us Salarius due to their size, cash resources and greater clinical development and commercialization capabilities. For example, we have Salarius has previously collaborated with academic institutions worldwide to accelerate our Salarius' 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 Salarius may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us Salarius. If we are Salarius is unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our Salarius' ability to pursue our its program. In addition, companies that perceive us Salarius to be a competitor may be unwilling to assign or license rights to us Salarius. We Salarius also may be unable to license or acquire third- party intellectual property rights on terms that would allow us Salarius to make an appropriate return on our Salarius' investment. If we are Salarius is unable to successfully obtain rights to third- party intellectual property rights, our Salarius' business, financial condition and prospects for growth could suffer. We Salarius intend-intends to rely on patent rights for our Salarius' product candidates and any future product candidates. If we are Salarius is unable to obtain or maintain exclusivity from the combination of these approaches, we Salarius may not be able to compete effectively in our Salarius' markets. We rely Salarius relies or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our Salarius' technologies and product candidates. Our Salarius' success depends in large part on our Salarius' and our its 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 Salarius' proprietary technology and products. We have Salarius has sought to protect our Salarius' proprietary position by filing patent applications in the United States and abroad related to our Salarius' product candidates that are important to our Salarius' business. This process is expensive and time consuming, and we Salarius 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 Salarius will fail to identify patentable aspects of our Salarius' 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 Salarius own-owns or in- licenses may fail to result in issued patents with claims that cover our Salarius' product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our Salarius' 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 Salarius' 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 Salarius' patents and patent applications may not adequately protect our Salarius' intellectual property, provide exclusivity for our Salarius' product candidates, or prevent others from designing around our Salarius' claims. Any of

these outcomes could impair our Salarius' ability to prevent competition from third parties, which may have an adverse impact on our Salarius' business. We Salarius, independently or together with our Salarius' licensors, have filed several patent applications covering various aspects of our Salarius' product candidates. We Salarius 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 Salarius after patent issuance could deprive us Salarius of rights necessary for the successful commercialization of any product candidates that we Salarius may develop. Further, if we Salarius encounter-encounters delays in regulatory approvals, the period of time during which we Salarius could market a product candidate under patent protection could be reduced. If we Salarius cannot obtain and maintain effective protection of exclusivity from our Salarius' regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our Salarius' product candidates, we Salarius may not be able to compete effectively and our Salarius' business and results of operations would be harmed. We Salarius may not have sufficient patent term protections for our Salarius' product candidates to effectively protect our Salarius' 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 Salarius' product candidates are obtained, once the patent life has expired for a product candidate, we Salarius 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 (the "USPTO"). Depending on the timing, duration, and conditions of FDA marketing approval of our Salarius' product candidates, one or more of our Salarius' 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 Salarius' product candidates. We Salarius will likely rely on patent term extensions, and we Salarius cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. However, we Salarius may not receive an extension if we Salarius fail-fails 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 Salarius request-requests. If we are Salarius is unable to obtain patent term extension or the term of any such extension is less than we Salarius request-requests, the period during which we Salarius can enforce our Salarius' 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 Salarius may not be able to maintain exclusivity for our Salarius' product candidates for an extended period after regulatory approval, if any, which would negatively impact our Salarius' business, financial condition, results of operations and prospects. If we do Salarius does not have sufficient patent terms or regulatory exclusivity to protect our Salarius' product candidates, our Salarius' 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 Salarius' ability to protect our Salarius' products, and recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our Salarius' patent applications and the enforcement or defense of our Salarius' issued patents. As is the case with other biotechnology companies, our Salarius' success is heavily dependent on patents and the ability to enforce and protect these patents. 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 Salarius' 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 Salarius' ability to obtain new patents or to enforce our Salarius' existing patents and patents that we Salarius might obtain in the future. Some of our Salarius' 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. If Salarius 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 Salarius’ product candidates or any future product candidates, we Salarius may not be able to compete effectively in our Salarius’ proposed markets. In addition to the protection afforded by patents, we rely Salarius relies on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we Salarius elect elects not to patent, processes for which patents are difficult to enforce and any other elements of our Salarius’ 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 Salarius seek to protect our Salarius’ proprietary technology and processes, in part, by entering into confidentiality agreements with our Salarius’ employees, consultants, scientific advisors, and contractors. We Salarius also seeks to preserve the integrity and confidentiality of our Salarius’ data and trade secrets by maintaining physical security of our Salarius’ premises and physical and electronic security of our Salarius’ information technology systems. While we have Salarius has confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we Salarius may not have adequate remedies for any breach. In addition, our Salarius’ 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 Salarius’ development and commercialization efforts. Our Salarius’ commercial success depends in part on our Salarius’ ability to develop, manufacture, market and sell our Salarius’ product candidates and use our Salarius’ 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 Salarius is aware of U. S. and foreign patents and pending patent applications owned by third parties that cover therapeutic uses of epigenetic inhibitors. We are Salarius is currently monitoring these patents and patent applications. We Salarius 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 Salarius 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 Salarius’ product candidates or technologies, we Salarius may not be free to manufacture or market our Salarius’ product candidates, as planned, absent such a license, which may not be available to us Salarius on commercially reasonable terms, or at all. Salarius may 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 Salarius' obligations under our Salarius' existing license agreements necessary to maintain our Salarius' product candidate licenses in effect. In addition, if required in order to commercialize our Salarius' product candidates, we Salarius may be unsuccessful in obtaining or maintaining necessary rights to our Salarius' product candidates through acquisitions and in- licenses. We Salarius currently have has rights to the intellectual property, through licenses from third parties and under patents that we do Salarius does not own, to develop and commercialize our Salarius' product candidates. Because our Salarius' programs may require the use of proprietary rights held by third parties, the growth of our Salarius' business will likely depend in part on our Salarius' ability to maintain in effect these proprietary rights. Any termination of license agreements with third parties with respect to our Salarius' product candidates would be expected to negatively impact our Salarius' business prospects. We Salarius 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 Salarius identify identifies as necessary for our Salarius' 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 Salarius 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 fails 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 Salarius licenses intellectual property and other rights from third parties or otherwise experience disruptions to our Salarius' business relationships with our Salarius' licensors, we Salarius could lose license rights that are important to our Salarius' business. We are Salarius is a party to intellectual property licenses and supply agreements that are important to our Salarius' business and may enter into additional license agreements in the future. Our Salarius' existing agreements impose, and we Salarius expect expects that future license agreements will impose on us Salarius, various diligence, milestone payment, royalty, purchasing, and other obligations. If we Salarius fail fails to comply with our Salarius' obligations under these agreements, or we are Salarius is subject to a bankruptcy, our Salarius' agreements may be subject to termination by the licensor, in which event we Salarius would not be able to develop, manufacture, or market products covered by the license or subject to supply commitments. We Salarius may be involved in lawsuits to protect or enforce our Salarius' patents or the patents of our Salarius' licensors, which could be expensive, time consuming, and unsuccessful. Competitors may infringe our Salarius' patents or the patents of our Salarius' licensors. If we Salarius or one of our Salarius' licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our Salarius' product candidates, the defendant could counterclaim that the patent covering our Salarius' 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. Salarius

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 make 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 Salarius' 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 Salarius' 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 Salarius' technologies in jurisdictions where we have Salarius has not obtained patent protection to develop our Salarius' own products and may also export infringing products to territories where we have Salarius has patent protection, but enforcement is not as strong as that in the United States. These products may compete with our Salarius' products and our Salarius' 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 Salarius' Reliance on Third Parties We rely Salarius relies on or will rely on third parties to conduct our Salarius' clinical trials. If these third parties do not successfully perform and comply with regulatory requirements, we Salarius may not be able to successfully complete clinical development, obtain regulatory approval or eventually commercialize our Salarius' product candidates and our Salarius' business could be substantially harmed. We have Salarius has relied upon and plan to continue to rely upon third parties such as contract research organizations ("CROs"), hospitals and clinical investigators to study our Salarius' product candidates in clinical trials. For example, we have Salarius has collaborated with The University of Texas MD Anderson Cancer Center ("MDACC") to study SP-2577 in combination with azacitidine for the treatment of patients with myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML). We rely Salarius relies on these parties for the execution of clinical trials and we Salarius only manage-manages and control-controls some aspects of their activities. With respect to the MDACC MD Anderson-sponsored investigator initiated trial, we supply Salarius supplies seclidemstat in quantities required to conduct the clinical trial, but do does not have any control over their development activities or the timing thereof. We Salarius remains responsible for ensuring that each of our Salarius' trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our Salarius' reliance on these third parties does not relieve us Salarius of our its regulatory responsibilities. In July 2024, We and our CROs and other-- the vendors are required to comply FDA placed the trial on partial clinical hold following a serious and unexpected grade 4 adverse event encephalopathy, which was reversible. In February 2025, Salarius announced that MDACC had addressed the FDA's questions and the partial clinical hold had been lifted, with patient enrollment resuming in all applicable laws, regulations and guidelines, including those-- the 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-party 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 Salarius expect expects to rely on third parties to manufacture our Salarius' clinical product supplies, and we Salarius intend-intends to rely on third parties to produce and process our Salarius' product candidates, if approved, and our Salarius' commercialization of any of our Salarius' 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 Salarius with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices. We do Salarius does not currently have nor do we does Salarius currently plan to develop the infrastructure or capability internally to manufacture our Salarius' clinical supplies for use in the conduct of our Salarius' clinical trials, and we Salarius lack-lacks the resources and the capability to manufacture any of our Salarius' product candidates on a clinical or commercial scale. We Salarius currently rely-relies on outside vendors to manufacture the clinical supplies of our Salarius' product candidates. We Salarius plan-plans to continue relying on third parties to manufacture our Salarius' product candidates on a commercial scale, if approved. We do Salarius does not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our Salarius' product candidates and our Salarius' current costs to manufacture our Salarius' drug products is not commercially feasible, and the actual cost to manufacture our Salarius' product candidates could materially and adversely affect the commercial viability of our Salarius' product candidates. As a result, we Salarius 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 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, 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 our Business Operations We are substantially dependent on our remaining employees and consultants to continue our operations and facilitate the consideration and consummation of a potential strategic transaction. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel, particularly David J. Arthur, our President and Chief Executive Officer, who has recently transitioned to a part-time consultant role, and, Mark J. Rosenblum our Chief Financial Officer. The loss of the services of either of these individuals could potentially harm our ability to continue our operations and evaluate and pursue strategic alternatives, as well as fulfill our reporting obligations as a public company.

Risks Related to Our Common Stock 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 – Risk Factors 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.