Risk Factors Comparison 2025-03-31 to 2024-03-05 Form: 10-K

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

Risks Related to our Financial Position and Capital Requirements We have incurred losses since inception, we expect to incur significant net losses in the foreseeable future and we may never become profitable and our operating results have been and will likely continue to be volatile. We have generated negative cash flows from operations and have incurred net operating losses each year since we started business. For the year ended December 31, ~~2023~~ **2024** , we incurred net losses of $ 13. ~~3~~ **0** million and our net cash used in operating activities was $ ~~12~~ **10** . ~~9~~ **6** million. As of December 31, ~~2023~~ **2024** , our accumulated deficit was $ ~~480~~ **493** . 5 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next twelve months. As our focus on development of nanomedicine and the development of therapeutic applications has increased, losses have resulted primarily from expenses associated with research and development and clinical trial- related activities, as well as general and administrative expenses. We expect to continue operating in a loss position and expect that recurring operating expenses will be at higher levels for the year ending December 31, ~~2024~~ **2025** as we perform clinical trials and other development activities for our nanomedicine product candidates. Our ability to generate sufficient revenue from any of our products, product candidates or technologies to achieve profitability will depend on a number of factors including, but not limited to: • our ability to manufacture, test and validate our product candidates **or clinical tests** in compliance with applicable laws and as required for submission to applicable regulatory bodies ~~, including manufacturing, testing and validation of our RNL candidates~~ ; • our or our partners' ability to successfully complete clinical trials of our product candidates; • our ability to obtain necessary regulatory approvals for our product candidates; • our or our partners' ability to negotiate and receive favorable reimbursement for our product candidates, including for our product candidates that have been granted or may be granted orphan drug status or otherwise command currently anticipated pricing levels; • our ability to negotiate favorable arrangements with third parties to help finance the development of, and market and distribute, our products and product candidates; ~~and~~ • the degree to which our approved products are accepted in the marketplace **; and • our success at commercializing our CNSideTM Portfolio** . Because of the numerous risks and uncertainties associated with our commercialization and product development efforts, we are unable to predict the extent of our future losses or when or if we will become profitable and it is possible we will never become profitable. If we do not generate significant sales from any of our product candidates that receive regulatory approval, there would be a material adverse effect on our business, results of operations, financial condition and prospects, which in turn could result in our inability to continue operations. Our prospects must be evaluated in light of the risks and difficulties frequently encountered by emerging companies and particularly by such companies in rapidly evolving and technologically advanced biotech, pharmaceutical and medical device fields. In addition, our budgeted expense levels are based in part on our expectations concerning future research and development activities. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events. Accordingly, unexpected events could have an immediate and material impact on our business and financial condition. From time to time, we have tried to update our investors' expectations as to our operating results. If we revise any timelines we may give with respect to our clinical trials, it could materially harm our reputation and the market' s perception of us and could cause our stock price to decline. Uncertainties relating to our ability to fund our operations for at least the next 12 months raises substantial doubt about our ability to continue as a going concern. As of December 31, ~~2023~~ **2024** , we had an accumulated stockholders' deficit of approximately $ ~~480~~ **493** . 5 million, a working capital deficit of approximately $ ~~0~~ **10** . ~~9~~ **3** million, and approximately $ ~~8~~ **3** . 6 million of cash and cash equivalents **and short-term investments** to fund our operations and capital requirements. We do not currently have sufficient available liquidity to fund our operations for at least the next 12 months. Consequently, absent further actions, these matters raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements in this Form 10- K are issued. We have a history of generating losses and negative cash flows from operations. Our financial statements have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our ability to continue as a going concern is dependent upon our ability to obtain additional debt, equity or other financing. Furthermore, we also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our intellectual property or product candidates or otherwise agree to terms unfavorable to us. If we are unsuccessful in our efforts to raise any such additional capital, we would be required to take actions that could materially and adversely affect our business, including significant reductions in our research, development and administrative operations (including reduction of our employee base), possible surrender or other disposition of our rights to some technologies or product opportunities, delaying of our clinical trials or curtailing or ceasing operations. We could be delisted from Nasdaq **for failure to comply with the minimum stockholders' equity continued listing requirement or other applicable continued listing requirements and standards of Nasdaq** , which would seriously harm the liquidity of our stock and our ability to raise capital. **Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain that listing, we must maintain compliance with Nasdaq' s continued listing requirements and standards. There can be no assurances that we will be able to comply with the applicable listing requirements and standards of Nasdaq.** Nasdaq requires ~~listing~~ **listed** issuers to comply with certain standards in order to remain listed on its exchange. These requirements include, among other things, maintaining a closing bid price for our common stock of $ 1. 00 per share ~~(the " minimum bid price requirement ")~~ and meeting one of the following three requirements: maintaining at least $ 2. 5 million in stockholders' equity **(the " Minimum Stockholders' Equity Requirement ")** ; maintaining $ 35 million of market value of listed securities; or having $ 500, 000 in net income over the prior two years or two of the prior three years. In **March** ~~2022~~ **2024** , we received notice **from the Listing Qualifications staff**

of Nasdaq (the " Staff "), notifying us that ~~because the closing bid price for our common stock had fallen below $ 1. 00 per share for 30 consecutive business days,~~ we no longer complied with the ~~minimum~~ **Minimum** ~~bid price requirement. While we cured this deficiency in 2023 after effecting the Reverse Stock Split (as defined below), there is no assurance that we will be able to maintain compliance with this standard. As of December 31, 2023, our stockholders~~ **Stockholders ' Equity Requirement** ~~' deficit was $ 1. 3 million. The market value of our listed securities was below $ 35 million and we did not have net income in the last three years. As a result, we no longer meet the alternative compliance standards of market value of listed securities or net income from continuing operations for continued listing on the Nasdaq Capital Market~~ under Nasdaq Listing Rule 5550 (b) (1) **. On September 5** , ~~which requires listed companies to maintain~~ **2024, Nasdaq notified us that we had not regained compliance with the Minimum** ~~stockholders~~ **Stockholders** ' ~~equity~~ **Equity Requirement and that, as a result, unless we timely requested an appeal** of ~~at least $ 2~~ **this determination to a Nasdaq Hearings Panel (the " Panel "), Nasdaq would move to suspend trading of our common stock and to have our shares of common stock delisted from The Nasdaq Capital Market** . ~~5 million~~ **The Company timely requested a hearing before the Panel, and the hearing was held on October 22, 2024. On October 30, 2024, Nasdaq provided us until March 4, 2025, to notify Nasdaq that we were in compliance with the Minimum Stockholders' Equity Requirement** . We ~~expect~~ **regained compliance with the Minimum Stockholders' Equity Requirement in connection with the private placement we closed on March 4, 2025. For more information regarding the private placement, see " Liquidity and Capital Resources " below. Pursuant** to ~~receive a written notice from~~ Nasdaq **Listing Rule 5815 (d) (4) (B), we will be subject to a Mandatory Panel Monitor until March 7, 2026. If the** ~~staff~~ **Staff** ~~indicating~~ **finds we are again out of compliance with the Minimum Stockholders' Equity Requirement before** that **date,** we **will** ~~no~~ **not be permitted** ~~longer meet the listing requirement subsequent~~ to **provide the Staff** ~~filing of this Form 10- K in March 2024,~~ with a **plan of** ~~period to cure such noncompliance~~ --- **compliance with respect** . ~~We intend~~ to ~~evaluate various courses of action~~ **that deficiency and the Staff would not be permitted to grant additional time for us** to regain compliance with ~~Nasdaq Listing Rule 5550 (b) (1) within the~~ **respect to that deficiency, nor would we be afforded an applicable cure or** compliance period **. Instead, the Staff would issue a " Delist Determination Letter " and we would have an opportunity** to **request a** ~~be specified by~~ Nasdaq **hearing panel** ~~. However, there can be no assurance that we will be able to regain~~ **regarding** ~~compliance within such compliance period or~~ **our** ~~, if we regain compliance, that we will not fall out of compliance with one of Nasdaq' s~~ continued listing ~~standards at some future point in time and without raising additional capital it will continue to decline~~ . **In** ~~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 **event that** ~~following may occur, each of which could materially adversely affect our stockholders: • the liquidity and marketability of~~ our common stock ~~; • the market price~~ **is delisted from Nasdaq, as a result** of **our failure to comply with the Minimum Stockholders' Equity Requirement,** ~~our~~ **or** ~~common stock; • as a result of~~ our ~~ability~~ **failure** to ~~obtain financing~~ **continue to comply with any other requirement** for **continued** ~~the continuation of our operations; • the number of institutional and general investors that will consider investing~~ --- **listing** ~~in our common stock; • the number of market makers in our common stock; • the availability of information concerning the trading prices and volume of our common stock; and • the number of broker- dealers willing to execute trades in shares of our common stock. In addition, if we cease to be eligible to trade~~ on Nasdaq, we may have to pursue trading on a less recognized or accepted market, such as the over the counter markets, our stock may be traded as a " penny stock, " which would make transactions in our **common** 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 decline. We will need substantial additional funding to develop our product candidates and conduct our future operations and to repay our outstanding debt obligations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development activities or may be unable to continue our business operations. We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to continue funding our operations, including our continuing substantial research and development expenses and potential commercialization activities. We do not currently believe that our cash balance will be sufficient to fund the development and marketing efforts required to reach profitability without raising additional capital from accessible sources of financing in the near future. Our future capital requirements will depend on many factors, including: • our ability to raise capital to fund our operations on terms acceptable to us, or at all; • our perceived capital needs with respect to our development programs, and any delays in, adverse events and excessive costs of such programs beyond what we currently anticipate; • our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our product candidates to market and the cost of such arrangements at the time; • costs associated with operating at our **Houston** ~~San Antonio~~ , Texas facility; • the cost of manufacturing our product candidates, including compliance with good manufacturing practices applicable to our product candidates; • expenses related to the establishment of sales and marketing capabilities for product candidates awaiting approval or products that have been approved; • competing technological and market developments; and • our ability to introduce and sell new products. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of ~~its~~ **our** clinical development efforts. We have secured capital historically from grant revenue, collaboration proceeds, and debt and equity offerings. To obtain additional capital, we may pursue debt and / or equity offering programs, strategic corporate partnerships, state and federal development programs, licensing arrangements, and sales of assets or debt or equity securities. We cannot be certain that additional capital will be available on terms acceptable to us, or at all. If we are unsuccessful in our efforts to raise any such additional capital, we may be required to take actions that could materially and adversely harm our business, including a possible significant reduction in our research, development and administrative operations (including reduction of our employee base), the surrender of our rights to some technologies or product opportunities, delay of our clinical trials or regulatory and

reimbursement efforts, or curtailment or cessation of operations. Depending on the type and the terms of any financing we pursue, stockholders' rights and the value of their investment in our common stock could be reduced. A financing could involve one or more types of securities including common stock, **preferred stock,** convertible debt or warrants to acquire common stock. These securities could be issued at or below the then prevailing market price for our common stock **or with terms or conditions that provide new investors with rights that are superior to those held by our existing stockholders or that have a negative impact on the value of securities held by our existing stockholders. For example, the terms of our recent offerings resulted in substantial dilution to our existing stockholders and significant protections to new investors that are not available to stockholders who invested prior to the offerings** . In addition, if we issue secured debt securities, the holders of the debt would have a claim to our assets that would be prior to the rights of stockholders until the debt is paid. Interest on these debt securities would increase costs and negatively impact operating results. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be negatively impacted. ~~On August 2, 2022, we entered into a purchase agreement (the " 2022 Purchase Agreement ") and registration rights agreement pursuant to which Lincoln Park Capital Fund (" Lincoln Park") committed to purchase up to $ 50. 0 million shares of our common stock. Under the terms and subject to the conditions of the 2022 Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $ 50. 0 million shares of our common stock, provided that we cannot sell more than 57. 5 million shares pursuant to the 2022 Purchase Agreement. Sales of common stock by us are subject to certain limitations, and can occur from time to time, at our sole discretion, over the 36- month period commencing on August 17, 2022, subject to the satisfaction of certain conditions. As consideration for Lincoln Park' s irrevocable commitment to purchase shares of our common stock upon the terms of and subject to satisfaction of the conditions set forth in the Purchase Agreement, we paid $ 0. 1 million in cash as an Initial Commitment Fee and issued 492, 698 Commitment Shares to Lincoln Park in consideration for its commitment to purchase shares of our common stock at our direction under the Purchase Agreement. On August 17, 2022, a registration statement (the" First Registration Statement") was declared effective covering the resale of up to 9, 500, 000 shares of our common stock comprised of (i) the 492, 698 Commitment Shares, and (ii) up to 9, 007, 302 shares that we reserved for issuance and sale to Lincoln Park under the Purchase Agreement.~~ We ~~cannot sell more shares under the 2022 Purchase Agreement without registering additional shares. We sold approximately 527, 166 shares under the First Registration Statement. On August 18, 2023, a second registration statement (the " Second Registration Statement ") was declared effective covering the resale of up to an additional 1, 500, 000 shares of our common stock that we reserved for issuance and sale to Lincoln Park under the 2022 Purchase Agreement from time to time. We sold 150, 000 shares under the Second Registration Statement. We cannot sell more shares pursuant to the 2022 Purchase Agreement than are registered under the Second Registration Statement without registering additional shares. Even with the arrangements described above, we~~ will need to complete additional financing transactions in order to continue operations. These arrangements may also not be sufficient in the near- term. Given, among other things, the current status of the capital markets ~~and ,~~ our recent stock price performance and **the terms of our recent capital** ~~financing~~ **financings** ~~strategies we may pursue may not be sufficient to fund our operations in the near term~~ , there can be no assurances that we will be able to secure additional financing, or if available, that it will be sufficient to meet our needs or be on favorable terms. Additionally, our cost of capital will depend upon numerous factors including, but not limited to, the strength of the financial markets, global market conditions, including inflationary pressures, interest rate fluctuations, our recovery and financial performance, the recovery and performance of our industry in general and the size, scope and timing of our financial needs. If we are unable to access current financings or secure future financings, including for any of the foregoing reasons, it will have a negative impact on our cash flows and our ability to meet our financial obligations. Failure to raise capital as and when needed, on favorable terms or at all, would have a significant negative impact on our financial condition and our ability to develop our product candidates.

Borrowings under ~~The volatility in the global capital markets may negatively impact~~ our ~~ability to obtain additional debt financings~~ **line of credit have the effect of limiting our use of cash and marketable securities. We have** ~~and~~ **an** ~~modify our~~ existing ~~debt~~ **margin loan** ~~facilities~~ **facility** ~~and may increase the risk of non- compliance with covenants~~ under **a line of credit** ~~our existing loan agreement. Under the Loan and Security Agreement, dated May 29, 2015~~ (the " **Pershing Credit Facility** ~~Loan and Security Agreement~~ ") ~~, as amended,~~ with **Pershing** ~~Oxford Finance,~~ LLC (" ~~Oxford~~ **Pershing** "), ~~Oxford made a term loan~~ **an affiliate of The Bank of New York Mellon Corporation. The available credit line limit under this facility fluctuates based on our request for extensions from time** to **time, subject to the value of the collateralized marketable securities we hold with Pershing, provided that the amount available to draw under the facility cannot exceed 91. 5 % of the value of the collateralized marketable securities deposited with Pershing. Depending on the value of the marketable securities we hold with Pershing, Pershing may require** us **from time- to- time to deposit additional funds or marketable securities** in **order to restore the level of collateral to** an ~~aggregate principal~~ **acceptable level, and the** ~~amount~~ **amounts borrowed under** ~~of $ 17. 7 million (~~ the **facility are due on demand** ~~" Term Loan ") subject to the terms and conditions set forth therein~~ . **Volatility in** ~~As of December 31, 2023,~~ the ~~outstanding principal balance of~~ **global markets could cause** the ~~Term Loan was $ 0. 8 million~~ **interest rate to fluctuate from time to time increasing our costs, or could cause Pershing to terminate our ability to borrow funds** . In addition, **borrowings** ~~we are obligated to pay a final payment fee of $ 3. 2 million at the earlier of the maturity date, acceleration, or payment of the Term Loan. The Term Loan accrues interest at a floating rate equal to the three- month LIBOR rate (with a floor of 1. 00 %) plus 7. 95 % per annum. Beginning November 1, 2021, we began to make payments of principal and accrued interest in equal monthly installments as required, to amortize the Term Loan through June 1, 2024. As security for our obligations~~ under the **Pershing Credit Facility** ~~Loan and Security Agreement, we granted a security interest in substantially all of our existing and after- acquired assets, excluding our intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement. If we are unable to discharge these obligations, Oxford could foreclose on these assets, which would, at a minimum,~~ have **the** ~~a severe material adverse~~ effect ~~on~~ **of limiting** our

~~ability to operate our business. Our indebtedness to Oxford could adversely affect our operations and liquidity, by, among other things: • causing us to~~ use ~~a larger portion~~ of ~~our~~ cash ~~flow to fund interest and principal payments, reducing the availability of cash to fund working capital and capital expenditures and other business activities; • making it more difficult for us to take advantage of significant business opportunities, such as acquisition opportunities, and to react to changes in market or industry conditions; and • limiting our ability to borrow additional monies in the future to fund working capital and capital expenditures and for other general corporate purposes. The Loan and Security Agreement, as amended, includes certain reporting and other covenants, that, among other things, restrict our ability to (i) dispose of assets, (ii) change the business we conduct, (iii) make acquisitions, (iv) engage in mergers or consolidations, (v) incur additional indebtedness, (vi) create liens on assets, (vii) maintain any collateral account, (viii) pay dividends, (ix) make investments, loans or advances, (x) engage in certain transactions with affiliates, and (xi) prepay certain other indebtedness or amend other financing arrangements. If we fail to comply with any of these covenants or restrictions, such failure may result in an~~ **and marketable securities** ~~event of default, which if not cured or waived, could result in Oxford causing the outstanding loan amount to become immediately due and payable. If the maturity of our indebtedness is accelerated, we may not have, or be able to timely procure, sufficient cash resources to satisfy our debt obligations, and such acceleration would adversely affect our business and financial condition. The global markets have experienced significant volatility and a continued downturn may affect our business, liquidity position, and financial results. This in turn may negatively impact our ability to remain in compliance with the financial and operating covenants under the Loan and Security Agreement and may restrict our ability to obtain covenant waivers, restructure or amend the terms of our existing debt, or obtain additional debt financing. If the maturity of our indebtedness is accelerated or if we are unable to amend the terms or obtain any necessary waivers under our debt facilities or obtain additional debt or other financing, it would materially and adversely affect our liquidity position and ability to fund our operations. This in turn would materially harm our business and financial conditions~~ . We maintain our cash at financial institutions, often in balances that exceed federally insured limits. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. The majority of our cash is held in accounts at U. S. banking institutions that we believe are of high quality. Cash held in depository accounts may exceed the $ 250, 000 Federal Deposit Insurance Corporation (" FDIC ") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. By way of example, the FDIC took control of Silicon Valley Bank (" SVB ") on March 10, 2023. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although depositors at SVB received access to their funds, uncertainty and liquidity concerns in the broader financial services industry remain. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. The U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments. However, widespread demands for customer withdrawals or other needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all. Additionally, in the future, our access to our cash in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. Any material loss that we may experience in the future could have a material adverse effect on our financial condition and could materially impact our ability to pay our operational expenses or make other payments. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. We do not expect to make profits in the near future. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an " ownership change " (generally defined as a greater than 50 % change, by value, in its equity ownership over a three year period), the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change taxable income and taxes may be limited. We have undergone " ownership changes " as a result of shifts in stock ownership in the past, which significantly limited our ability to use net operating loss carryforwards and other pre- change tax attributes. Any additional ownership change within the definition of Section 382 would further limit our ability to use net operating loss carryforwards and other tax attributes. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years. Risks Related to Our Business and Industry If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the rules and regulations of Nasdaq. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in ~~our~~ **each** Form 10- K ~~and Form 10- Q~~ , as required by Section 404 of the Sarbanes- Oxley Act. During the quarter ended June 30, 2023, we recognized immaterial grant revenue related to reimbursable development costs incurred in the fourth quarter of 2022 and the first quarter of 2023 that were eligible for revenue recognition in those respective prior periods. These costs were eligible for reimbursement under our CPRIT Grant, but were not correctly recognized in prior period grant revenue due to management' s view that insufficient progress had been made in the ReSPECT- LM clinical trial, despite no performance specific milestones in the grant outside of a reasonableness test for reimbursement of expenses. Management has concluded that the correction to grant revenue in the prior periods did not cause a material misstatement of our financial statements. We did not have adequate controls to apply appropriate accounting principles to significant and unusual grant revenue transactions. Specifically, controls over identification

of significant and / or unusual transactions requiring technical analysis were not operating effectively. Management evaluated the impact of this deficiency on our disclosure controls and procedures and concluded that the control deficiency represents a material weakness. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company' s annual or interim financial statements will not be prevented or detected on a timely basis. **In** ~~While we have taken remediation measures, these~~ -- **the** ~~review processes~~ **first quarter of fiscal year 2024, the Company completed the testing of the design and operating effectiveness of the controls over application of appropriate accounting principles to significant and unusual grant revenue transaction. Management has determined that the controls** are **adequately designed** ~~too new to be fully tested~~ and ~~therefore we cannot assure investors~~ **are operating effectively, and concluded** that ~~these measures will significantly improve or remediate~~ the material weakness ~~described above~~ **identified in the Quarterly Report on Form 10- Q for the quarter ended June 30, 2023 had been remediated** . We may in the future discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Furthermore, if our remediation of the material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock. Our future success is in large part dependent upon our ability to successfully develop our nanomedicine platform and commercialize **REYOBIQ ™** ~~rhenium (186Re) obisbemeda~~ and 188RNL- BAM and any failure to do so could significantly harm our business and prospects. Our ability to successfully develop and commercialize **REYOBIQ ™** ~~rhenium (186Re) obisbemeda~~ and 188RNL- BAM is subject to a number of risks, including the following: • we do not have substantive drug development, manufacturing, and commercialization experience, and thus we may be required to hire and rely on significant numbers of scientific, quality, regulatory and other technical personnel with the experience and expertise necessary to develop, manufacture, and commercialize our nanomedicine product candidates. We may be unable to identify, hire and retain personnel with the requisite experience to conduct the operations necessary to obtain regulatory approval and commercialize our RNL product candidates, in which case our business would be materially harmed; • we intend to find a commercialization partner to share or assume responsibility for marketing, sales, and distribution activities and related costs and expenses for our RNL product candidates. There can be no assurance that we would obtain sufficient capital to fund the development, manufacturing, and commercialization of our nanomedicine program ourselves, or if we do obtain such capital, that our development, manufacturing, and commercialization efforts would be successful; and • to the extent that we incur unanticipated expenses in our business, are unable to timely obtain sufficient additional capital on terms acceptable to us (or at all) to fund this business, our ability to develop our RNL product candidates could be materially and adversely impacted **. 188RNL- BAM will be regulated as a medical device, which may result in additional regulatory and other risks. 188RNL- BAM was developed and tested preclinically as a drug product. The FDA has informed us that 188RNL- BAM will, moving forward, be regulated instead as a medical device. In the United States, before we can market a new medical device, we must first receive either clearance under Section 510 (k) of the FDCA or premarket approval (" PMA "), from the FDA, unless an exemption applies. In the process of obtaining either premarket clearance or approval, following these routes respectively, the FDA must determine that a proposed device is either substantially equivalent to a legally marketed predicate device with similar intended uses and the same technological characteristics or technological characteristics that do not raise different questions of safety or effectiveness, or that it is safe and effective for its intended use, based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life sustaining, life supporting or implantable devices. Modifications to products that are approved through a PMA generally require FDA approval of the modifications through a PMA supplemental application. Both the PMA approval and the 510 (k) clearance process can be expensive, lengthy and uncertain. The process of obtaining a PMA is particularly costly and uncertain and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical studies. Despite the time, effort and cost, a medical device may not be approved by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business. Furthermore, even if we are granted regulatory approvals, they may include significant limitations on the approved and labeled indications for use for the device, which may limit the market for the device. In addition, comparable foreign regulatory authorities to the FDA have approval policies and regulations related to the safety and performance requirements that apply to 188RNL- BAM, either as medical devices or as drugs, depending on each jurisdiction' s regulatory requirements. Accordingly, to the extent that we intend to sell medical devices or drugs in Member States of the EU or other foreign jurisdictions, the regulatory approval pathway for our product candidates, including 188RNL- BAM, may be uncertain, complex, expensive and lengthy, and approval may not be obtained. Failure to successfully develop or supply the 188RNL- BAM medical device component, delays in or failure of the studies conducted by us, our collaborators, or third- party providers, or failure of our management, our collaborators, or third- party providers to obtain or maintain regulatory clearance or approval of**

188RNL- BAM as a medical device or drug, as applicable in each jurisdiction, could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in 188RNL- BAM reaching the market. Further, failure to successfully develop or supply the device, or to gain or maintain its approval, could adversely affect our operations. We recently acquired the CNSideTM Portfolio, and we may not be successful in our efforts to develop, fully utilize and monetize it. In April 2024, we completed the acquisition of substantially all of the right, title and interest in the CNSideTM Platform, including the CNSideTM Test, which is designed to detect, quantify, and monitor tumor status in LM. We are currently evaluating and developing our business plan for developing the CNSideTM Portfolio alongside our lead radio therapeutic candidate, REYOBIQ ™, and seeking partnering and financing opportunities for CNSideTM. We are planning for the CNSideTM Test to be re- introduced to the U. S. market starting in the second quarter of 2025. However, there can be no assurances that we will be able to develop the technology to allow for commercial applications, or successfully utilize and fully integrate the CNSideTM Portfolio into our operations. We may not generate revenues from or realize the anticipated benefits of the CNSideTM Platform within our expected timeline or at all. Contingent on our launch are a number of steps related to certifications, state licensures, payor coverages and reimbursement codes are completed. In addition, the FDA historically exercised enforcement discretion with respect to LDTs and did not require these tests to be cleared or approved by FDA as long as they complied with CLIA standards. However, on May 6, 2024, the FDA issued a final rule in which it announced it was phasing out its general enforcement discretion approach so that LDTs manufactured by a laboratory will generally fall under the same enforcement approach as other medical devices. According to the final rule this phase out will take place over a period of several years. As a result, CNSide Diagnostics may also be required to comply with these FDA regulations if FDA implements and enforces the final LDT rule, including, among other things, registration and listing, quality system regulations, and premarket authorization. Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA, and may disqualify or delay a company from launching an LDT product, or prevent a company with an LDT on the marketing from continuing to sell their test . If we are unable to successfully partner with other companies to commercialize our product candidates, our business could materially suffer. A key part of our business strategy is to leverage strategic partnerships and collaborations to commercialize our product candidates. We do not have the financial, human or other resources necessary to develop, commercialize, launch or sell our therapeutic offerings in all of the geographies that we are targeting, and thus it is important that we identify and partner with third parties who possess the necessary resources to bring our product candidates to market. We expect that any such partners will provide regulatory and reimbursement / pricing expertise, sales and marketing resources, and other expertise and resources vital to the success of our product offerings in their territories. We further expect, but cannot guarantee, that any such partnering arrangements will include upfront cash payments to us in return for the rights to develop, manufacture, and / or sell our product candidates in specified territories, as well as downstream revenue in the form of milestone payments and royalties. If we are unable to successfully partner with other companies to commercialize our product candidates, our business could materially suffer. Our success depends in substantial part on our ability to obtain regulatory approvals for our RNL product candidates. However, we cannot be certain that we will receive regulatory approval for these product candidates or our other product candidates. We have a limited number of product candidates in development, and our business depends substantially on their successful development and commercialization. Our product candidates will require development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from sales of our product candidates. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, whose regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries (including centralized marketing authorization from ~~EMA~~ **the European Commission**), and we may never receive such regulatory approvals. Obtaining regulatory approval for a product candidate is a lengthy, expensive and uncertain process, and may not be obtained. Any failure to obtain regulatory approval of any of our product candidates would limit our ability to generate future revenue (and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue), would potentially harm the development prospects of our product candidates and would have a material and adverse impact on our business. Even if we successfully obtain regulatory approvals to market our product candidates, our revenue will be dependent, in part, on our ability to commercialize such products as well as the size of the markets in the territories for which we gain regulatory approval. If the markets for our product candidates are not as significant as we estimate, our business and prospects will be harmed. If a product candidate is not approved in a timely fashion on commercially viable terms, or if development of any product candidate is terminated due to difficulties or delays encountered in the regulatory approval process, it could have a material adverse effect on our business, and we may become more dependent on the development of other proprietary products and / or our ability to successfully acquire other products and technologies. There can be no assurance that any product candidate will receive regulatory approval in a timely manner, or at all. If we or any party to a key collaboration, licensing, development, acquisition or similar arrangement fail to perform material obligations, or commit a breach, under such arrangement, or any arrangement is terminated for any reason, there could be an adverse effect on our business. We are currently party to certain licensing, collaboration and acquisition agreements under which we may make or receive future payments in the form of milestone payments, maintenance fees, royalties and / or minimum product purchases. Our collaborators may not devote the attention and resources to such efforts to be successful. The termination of a key collaboration agreement by one of our collaborators could materially impact our ability to enter into additional collaboration agreements with new collaborators on favorable terms. On March 29, 2020, we entered into an exclusive license agreement with NanoTx for the global rights to develop and

commercialize NanoTx' s glioblastoma treatment, **REYOBIQ ™** ~~rhenium (186Re) obisbemeda~~. Under the license agreement with NanoTx, we are required to use commercial reasonable efforts to develop the **REYOBIQ ™** ~~rhenium (186Re) obisbemeda~~ product candidate acquired under the license agreement. Further, we are subject to future milestone, earn- out and other payments to NanoTx all of which are tied to our commercialization and sale activities for product candidates. If we are unsuccessful in our efforts to develop these assets, or if NanoTx and we were to enter into a dispute over the terms of our agreement, then our business could be seriously harmed. On December 31, 2021, we entered into an exclusive license agreement with **UTHSCSA** ~~UT Health Science Center at San Antonio~~ for the global rights to develop and commercialize Rhenium- 188 NanoLiposome biodegradable alginate microspheres (188RNL- BAM). Under the license agreement with ~~UTHSA~~ **UTHSCSA**, we are required to use commercial reasonable efforts to develop the 188RNL- BAM product candidate acquired under the license agreement. Further, we are subject to future milestone, earn- out and other payments to ~~UTHSA~~ **UTHSCSA** all of which are tied to our commercialization and sale activities for product candidates. If we are unsuccessful in our efforts to develop these assets, or if ~~UTHSA~~ **UTHSCSA** and we were to enter into a dispute over the terms of our agreement, then our business could be seriously harmed. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties, we could lose license rights that are important to our business. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • our right to sublicense patents and other intellectual property rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • whether and the extent to which inventors are able to contest the assignment of their rights to our licensors. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and commercialize the affected product candidates. In addition, if disputes arise as to ownership of licensed intellectual property, our ability to pursue or enforce the licensed patent rights may be jeopardized. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. Our current business strategy is high- risk and may not be successful. Our current business strategy is to aggressively develop our nanomedicine platforms **and CNSide ™ Platform**, while simultaneously controlling expenses, which is a high- risk strategy for a number of reasons including the following: • we do not have prior experience with obtaining regulatory, reimbursement, or other approvals for product candidates such as **REYOBIQ ™** ~~rhenium (186Re) obisbemeda~~ and 188RNL- BAM **or the CNSide ™ Test**; • our nanomedicine product candidates, if commercialized, will compete against established competitive drugs that are marketed and sold by large companies with significant human, technical and financial resources; • we are not experienced in acquiring and integrating new assets; • there is an intense and rapidly evolving competitive landscape for our nanomedicine product candidates, including chemotherapies, targeted therapies and immuno- oncology therapies, and as such key assumptions regarding market entry, pricing, and revenue / unit share may not be realized; • our product candidates **and clinical laboratory tests** may never become commercially viable; and • we may not be able to prevent other companies from depriving us of market share and profit margins by selling products based on our intellectual property and developments. Reliance on government funding for our programs may impose requirements that limit our ability to take certain actions, and subject it to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations. A significant portion of our funding will come from grants received from CPRIT. The CPRIT Grant includes 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 potentially require repayment of all or a portion of the grant award proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters that include any potential relocation outside of the State of Texas. After the CPRIT Grant ends, we are not permitted to retain any unused grant award proceeds without CPRIT' s approval, but our obligation to pay CPRIT sales- based royalty, if and when commercialization is achieved, and other obligations, including our obligation to repay the disbursed grant proceeds under certain circumstances, to maintain certain records and documentation, to notify CPRIT of certain unexpected adverse events and our obligation to use reasonable efforts to ensure that any new or expanded preclinical testing, clinical trials, commercialization or manufacturing related to any aspect to our CPRIT project take place in Texas, survive the termination of the agreement. Our award from CPRIT requires us to pay CPRIT a portion of our revenues from sales of certain products by us, or received from our licensees or sublicensees, at tiered percentages of revenue in the low- to mid- single digits until the aggregate amount of such payments equals 400 % of the grant award proceeds, and thereafter at a rate of 0. 5 % for as long as we maintain government exclusivity, subject to our right, under certain circumstances, to make a one- time payment in a specified amount to CPRIT to terminate such payment obligations. In addition, the grant contract also contains a provision that provides for repayment to CPRIT of some amount not to exceed the full amount of the grant proceeds under certain specified circumstances involving relocation of our principal place of business outside Texas. The CPRIT Grant requires us, as a Texas- based company, to meet certain criteria, including among other things, that we maintain our headquarters in Texas and use certain vendors, consultants and employees that are located in Texas. 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, and potentially full repayment of the CPRIT Grant. **The DoD Award is dependent on continued U. S. government funding and government appropriations, which may not be forthcoming on a timely basis or at all. The DoD Award, which entitles us to receive a $ 3. 0 million fund for research and development purposes**

over a three- year period, and any future U. S. federal government grants we may receive, are dependent on government funding, which is generally subject to Congressional appropriations or continued government operations. Such grants are dependent upon sufficient funding for, and timely payment by, the entities providing any such grants. If the granting governmental agency does not receive sufficient appropriations for any reason, including due to a government shutdown or changes in the prevailing policies and budgetary priorities of the incumbent administration, it may terminate our grant (in whole or in part) or reduce the scope of our grant, or delay or reduce payment to us. Any inability to award us any part of the DoD Award, any delay in payment, or the termination of the DoD Award, in whole or in part, due to a lapse in funding or otherwise, could adversely affect our business, financial condition or results of operations, or cash flows. The nature and timing of any related developments remain uncertain. If our competitors market or develop products that are marketed more effectively, approved more quickly than our product candidates, or demonstrated to be safer or more effective than our product candidates, our commercial opportunities could be reduced or eliminated. The life science industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products or product candidates, including small and large, domestic and multinational, medical device, biotechnology and pharmaceutical companies, academic institutions, government agencies, and private and public research institutions. Competitors may have greater experience in developing drugs **and clinical laboratory tests** , conducting clinical trials, obtaining regulatory clearances or approvals, manufacturing and commercialization. It is possible that competitors may obtain patent protection, approval, or clearance from the FDA or achieve commercialization earlier than we can, any of which could have a substantial negative effect on our business. Many of our potential competitors have substantially greater: • capital resources; • research and development resources and experience, including personnel and experience; • product development, clinical trial and regulatory resources and experience; • sales and marketing resources and experience; • manufacturing and distribution resources and experience; • name, brand and product recognition; and • resources, experience and expertise in prosecution and enforcement of intellectual property rights. We expect ~~that~~ **the** product candidates in our pipeline, if approved, to compete on the basis of, among other things, product efficacy and safety, time to market, price, coverage, and reimbursement by third- party payers, extent of adverse side effects, and convenience of treatment procedures. One or more of our competitors may develop other products that compete with ours, obtain necessary approvals for such products from the FDA, ~~EMA~~ **the European Commission** , Ministry of Health, Labour and Welfare or other agencies, if required, more rapidly than we do or develop alternative products or therapies that are safer, more effective and / or more cost effective than any products developed by us. The competition that we encounter with respect to any of our product candidates that receive the requisite regulatory approval and classification and are marketed may have an effect on our product prices, market share, and results of operations. We may not be able to differentiate any products that we are able to market from those of our competitors, successfully develop or introduce new products that are less costly or offer better results than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors. As a result of these factors, our competitors may obtain regulatory approval of their products more quickly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop products that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted, or less costly than ours and may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that compete with any of our product candidates that are approved, our business, results of operations, financial condition, and prospects may be materially adversely affected. Product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Clinical testing of our product candidates is a long, expensive and uncertain process, and the failure or delay of a clinical trial can occur at any stage. Many factors, currently known and unknown, can adversely affect clinical trials and the ability to evaluate a product candidate' s efficacy. During the course of treatment, patients can die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. Even if initial results of preclinical and nonclinical studies or clinical trial results are promising, we may obtain different results in subsequent trials or studies that fail to show the desired levels of safety and efficacy, or we may not obtain applicable regulatory approval for a variety of other reasons. Further, with respect to the conduct and results of clinical trials generally, in the United States, Europe, Japan, and other jurisdictions, the conduct and results of clinical trials can be delayed, limited, suspended, or otherwise adversely affected for many reasons, including, among others: • delay or failure in reaching agreement with the FDA or other regulatory authorities outside of the United States on acceptable clinical trial design, or in obtaining authorization to commence a trial; • delay or failure in reaching agreement on acceptable terms with prospective clinical research organizations (" ~~CRO~~ **CROs** "), and clinical trial sites; • delay or failure in obtaining approval of an IRB or ethics committees before a clinical trial can be initiated at a prospective trial site; • 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; • clinical results may not meet prescribed endpoints for the studies, produce negative or inconclusive results, or otherwise not provide sufficient data to support the efficacy of our product candidates; • clinical and nonclinical test results may reveal side effects, adverse events or unexpected safety issues associated with the use of our product candidates; • emerging of dosing issues; • lack of adequate funding to continue the clinical trials, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies, and increased expenses associated with the services of our ~~contract research organization (" CROs ")~~ and other third parties; • inability to design appropriate clinical trial protocols; • slower than expected rates of subject recruitment and enrollment rates in clinical trials; • clinical sites or investigators may deviate from trial protocol or fail to conduct the trial in accordance with applicable regulatory requirements, or drop out of a trial; • regulatory review may not find a

product safe or effective enough to merit either continued testing or final approval; • regulatory authorities may require that we change our studies or conduct additional studies which may significantly delay or make continued pursuit of approval commercially unattractive; • a regulatory agency may reject our trial data or disagree with our interpretations of either clinical trial data or applicable regulations; • the cost of clinical trials required for product approval may be greater than what we originally anticipate, and we may decide to not pursue regulatory approval for such a product; • changes in the standard of care of the indication being studied; • a regulatory agency may identify problems or other deficiencies in our existing manufacturing processes or facilities or the existing processes or facilities of our collaborators, our contract manufacturers, or our raw material suppliers; • a regulatory agency may change its formal or informal approval requirements and policies, act contrary to previous guidance, adopt new regulations, or raise new issues or concerns late in the approval process; and • a regulatory agency may ~~ask us to~~ put a clinical study on hold pending additional safety data (and there can be no assurance that we will be able to satisfy the regulator agencies' requests in a timely manner, which can lead to significant uncertainty in the completion of a clinical study). We also face clinical trial- related risks with regard to our reliance on other third parties in the performance of many of the clinical trial functions, including CROs that help execute our clinical trials, the hospitals and clinics at which our trials are conducted, the clinical investigators at the trial sites, and other third- party service providers. Failure of any third- party service provider to adhere to applicable trial protocols, laws and regulations in the conduct of one of our clinical trials could adversely affect the conduct and results of such trial (including possible data integrity issues), which could seriously harm our business. 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. If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed or inhibited. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations, cash flows and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. **The development of our product candidates also may be delayed by other events beyond our control. For example, actions to limit federal agency budgets or personnel, may result in reductions to the FDA' s budget, employees, and operations, as well as changes to FDA regulatory programs, all of which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates, undergo regulatory inspections or obtain regulatory approval for our product candidates.** Pre- clinical studies and preliminary and interim data from clinical trials of our product candidates are not necessarily predictive of the results or success of ongoing or future clinical trials of our product candidates. Pre- clinical studies and any positive preliminary and interim data from our clinical trials of our product candidates may not necessarily be predictive of the results of ongoing or later clinical trials. A number of companies in the pharmaceutical and biotechnology industries, including us and many other companies with greater resources and experience than ~~we~~ **us** , have suffered significant setbacks in clinical trials, even after seeing promising results in prior pre- clinical studies and clinical trials **. Preclinical studies and Phase 1 clinical trials are primarily designed and operate to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules** . Even if we are able to complete our planned clinical trials of our product candidates according to our current development timeline, initial positive results from pre- clinical studies and **early** clinical trials of our product candidates may not be replicated in subsequent clinical trials. The design of our later stage clinical trials could differ in significant ways (e. g., inclusion and exclusion criteria, endpoints, statistical analysis plan) from our earlier stage clinical trials, which could cause the outcomes of the later stage trials to differ from those of our earlier stage clinical trials. If we fail to produce positive results in our planned clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, could be materially adversely affected. If we fail to produce positive results in our planned clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for such product candidates, and, correspondingly, our business and financial prospects, could be materially adversely affected. Because we have limited resources, we may decide to pursue a particular product candidate and fail to advance product candidates that later demonstrate a greater chance of clinical and commercial success. We are an early- stage company with limited resources and revenues. The product candidates we currently have under development will require significant development, pre- clinical and clinical testing and investment of significant funds before their commercialization. Because of this, we must make strategic decisions regarding resource allocations and which product candidates to pursue. There can be no assurance that we will be able to develop all potentially promising product candidates that we may identify. Based on preliminary results, we may choose to advance a particular product candidate that later fails to be successful, and simultaneously forgo or defer further investment in other product candidates that later are discovered to demonstrate greater promise in terms of clinical and commercial success. If we make resource allocation decisions that later are shown to be inaccurate, our business and prospects could be harmed. Clinical trial results may fail to support approval of our product candidates. Even if our clinical trials are successfully completed as planned, 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 / or 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. **The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post- approval, or it may object to elements of our clinical development program, requiring their alteration.** This, in turn, would significantly adversely affect our business prospects. If third parties we engage are not able to successfully perform, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates and our business could be substantially harmed. We rely on third parties in the performance of many of the clinical trial functions, including CROs, which help execute our clinical trials, the hospitals and clinics at which our trials are conducted, the clinical investigators at the trial sites, and other third- party service providers. Failure of any third- party service provider to adhere to applicable trial protocols, laws and regulations in the conduct of one of our clinical trials could adversely affect the conduct and results of such trial (including possible data integrity issues), which could seriously harm our business. As a result, results from our clinical trials may be delayed, which in turn would have a material adverse impact on our clinical trial plans and timelines and impair our ability to successfully complete clinical development, obtain regulatory approval, or commercialize our product candidates. This in turn would substantially harm our business and operations. We also rely on third- party ~~expertise to support us in this area~~ **contract manufacturing organizations (" CMOs ") for all our requirements for raw materials, drug substance, and drug product** . We have entered into contracts with third- party manufacturers to manufacture, supply, store and distribute supplies of our product candidates for our clinical trials. If any of our product candidates receives FDA approval, we expect to rely on third- party contractors to manufacture our drugs. We have no current plans to build internal manufacturing capacity for any product candidate, and we have no long- term supply arrangements **with our current CMOs** . Our reliance on third- party manufacturers exposes us to potential risks, such as the following: • we may be unable to contract with third- party manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited. Potential manufacturers of any product candidate that is approved will be subject to FDA compliance inspections and any new manufacturer would have to be qualified to produce our products; • our third- party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any; • our 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 through completion or to successfully produce, store and distribute our commercial products, if approved **; • changes to our CMOs during clinical trials or after approval may require us to conduct additional studies to demonstrate comparability between the products** ; • drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and other government agencies to ensure compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third- party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures; • if any third- party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to such improvements; and • a third- party manufacturer may gain knowledge from working with us that could be used to supply one of our competitors with a product that competes with ours. Each of these risks could delay or have other adverse impacts on our clinical trials and the approval and commercialization of our product candidates, potentially resulting in higher costs, reduced revenues or both. We may have difficulty enrolling, or fail to enroll patients, in our clinical trials, which could delay or prevent clinical trials of our drug candidates. Identifying and enrolling patients to participate in clinical trials of our product candidates is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. The eligibility criteria of our planned clinical trials may further limit the available eligible trial participants as we require that patients have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical trials. We may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical trials in a timely manner because of the perceived risks and benefits of the drug candidate under study, the availability and efficacy of competing therapies and clinical trials, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our drug candidates may be delayed. If we experience delays in the completion of, or termination of, any clinical trials of our drug candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may materially and adversely harm our business, financial condition, and prospects. If a particular product candidate causes significant adverse events, then we may be unable to receive regulatory approval or market acceptance for such product candidate. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any of our product candidates, including the occurrence of significant adverse events in clinical trials. Such significant adverse events could lead to clinical trial challenges, such as difficulties in patient recruitment, retention, and adherence, potential product liability claims, and possible trial termination by us, regulatory authorities, and / or an IRB or ethics committees. These types of clinical trial challenges could delay or prevent regulatory approval of our product candidate. Significant adverse events may also lead regulatory authorities to require additional warnings on the label for such product, require us to conduct additional costly post- marketing studies, require us to develop a ~~risk evaluation and mitigation strategy (" REMS ")~~, among other possible requirements. If the product candidate has already been approved, such approval may be withdrawn. Any delay in, denial, or withdrawal of marketing approval for one of our product candidates will adversely affect our financial position. Even if our product candidates receive marketing approval, undesirable side effects may limit the product' s commercial viability. Patients may not wish to use our product, physicians may not prescribe our product, and our reputation

may suffer. Any of these events may significantly harm our business and financial prospects. If our product candidates and technologies receive regulatory approval but do not achieve broad market acceptance, especially by physicians, the revenue that we generate will be limited. The commercial success of any of our approved products or technologies will depend upon the acceptance of these products and technologies by physicians, patients and the medical community. The degree of market acceptance of these products and technologies will depend on a number of factors, including, among others: • acceptance by physicians and patients of the product as a safe and effective treatment; • any negative publicity or political action related to our or our competitors' products or technologies; • the relative convenience and ease of administration; • the prevalence and severity of adverse side effects; • demonstration to authorities of the pharmacoeconomic benefits; • demonstration to authorities of the improvement in burden of illness; • limitations or warnings contained in a product' s approved labeling; • payers' level of restrictions and / or barriers to coverage; • the clinical indications for which a product is approved; • availability and perceived advantages of alternative treatments; • the effectiveness of our or future collaborators' sales, marketing and distribution strategies; and • pricing and cost effectiveness. We expect physicians' inertia and skepticism to also be a significant barrier as we attempt to gain market penetration with our future products. We believe we will continue to need to finance lengthy and time- consuming clinical studies to provide evidence of the medical benefit of our products and resulting therapies in order to overcome this inertia and skepticism. Overall, our efforts to educate the medical community on the benefits of any of our products or technologies for which we obtain marketing approval from the FDA or other regulatory authorities **, including foreign regulatory authorities,** and gain broad market acceptance may require significant resources and may never be successful. If our products and technologies do not achieve an adequate level of acceptance by physicians, pharmacists and patients, we may not generate sufficient revenue from these products to become or remain profitable. All potential applications of our product candidates are investigational, which subjects us to development and marketing risks. Our product candidates are at various stages of development. Successful development and market acceptance of our products is subject to developmental risks, including risk of negative clinical data from current and anticipated trials, failure of inventive imagination, ineffectiveness, lack of safety, unreliability, manufacturing hurdles, failure to receive necessary regulatory clearances or approvals, high commercial cost, preclusion or obsolescence resulting from third parties' proprietary rights or superior or equivalent products, competition from copycat products and general economic conditions affecting purchasing patterns. There can be no assurance that we or our partners will successfully develop and commercialize our product candidates, or that our competitors will not develop competing technologies that are superior or less expensive. Failure to successfully develop and market our product candidates would have a substantial negative effect on our results of operations and financial condition. If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third- party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. We and our product candidates are subject to extensive regulation, and the requirements to obtain regulatory approvals in the United States and other jurisdictions can be costly, time- consuming and unpredictable. If we or our partners are unable to obtain timely regulatory approval for our product candidates, our business may be substantially harmed. The worldwide regulatory process for our nanomedicine drug candidates can be lengthy and expensive, with no guarantee of approval. Before any new drugs may be introduced to the U. S. market, the manufacturer generally must obtain FDA approval through either an ~~abbreviated new drug application (" ~~ANDA ~~")~~ process for generic drugs off patent that allow for bioequivalence to an existing ~~reference listing drug (" ~~RLD ~~")~~ or the lengthier NDA process, which typically requires multiple successful and successive clinical trials to generate clinical data supportive of safety and efficacy along with extensive pharmacodynamic and pharmacokinetic preclinical testing to demonstrate safety. Our RNL product candidates are subject to the FDA' s 505 (b) (1) NDA process. NDA drugs can take significant time due to the preclinical and clinical trial requirements. There are numerous risks arising out of the regulation of our nanomedicine product candidates include the following: • we can provide no assurances that our current and future oncology drugs will meet all of the stringent government regulation in the United States under the **FDCA** ~~Federal Food, Drug and Cosmetic Act~~ , and / or in international markets such as ~~Europe~~ **the EU** , by the EMA under its Medicinal Products Directive; • our nanomedicine product candidates, if approved, will still be subject to post- market reporting requirements for instances where the drug may have caused or contributed to the death or serious injury, or serious adverse events; • there are no assurances that our product candidates will not have safety or effectiveness problems occurring after the drugs reach the market; • there are no assurances that regulatory authorities will not take steps to prevent or limit further marketing of the drug due to safety concerns; and • it is possible that the new legislation in our priority markets will yield additional regulatory requirements for therapeutic drugs for our nanomedicine product candidates. We will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant expense, and if we or our collaborators fail to comply with such requirements, regulatory agencies may take action against us or them, which could significantly harm our business. Approved drug products are subject to ongoing regulatory requirements and oversight, including requirements related to manufacturing, quality control, conduct of post- marketing studies, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting. Regulatory authorities subject a marketed product, its manufacturer, and the manufacturing facilities to continual review and periodic inspections. We, our collaborators, and our and their respective contractors, suppliers and vendors, will be subject to ongoing regulatory requirements, including complying with regulations and laws regarding advertising, promotion and sales of products (including applicable anti- kickback, fraud and abuse and other health care laws and regulations), required submissions of safety and other post- market information and reports, registration requirements, **cGMP** ~~Clinical Good Manufacturing Practices~~ regulations (including requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation), and the requirements regarding the distribution of samples to physicians and recordkeeping requirements. Regulatory agencies may change existing requirements or adopt new requirements or policies **that may be costly to comply with** . We, our collaborators, and our and their respective contractors, suppliers, and vendors, may be slow to adapt or

may not be able to adapt to these changes or new requirements. Failure to comply with regulatory requirements may result in any of the following: • restrictions on the marketing of our product candidates or manufacturing processes; • warning letters or untitled letters; • withdrawal of the products from the market; • voluntary or mandatory recall; • fines; • suspension or withdrawal of regulatory approvals; • suspension or termination of any of our ongoing clinical trials; • refusal to permit the import or export of our product candidates; • refusal to approve pending applications or supplements to approved applications that we submit; • product seizure; • injunctions; or • imposition of civil or criminal penalties. **The future regulatory processes that will be applicable to Laboratory Developed Tests (LDTs) are uncertain and may prevent us from obtaining required authorizations for the commercialization of our products and / or introduce additional costs associated with those products. Within the laboratory, most tests can be divided into two categories: in vitro diagnostics (IVDs) and laboratory developed tests (LDTs). IVDs are commercially manufactured assays and make up the majority of clinical laboratory tests, such as those in a comprehensive metabolic panel (CMP) and a complete blood count (CBC). LDTs, on the other hand, are developed by individual laboratories and overseen by highly trained and qualified laboratory directors. We plan to offer an LDT in the U. S. beginning in 2025. In 1976, Congress passed the Medical Device Amendments to the FDCA. These amendments gave the FDA explicit authority to regulate medical devices. These included tests developed by manufacturers sold for commercial purposes to laboratories around the country. However, the amendments did not specifically include tests developed by laboratories for their own use. Then, in 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA). These gave clinical laboratories the ability to develop and perform their own tests to fill gaps in available testing and provided the framework for LDT regulation. Today, all laboratories must have appropriate CLIA accreditation, overseen by the Centers for Medicare and Medicaid Services (CMS), to perform LDTs. Historically, the FDA has exercised enforcement discretion for LDTs, allowing labs to offer tests with little input from the agency. However, on May 6, 2024, the FDA issued a final rule in which it announced it was phasing out its general enforcement discretion approach so that LDTs manufactured by a laboratory will generally fall under the same enforcement approach as medical devices. If implemented, this phase out of enforcement discretion will take place over several years. Congress is also working on legislative language that would clarify the FDA' s authority with respect to LDTs – and if enacted, would potentially supersede the final rule. In this regard, the " Verifying Accurate Leading- edge IVCT Development Act, " or VALID Act, was most recently introduced in March 2023. The bill proposes a risk- based approach that would subject many LDTs to FDA regulation by creating a new in vitro clinical test, or IVCT, category of regulated products. As proposed, the bill would grandfather many existing LDTs from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (e. g., registration / listing, adverse event reporting). To market a high- risk IVCT, reasonable assurance of analytical and clinical validity for the intended use would be needed to be established. Under VALID, a precertification process would be established that would allow a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs meet quality system requirements. If pre- certified, low- risk IVCTs developed by the laboratory and falling within the scope of the FDA' s precertification order would not be subject to test- specific pre- market review. The new regulatory framework would include quality control and post- market reporting requirements. The FDA would have the authority to withdraw approvals for IVCTs for various reasons, including (for example) if there were a reasonable likelihood that the test would cause death or serious adverse health consequences. However, we cannot predict if this (or any other bill) will be enacted in its current (or any other) form and cannot quantify the effect of such proposals on our business. To the extent that the FDA ultimately regulates certain LDTs, whether via final rule, final guidance, or as instructed by Congress, our LDTs may be subject to certain additional regulatory requirements. Complying with the FDA' s requirements may be expensive, time- consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA' s requirements to our tests could materially and adversely affect our business, financial condition, and results of operations. Compliance with the FDCA for a medical device includes, among other things, registration and listing, quality system regulations, and premarket authorization. Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA, including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity. Risks associated with the new landscape of LDTs include but are not limited to: • Our inability to implement quality standards included in the new guidelines • Our inability to implement all FDA requirements for medical device LDTs • Backlog at the FDA for review of submission • Additional regulations being adopted by the FDA • Increased timeline to product launch, delaying revenue for the company • Increased regulatory oversight resulting in delays for product launch • Increased costs of product development and regulatory compliance, including: oMore expansive validation study design oHiring additional regulatory compliance talent oHiring additional statistical experts oOther unanticipated costs** Changing, new and / or emerging government regulations, including healthcare legislative reform measures, may adversely affect us. Our nanoparticle and microparticle technologies and pipeline oncology products **and laboratory test** are being developed under existing government criteria, which are subject to change in the future. Clinical and / or pre- clinical criteria and cGMP manufacturing requirements may change and additional regulatory burdens may be imposed. Any regulatory review committees and advisory groups and any contemplated new guidelines may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions

and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we may be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient revenue to maintain our business. Divergence in regulatory criteria for different regulatory agencies in international jurisdictions could result in the repeat of clinical studies and / or preclinical studies to satisfy local territory requirements, resulting in the repeating of studies and / or delays in the regulatory process. Some territories may require clinical data in their indigenous population, resulting in the repeat of clinical studies in whole or in part. Some territories may object to the formulation ingredients in the final finished product and may require reformulation to modify or remove objectionable components; resulting in delays in regulatory approvals. Such objectionable reformulations include, but are not limited to, human or animal components, Bovine Spongiform Encephalopathy and / or Transmissible Spongiform Encephalopathy risks, banned packaging components, prohibited chemicals, and banned substances. There can be no assurances that the FDA or foreign regulatory authorities will accept our pre- clinical and / or clinical data. Anticipated or unanticipated changes in the way or manner in which the FDA or other regulators regulate products or classes and groups of products **, including LDTs,** can delay, further burden, or alleviate regulatory pathways that were once available to other products. There are no guarantees that such changes in the FDA' s or other regulators' approach to the regulatory process will not deleteriously affect some or all of our product candidates or product applications. In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities, or affect our ability to profitably sell any drug candidates for which we obtain marketing approval, if any. Further, any increased scrutiny of the FDA' s approval process for drugs and biological products may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. There also are a number of state and local legislative and regulatory efforts related to drug pricing, including drug price transparency laws that apply to pharmaceutical manufacturers, which may have an impact on our business **. On May 6, 2024, the FDA issued a final rule in which it announced it was phasing out its general enforcement discretion approach so that LDTs manufactured by a laboratory will generally fall under the same enforcement approach as medical devices. At this time it is unclear whether the current Administration will rescind, revise, or continue with this regulatory scheme or if it will be superseded by Congressional action. Complying with these FDA requirements, or adapting to revised requirements applicable to LDTs, may be costly and may cause delays in our plans to commercialize the CNSideTM Test** . In addition, the Drug Supply Chain Security Act enacted in 2013 imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing. In December 2019, the Further Consolidated Appropriations Act for 2020 was signed into law (P. L. 116- 94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the " CREATES Act "). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. The CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on " commercially reasonable, market-based terms. " Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. Other legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our drug candidates, may be or whether such changes will have any other impacts on our business. In addition, increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing conditions and other requirements. In the **EU** ~~European Union~~ , similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates. In addition to continuing pressure on prices and cost containment measures, legislative developments at the **EU** ~~European Union~~ or **EU** ~~E. U. member~~ **Member** ~~state~~ **State** level may result in significant additional requirements or obstacles that may increase our operating costs. We expect that other legislative or healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, lower reimbursement, and additional downward pressure on the price that we will receive for any approved product. Any reduction in payments from Medicare or other government- funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates. Adequate coverage and reimbursement from third party payors may not be available for our ~~products~~ **product candidates** ~~and we may be unable to successfully contract for coverage from pharmacy benefit managers and other organizations; conversely~~ , ~~to secure coverage from these organizations, we may be required to pay rebates or other discounts or other restrictions to reimbursement, either of~~ which could diminish our sales or adversely affect our ability to sell our products profitably. In both U. S. and non- U. S. markets, our ability to successfully commercialize and achieve market acceptance of our ~~products~~ **product candidates, if approved,** depends in significant part on adequate financial coverage and reimbursement from third party payors, including governmental payors (such as the Medicare and Medicaid programs in the U. S.), managed care organizations and private health insurers. Without third party payor reimbursement, patients may not be able to obtain or afford prescribed medications. In addition, **coverage and** reimbursement guidelines and **restrictions set** ~~incentives provided to prescribing physicians~~ by third party payors may have a significant impact on the

prescribing physicians' willingness and ability to prescribe our products. The demand for, and the profitability of, our products could be materially harmed if the state Medicaid programs, Medicare program, other healthcare programs in the U. S. or elsewhere, or third party commercial payors in the U. S. or elsewhere deny reimbursement for our products, limit the indications for which our products will be reimbursed, or provide reimbursement only on unfavorable terms. As part of the overall trend toward cost containment, third party payors often require prior authorization for, and require reauthorization for continuation of, prescription products or impose step edits, which require prior use of another medication, usually a generic or preferred brand, prior to approving coverage for a new or more expensive product. Such restrictive conditions for reimbursement and an increase in reimbursement- related activities can extend the time required to fill prescriptions and may discourage patients from seeking treatment. We cannot predict actions that third party payors may take, or whether they will limit the access and level of reimbursement for our ~~products~~ **product candidates, if commercialized** or refuse to provide any approvals or coverage ~~. From time to time, third party payors have refused to provide reimbursement for our products, and others may do so in the future~~ . Third party payors increasingly examine the cost- effectiveness of pharmaceutical products, in addition to their safety and efficacy, when making coverage and reimbursement decisions. We may need to conduct expensive pharmacoeconomic and / or clinical studies in order to demonstrate the cost- effectiveness of our products. If our competitors offer their products at prices that provide purportedly lower treatment costs than our products, or otherwise suggest that their products are safer, more effective or more cost- effective than our products, this may result in a greater level of access for their products relative to our products, which would reduce our sales and harm our results of operations. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefit coverage and reimbursement and co- pay policies. Because some of our ~~products~~ **product candidates, once commercialized, may** compete in a market with both branded and generic products, obtaining and maintaining access and reimbursement coverage for our products may be more challenging than for products that are new chemical entities for which no therapeutic alternatives exist. **If our competitors offer a clinical lab test that competes with our CNSideTM Test but is viewed by clinicians or payers as being more cost effective or having greater clinical utility, we may not be able to realize the expected benefits of our test.** Some intellectual property that we have in- licensed has been discovered through government funded programs and thus may be subject to federal regulations such as ~~"~~ **“** march- in ~~"~~ **”** rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- U. S. manufacturers. Some of the intellectual property rights we have licensed are generated through the use of U. S. government funding and are therefore subject to certain federal regulations. As a result, the U. S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh- Dole Act of 1980 ~~, or~~ **(the “** Bayh- Dole Act **”)** , and implementing regulations. These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as ~~"~~ **“** march- in **”** rights ~~"~~). The U. S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation and may change in the future. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U. S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. manufacturers may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. Orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed **. In September 2020, the FDA granted both orphan drug designation and Fast Track designation to REYOBIQ ™ for the treatment of patients with GBM. In November 2021, the FDA granted Fast Track designation to REYOBIQ ™ for the treatment of patients with LM. In March 2025, the FDA granted orphan drug designation to REYOBIQ ™ for the treatment of LM in patients with lung cancer** . A product candidate that receives orphan drug designation can benefit from potential commercial benefits following approval. Under the U. S. Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, defined as affecting a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the **EU** ~~European Union~~ , the EMA' s Committee for Orphan Medicinal Products ~~,~~ grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition affecting not more than 10, 000 persons in the **EU** ~~European Union~~ . Currently, this designation ~~provides~~ **makes the product eligible for** market exclusivity in the U. S. and the **EU** ~~European Union~~ for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug ~~was specifically~~ **is indicated for, which can be narrower than the orphan drug** ~~designated~~ **designation** ~~in the approval~~ , nor

does it prevent ~~other types of drugs~~ **drug products containing a different active moiety** from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve a drug with similar chemical structure for the same ~~condition~~ **indication** if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs. In the **EU** ~~European Union~~, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is " clinically superior " to the original orphan drug. **Notwithstanding** ~~In September 2020, the FDA granted both Orphan~~ **orphan** ~~Drug~~ **drug** designation **for some of our product candidates, we may not enjoy market exclusivity in a particular market,** and ~~Fast Track~~ **if we fail to obtain or maintain orphan drug** designation **or other regulatory exclusivity** ~~to rhenium (186Re) obisbemeda~~ for **some** ~~the treatment~~ of **our product candidates** ~~patients with GBM. In November 2021~~, **our competitive position would be harmed** ~~the FDA granted Fast Track designation to rhenium (186Re) obisbemeda for the treatment of patients with LM~~. If we experience an interruption in supply from a material sole source supplier, our business may be harmed **.** We acquire some of our components and other raw materials from sole source suppliers. If there is an interruption in supply of our raw materials from a sole source supplier, for any reason, there can be no assurance that we will be able to obtain adequate quantities of the raw materials within a reasonable time or at commercially reasonable prices. Interruptions in supplies due to pricing, timing, availability, or other issues with our sole source suppliers could have a negative impact on our ability to manufacture products and product candidates, which in turn could adversely affect the development and commercialization of our nanomedicine product candidates and cause us to potentially breach our supply or other obligations under our agreements with certain other counterparties. We are dependent on sole source suppliers to manufacture the active pharmaceutical ingredients (**"** ~~"~~ API **"** ~~"~~) and certain other components of our nanomedicine product candidates. There is no assurance that these sole source suppliers will enter into supply agreements with us to provide contractual assurance to us around supply and pricing. Regardless of whether a sole source supplier enters into a written supply arrangement with us, such supplier could still delay, suspend, or terminate supply of raw materials to us for a number of reasons, including manufacturing or quality issues, payment disputes with us, bankruptcy or insolvency, or other occurrences. Manufacturing or quality assurance difficulties at our contractors and suppliers, the failure or refusal of a supplier or contract manufacturer to supply contracted quantities, or increases in demand on a supplier with constrained capacity could result in delays and disruptions in the manufacturing, distribution, and sale of our products and / or product candidates, leading to lost revenue or reduced market opportunities. Supply constraints may also lead to pauses, discontinuations, or other product availability issues in one or more markets, which could have a material adverse effect on our consolidated results of operations and cash flows. Further, cost inflation and global transportation and logistics challenges, as well as tight labor markets, have caused, and in the future may cause, delays in, and increase costs related to, distribution of our products, the construction or other acquisition of additional manufacturing capacity, procurement activity, and supplier or contract manufacturer arrangements. These disruptions and challenges could result from actual or perceived quality, oversight, or regulatory compliance problems; natural disasters (including increased instances or severity of natural disasters or other events that may be due to climate change), public health outbreaks, epidemics, or pandemics; periods of uneven economic growth or downturns; emergence or escalation of, and responses to international tension and conflicts; equipment, mechanical, data, or information technology system (" IT system ") vulnerabilities, such as system inadequacies, inadequate controls or procedures, operating failures, unauthorized access, service interruptions or failures, security breaches, malicious intrusions, theft, exfiltration, ransomware or other cyber- attacks from a variety of sources; labor shortages; challenges and complexities in manufacturing new drug modalities; contractual disputes with our suppliers and contract manufacturers; vertical integration by competitors within our supply chain; or inability to obtain single- source or other raw or intermediate materials. If a sole source supplier ceases supply of raw materials necessary, there is no guarantee that we will find an alternative supplier for the necessary raw materials on terms acceptable to us, or at all. Finding alternative suppliers if and as necessary due to geopolitical developments or otherwise may not be feasible or could take a significant amount of time and involve significant expense due to the nature of our products and product candidates. Further the qualification process for a new vendor could take months or years, and any such day in qualification could significantly harm our business. We may engage in strategic transactions that could impact our liquidity, increase our expenses, and present significant distractions to our management. From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out- licensing or in- licensing of products, product candidates or technologies. Growth of the nanomedicine business will require significant management time and attention. Further, the future growth of our business will depend in part on our ability to in- license or otherwise acquire the rights to additional product candidates or technologies. We cannot assure you that we will be able to in- license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all. Additional potential transactions that we may consider include a variety of different business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non- recurring or other charges, may increase our near and long- term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including: • exposure to unknown liabilities; • disruption of our business and diversion of our management' s time and attention in order to develop acquired products, product candidates or technologies; • incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions; • higher than expected acquisition and integration costs; • write- downs of assets or goodwill or impairment charges; • increased amortization expenses; • difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel; • impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and • inability to retain key employees of any acquired businesses. The in- licensing and acquisition of these technologies is a competitive area, and a

number of more established companies are also pursuing strategies to license or acquire product candidates or technologies that we may consider attractive. In addition, companies that perceive us to be a competitor may be unwilling to license rights to us. Furthermore, we may be unable to identify suitable product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable product candidates or technologies ~~undertake~~ or to successfully complete any additional transactions of the nature described above, our business, financial condition and prospects could suffer. In addition, even if we are able to successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition, and prospects. We must maintain quality controls and compliance with manufacturing standards. The manufacture of our product candidates is, and the manufacture of any future drug **, device,** and / or cell- related therapeutic products would be, subject to periodic inspection by regulatory authorities and distribution partners. The manufacture of drug and device products for human use is subject to **extensive** regulation and inspection from time to time by the FDA for compliance with the FDA' s cGMP, **the** Quality System ~~Regulations~~ **Regulation** (" ~~QSRs~~ **QSR** "), as well as equivalent requirements and inspections by state and **foreign** ~~non- U. S~~. regulatory authorities. There can be no assurance that the FDA or other authorities will not, during the course of an inspection of existing or new facilities, identify what they consider to be deficiencies in our compliance with QSRs or other requirements and request, or seek remedial action. Failure to comply with such regulations or a potential delay in attaining compliance may adversely affect our manufacturing activities and could result in, among other things, injunctions, civil penalties, FDA refusal to grant pre- market approvals or clearances of future or pending product submissions, fines, recalls **, import** or seizures of products, total or partial suspensions of production and criminal prosecution. There can be no assurance that after such occurrences that we will be able to obtain additional necessary regulatory approvals or clearances on a timely basis, if at all. Delays in receipt of or failure to receive such approvals or clearances, or the loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition. If we are unable to identify, hire and / or retain key personnel, we may not be able to sustain or grow our business. We maintain a small executive team. Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain, and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We compete for talent with numerous companies, as well as universities and non- profit research organizations. In the future, we may hire a significant number of scientists, quality and regulatory personnel, and other technical staff with the requisite expertise to support and expand our nanomedicine business. The manufacturing of our oncology drug assets is a highly complex process that requires significant experience and know- how. If we are unable to attract personnel with the necessary skills and experience to reestablish and expand our nanomedicine business, which is currently conducted out of our **Houston** ~~San Antonio~~, Texas facility, our business could suffer. Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations, and maintain a cohesive and stable environment. In particular, we are highly dependent on our executive officers, especially Marc Hedrick, M. D., our Chief Executive Officer. Given his leadership, extensive technical, scientific, and financial expertise and management and operational experience, if we were unable to retain the services of Dr. Hedrick for any reason, it would materially and adversely impact our business and operations. Further, the loss of services of Dr. Hedrick or any other executive officer could result in product development delays or the failure of our collaborations with current and future collaborators, which, in turn, may hurt our ability to develop and commercialize products and generate revenue. We do not maintain key man life insurance on the lives of any of the members of our senior management. The loss of key personnel for any reason or our inability to hire, retain, and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business. The loss of services of any of our personnel, including Dr. Hedrick, particularly for an extended period, would likely result in product development delays or the failure of our collaborations with current and future collaborators, which, in turn, may impede or delay our ability to develop and commercialize products and generate revenue. In addition, it could also result in difficulty to obtain additional funding for our development of products and our future operations. We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate. The clinical use of our product candidates exposes us to the risk of product liability claims. This risk exists even if a product or product candidate is approved for commercial sale by applicable regulatory authorities and manufactured in facilities regulated by such authorities. Our product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse, or abuse associated with our product candidates could result in injury to a patient or even death. For example, **REYOBIQ ™** ~~rhenium (186Re) obisbemeda~~ and 188RNL- BAM are cytotoxic, or toxic to living cells, and, if incorrectly or defectively manufactured or labeled, or incorrectly dosed or otherwise used in a manner not contemplated by its label, could result in patient harm and even death. In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, if approved, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in: • the inability to commercialize our product candidates; • decreased demand for our product candidates, if approved; • impairment of our business reputation; • product recall or withdrawal from the market; • withdrawal of clinical trial participants; • costs of related litigation; • distraction of management' s attention from our primary business; • substantial monetary awards to patients or other claimants; or • loss of revenue. We have obtained product liability insurance coverage for clinical trials with a $ 10 million per occurrence and annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to

product liability. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse effect on our business, results of operations, financial condition and prospects. A failure to adequately protect ~~private~~ health information could result in severe harm to our reputation and subject us to significant liabilities, each of which could have a material adverse effect on our business. Throughout the clinical trial process, we may obtain the ~~private~~ health information of our trial subjects. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. **For example,** ~~The Healthcare Information Portability and Accountability Act (“~~ HIPAA ~~")~~ imposes privacy, security, breach reporting obligations, and mandatory contractual terms on covered entity health care providers, health plans, and health care clearinghouses, as well as their ~~"~~ **“** business associates ~~"~~ **”** – certain persons or covered entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. We could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly **receive** ~~use or disclose~~ individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA **. The Federal Trade Commission (" FTC") also sets expectations for taking appropriate steps to safeguard consumers' personal information, and providing a level of privacy or security commensurate to promises made to individuals. The FTC expects a company' s data privacy and security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Failure to meet these standards may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. Enforcement by the FTC under the FTC Act and Health Breach Notification Rule can result in civil penalties or enforcement actions** . Most states have laws requiring notification of affected individuals and state regulators (breach notification laws) in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. ~~Additionally~~ **For example** , in California, the California Consumer Privacy **Act, as amended by the California Privacy Rights** Act (“ CCPA ”) establishes certain requirements for data use and sharing transparency and creates new data privacy rights for California ~~residents. The CCPA and~~ **consumers, as that term** ~~its~~ **is defined** ~~implementing regulations have already been amended multiple times since their enactment. In November 2020, California voters approved the California Privacy Rights Act (“ CPRA ”) ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency (“ CPPA ”). The amendments introduced~~ by **law** ~~the CPRA went into effect on January 1, 2023~~ . Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California ~~residents~~ **consumers** have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and damages **. Other jurisdictions have enacted or proposed similar legislation and / or regulations, such as consumer privacy laws that went into effect in 2023 in Virginia, Colorado, Utah, and Connecticut. Health- specific Consumer privacy laws were also passed in multiple other states, including consumer health privacy laws in Washington and Nevada, which govern consumer health data** . Activities outside of the U. S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non- compliance. ~~The European Union~~ **For example, the EU** ’ s General Data Protection Regulation, ~~which~~ **including as implemented in the UK (collectively “ GDPR ”)** imposes fines of up to EUR 20 million or 4 % of the annual global revenue of a noncompliant company, whichever is greater **. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with data protection authorities** , **seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.** Canada’ s Personal Information Protection and Electronic Documents Act and other data protection, privacy and similar national, state / provincial and local laws may also restrict the access, use and disclosure of patient health information abroad **. Moreover, as a result of the broad scale release and availability of Artificial Intelligence (AI) technologies such as generative AI, there is a global trend towards more regulation (e. g., the EU AI Act and AI laws passed in U. S. states) to ensure the ethical use, privacy, and security of AI and the data that it processes. Compliance with such laws will likely be an increasing and substantial cost in the future** . We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers, or to alleviate problems caused by such breaches. Compliance with these laws is difficult, constantly evolving, time consuming, and requires a flexible privacy framework and substantial resources. Compliance efforts will likely be an increasing and substantial cost in the future. We and our collaborators must comply with environmental laws and regulations, including those pertaining to use of hazardous and biological materials in our business, and failure to comply with these laws and regulations could expose us to significant liabilities. We and our collaborators are subject to various federal, state, and local environmental laws, rules and regulations, including those relating to discharge of materials into the air, water and ground, those relating to manufacturing, storage, use, transportation and disposal of hazardous and biological materials, and those relating to the health and safety of employees with respect to laboratory activities required for the development of our products and activities. In particular, our nanomedicine products and processes involve the controlled storage, use and disposal of certain cytotoxic, or toxic to living cells, materials. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials, or other violations of applicable environmental laws, rules or

regulations cannot be completely eliminated. In the event of any violation of such laws, rules or regulations, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of any insurance we may obtain and could exceed our financial resources. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs in complying with environmental laws, rules and regulations. **We recently acquired the CNSideTM diagnostic portfolio, and we may not be successful in our efforts to develop, fully utilize and monetize it. In April 2024, we completed the acquisition of substantially all of the right, title and interest in CNSideTM, including the CNSide Test, which is designed to detect, quantify, and monitor tumor status in LM. We are currently evaluating and developing our business plan for developing the CNSideTM diagnostic portfolio alongside our lead radio therapeutic candidate, rhenium (186Re) obisbemeda, and seeking partnering opportunities for CNSideTM but there can be no assurances that we will be able to develop the technology to allow for commercial applications, or successfully utilize and fully integrate CNSideTM into our operations. We may not generate revenues from or realize the anticipated benefits of CNSideTM within our expected timeline or at all. Clinical laboratories are highly regulated and if we are unable to maintain compliance with these regulations, or if the regulations change in ways that make it more difficult or costly to comply, our financial condition and our business may be harmed. Clinical laboratories in the U. S. must maintain compliance with the federal CLIA standards and with applicable state law licensure requirements, and if we are unable to do so we may be unable to offer the CNSideTM Test to patients. In order to be commercially viable, clinical lab tests must be covered and reimbursed by third party payers. If payers fail to cover the test, impose restrictions on the scope of coverage, or do not provide sufficient reimbursement for the CNSideTM Test we may be unable to realize the expected benefits of the test and may not be able to offer it within the expected timeline, or at all. Our relationships with customers, healthcare providers, including physicians, and third- party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers, including physicians, and third- party payors in the U. S. and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval and the ordering of the CNSideTM Test. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti- Kickback Statute, the federal civil and criminal false claims laws, the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals and patients. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws are described in greater detail in Item 1: Business: Other U. S. Healthcare Laws and Compliance Requirements. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business. 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. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.** Risks Relating to Our Intellectual Property Our success depends in part on our ability to protect our intellectual property. Our success depends in part on our ability to obtain and maintain patent, trademark, and trade secret protection of our platform technology and current product candidates, including but not limited to our nanomedicine product candidates, including **REYOBIQ ™** ~~rhenium (186Re) obisbemeda~~ and 188RNL- BAM **, and our CNSideTM Platform** , as well as successfully defending our intellectual property against third- party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, or importing our platform technology and / or our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: • we, NanoTx, or ~~UTHSA~~ **UTHSCSA** , as the case may be, might not have been the first to file patent applications for **REYOBIQ ™ or 188RNL- BAM; • we, or Biocept, as** the ~~covered inventions~~ **case may be, might not have been the first to file patent applications for the CNSideTM Platform** ; • it is possible that our pending patent applications will not result in issued patents; • it is possible that there are dominating patents to our product candidates of which we are not aware; • it is possible that there are prior public disclosures that could invalidate our patents, of which we are not aware; • it is

possible that others may circumvent our patents; • it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours; • the claims of our patents or patent applications, if and when issued, may not cover our system or products, or our system or product candidates; • our owned or in- licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal administrative challenges by third parties; • others may be able to make or use compounds that are the same or similar to the **REYOBIQ ™** ~~rhenium (186Re) obisbemeda~~ or 188RNL- BAM product candidates but that are not covered by the claims of our patents; • we may not be able to detect infringement against our patents, which may be especially difficult for manufacturing processes or formulation patents, such as the patents / applications related to **REYOBIQ ™** ~~rhenium (186Re) obisbemeda~~ or **188RNL** ~~188 RNL~~ - BAM; • the API used in **REYOBIQ ™** ~~rhenium (186Re) obisbemeda~~, 186- Re, is routinely produced in nuclear reactors or at a particle accelerator and is commercially available as 186- Re Sulfide for isotropic radiation synovectomy of medium sized joints and in developing countries as 186- Re- HEDP for bone pain palliation; • we may not develop additional proprietary technologies for which we can obtain patent protection; or • the patents of others may have an adverse effect on our business. The patent positions of pharmaceutical, biopharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States. There have been recent changes regarding how patent laws are interpreted, and both the USPTO and Congress have recently made significant changes to the patent system. There have been three U. S. Supreme Court decisions that now show a trend of the Supreme Court which is distinctly negative on patents. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our product candidates. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents and / or the patents and applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third- party patents. Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition. Failure to obtain or maintain patent protection or protect trade secrets, for any reason (or third- party claims against our patents, trade secrets, or proprietary rights, or our involvement in disputes over our patents, trade secrets, or proprietary rights, including involvement in litigation), could have a substantial negative effect on our results of operations and financial condition. We may not be able to protect our trade secrets. We may rely on trade secrets to protect our technology, especially with respect to the nanomedicine products, as well as in areas where we do not believe patent protection is appropriate or obtainable. Trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, state laws in the Unites States vary, and their courts as well as courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know- how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. As is common in the device, biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, which would adversely affect our financial condition. We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our product candidates and technology. Litigation may be necessary to enforce or confirm the ownership of any patents issued or licensed to us, or to determine the scope and validity of third- party proprietary rights, which would result in substantial costs to us and diversion of effort on our part. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the USPTO or a foreign patent office to determine priority of invention, which could result in substantial costs to and diversion of effort, even if the eventual outcome is favorable to us. Any such litigation or interference proceeding, regardless of outcome, could be expensive and time- consuming. Successful challenges to our patents through oppositions, reexamination proceedings or interference proceedings could result in a loss of patent rights in the relevant jurisdiction. If we are unsuccessful in actions we bring against

the patents of other parties, and it is determined that we infringe the patents of third- parties, we may be subject to litigation, prevented from commercializing potential products in the relevant jurisdiction and / or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business. Furthermore, if such challenges to our patent rights are not resolved in our favor, we could be delayed or prevented from entering into new collaborations or from commercializing certain products, which could adversely affect our business and results of operations. Competitors or third parties may infringe on or upon our patents. We may be required to file patent infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or that the third party' s technology does not in fact infringe upon our patents. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing. Litigation may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our proprietary rights, particularly in countries outside the United States where patent rights may be more difficult to enforce. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or otherwise have a material adverse effect on our business, results of operations, financial condition, and prospects. If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business. Our commercial success will also depend, in part, on our ability to avoid infringing on patents issued by others. There may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our product candidate or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in- licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and / or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party' s patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party' s patents. If a third- party' s patent were found to cover our product candidates, proprietary technologies or their uses, we could be enjoined by a court and required to pay damages and could be unable to commercialize our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our product candidates, technologies or methods pending a trial on the merits, which could be years away. Risks Relating to the **Issuances of Capital Stock, the** Securities Markets and an Investment in our Common Stock Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock ~~, including in connection with the sale or issuance of our common stock to Lincoln Park and the sale of the shares of common stock acquired by Lincoln Park and the sale of our common stock by Canaccord~~ . Our certificate of incorporation allows us to issue up to 100, 000, 000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 5, 000, 000 shares of preferred stock. **Significant additional capital will be needed in the future to continue our planned operations, including further development of our product candidates, preparing IND or equivalent filings, conducting preclinical studies and clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company.** To raise ~~additional~~ capital, we may ~~in the future~~ sell **common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our shares of common stock. We may also issue** additional shares of ~~our~~ common stock or other **equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, including without stockholder approval, in a number of circumstances. The issuance of additional shares or other equity securities of equal or senior rank would result in a decrease in existing stockholders' proportionate ownership interest in us and the relative voting strength of each previously outstanding share of common stock, and may adversely affect the market price of our common stock. Stockholders will suffer substantial additional dilution if certain provisions in the outstanding March 2025 Warrants are utilized. On March 4, 2025, we entered into a securities purchase agreement (the " March 2025 Purchase Agreement ") with accredited investors, including certain of our**

existing stockholders, identified on the signature page thereto (collectively, the " March 2025 Private Placement Purchasers ") for a private placement of securities (the " March 2025 Private Placement ") for gross proceeds of approximately $ 15. 0 million. Pursuant to the March 2025 Purchase Agreement, we issued an aggregate of 4, 069, 738 shares (the " March 2025 Private Placement Shares ") of our common stock and 23, 972, 400 Prefunded Warrants, with each March 2025 Private Placement Share or Prefunded Warrant accompanied by (i) a Series A common warrant (the " March 2025 Series A Warrants ") to purchase one share of common stock and (ii) one Series B common warrant (the " March 2025 Series B Warrants " and together with the March 2025 Series A Warrants, the " March 2025 Warrants ") to purchase one share of common stock. Certain provisions in our outstanding March 2025 Warrants may result in significant dilution. The exercise price of the March 2025 Warrants will reset to a price equal to the greater of (i) the floor price of $ 0. 132 (the " Floor Price "), and (ii) the lowest volume weighted average price (" VWAP ") during a period commencing on the first trading day immediately following the later of (x) the earlier of (A) the first trading day after the initial registration statement that we are required to file to register the resale of the securities in the March 2025 Private Placement, or (B) the first trading day after the date on which the holder of those securities can sell them pursuant to Rule 144 under the Securities Act of 1933, as amended, without restriction or limitation, or (y) the first trading day after stockholder approval of certain provisions of the March 2025 Warrants is obtained, and the number of shares issuable upon exercise will be proportionately adjusted such that the aggregate exercise price will remain unchanged. Subject to certain exceptions, if we sell any common stock (or securities convertible into or **exercisable into** ~~exchangeable for our~~ common stock **)** at **a** ~~prices~~ **price** ~~that~~ **per** ~~are~~ **share (or conversion or exercise price, as applicable) less than the exercise price of the March 2025 Series A Warrants then in effect, then the exercise price of the March 2025 Series A Warrants will be reduced to such lower price, but no** lower than the **Floor Price** ~~prices paid by existing stockholders~~, and ~~investors purchasing~~ **the number of** shares ~~or~~ **issuable upon exercise will be proportionately adjusted such that** ~~other~~ **the** ~~securities in~~ **aggregate exercise price will remain unchanged. Under** the ~~future could have~~ **alternative cashless exercise option of the March 2025 Series B Warrant, a holder has the** ~~rights~~ **right** ~~superior~~ to **receive an aggregate number** ~~existing stockholders, which could result in substantial dilution to the interests~~ of ~~existing stockholders. On August 2, 2022, we entered into the 2022 Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park committed to purchase up to $ 50. 0 million (the " Commitment Amount ") of our common stock, subject to certain limitations. As consideration for Lincoln Park' s irrevocable commitment to purchase~~ shares ~~of our common stock upon the terms of and subject to satisfaction of the conditions set forth in the 2022 Purchase Agreement, upon execution of the 2022 Purchase Agreement, we agreed to pay Lincoln Park an initial commitment fee~~ equal to ~~1. 5 % of the~~ **three times** ~~Commitment Amount. The initial commitment fee was paid upon execution of~~ the **aggregate number** ~~2022 Purchase Agreement through the issuance~~ of ~~492, 698~~ shares of ~~common stock and $ 0. 1 million in cash. An additional commitment fee equal to 2. 5 % of the remainder of the Commitment Amount will be paid if and when we sell over $ 25. 0 million of our common stock under the 2022 Purchase Agreement. The additional commitment fee may be paid in cash, common stock, or a combination of cash and common stock. The remaining shares of our~~ common stock that ~~may~~ **would** be ~~issued under~~ **issuable upon a cash exercise of** the **March** ~~2022~~ **2025** ~~Purchase Agreement may be sold by~~ **Series B Warrant, without any further payment to** us ~~to Lincoln Park at our discretion from time to time over a 36- month period commencing August 17, 2022, subject to satisfaction of certain conditions~~. **Finally** ~~The purchase price for the shares that we may sell to Lincoln Park under the 2022 Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time~~, **if** ~~sales of such shares may cause the trading price of our common stock to fall. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all or some of those shares~~ at any time **there occurs any share split, share dividend, share combination recapitalization or other similar transaction involving** ~~or~~ **our** ~~from time to time in~~ **common stock and the lowest daily VWAP during the period commencing on the trading day immediately following the applicable date of share combination event and ending on the fifth trading day immediately following such date** ~~its~~ **is** ~~discretion. Therefore~~ **less than the exercise price of the March 2025 Warrants then in effect** , **then the exercise price of the March 2025 Warrants will be reduced to the lowest daily VWAP during such period (subject to a minimum exercise price of the Floor Price), and the number of shares issuable upon exercise will be proportionately adjusted such that the aggregate exercise price will remain unchanged. If any of the provisions described above are utilized, our stockholders would suffer substantial additional dilution. There are a large number of shares of common stock underlying our outstanding Warrants and Prefunded Warrants and the** ~~sales~~ **sale** ~~to Lincoln Park by us could result in~~ **of these shares may depress the market price of our common stock and cause immediate and** substantial dilution to ~~the interests of other holders of~~ our **existing stockholders. As of March 21, 2025, we had 16, 999, 626 shares of** common stock **issued and outstanding** . ~~Additionally~~ **In addition** , **we had** the **March 2025 Warrants outstanding, as well as the Prefunded Warrants, Series A Warrants and Series B Warrants under the May 2024 Purchase Agreement, and 84, 767 shares available for grant under our stock incentive plans. The issuance of shares upon exercise of our March 2025 Warrants, Prefunded Warrants, Series A Warrants and Series B Warrants under the May 2024 Purchase Agreement and options will cause immediate and substantial dilution to our stockholders and any** sale **thereof** ~~of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity- related securities in the future at a time and at a price that we might otherwise wish to effect sale. Future sales of our common stock~~ may depress ~~our share price. As of December 31, 2023, we had issued 4, 522, 656 shares of our common stock, of which 4, 444, 097 shares were outstanding. Sales of a number of shares of common stock in the public market could cause the market price of our common stock to decline. We may also sell additional common stock or securities convertible into or exercisable or exchangeable for common stock in subsequent public or private offerings or other transactions, which may adversely affect~~ the market price of our common stock. The market price of our common stock may be volatile and fluctuate significantly, which could result in

substantial losses for stockholders. The market price of our common stock has been, and may continue to be, subject to significant fluctuations. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this " Risk Factors " section and other factors, including: • fluctuations in our operating results or the operating results of our competitors; • the outcome of clinical trials involving the use of our product candidates, including our sponsored trials; • changes in estimates of our financial results or recommendations by securities analysts; • variance in our financial performance from the expectations of securities analysts; • changes in the estimates of the future size and growth rate of our markets; • changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results; • conditions and trends in the markets we currently serve or which we intend to target with our product candidates; • changes in general economic, industry and market conditions; • success of competitive products and services; • changes in market valuations or earnings of our competitors; • announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors; • our continuing ability to list our securities on an established market or exchange; • the timing and outcome of regulatory reviews and approvals of our product candidates; • the commencement or outcome of litigation involving our company, our general industry or both; • changes in our capital structure, such as future issuances of securities or the incurrence of additional debt; • actual or expected sales of our common stock by the holders of our common stock; and • the trading volume of our common stock. In addition, the financial markets may experience a loss of investor confidence or otherwise experience continued volatility and deterioration. A loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, our financial condition or results of operations, which may materially harm the market price of our common stock and result in substantial losses for stockholders. Further, although our common stock is traded on the Nasdaq, there is currently a limited market for our common stock and an active market may never develop. An active trading market in our common stock may not develop. We may be or become the target of securities litigation, which is costly and time- consuming to defend. In the past, following periods of market volatility in the price of a company' s securities, the reporting of unfavorable news or continued decline in a company' s stock price, security holders have often instituted class action litigation. The market value of our securities has steadily declined over the past several years for a variety of reasons discussed elsewhere in this " Risk Factors " section, which heightens our litigation risk. If we face such litigation, we could incur substantial legal costs and our management' s attention could be diverted from the operation of our business, causing our business to suffer. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments. We may issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock. In the future, we may attempt to increase our capital resources by entering into debt or debt- like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium- term notes, senior notes, subordinated notes, guarantees, preferred stock, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and preferred securities would receive distributions of our available assets before distributions to the holders of our common stock. Because our decision to incur debt and issue securities in future offerings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future. Our charter documents contain anti- takeover provisions. Certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable. These provisions could also prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors (the " Board "). Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions: • authorize our Board to issue without stockholder approval up to 5, 000, 000 shares of preferred stock, the rights of which will be determined at the discretion of the Board; • require that stockholder actions must be effected at a duly called stockholder meeting and cannot be taken by written consent; • establish advance notice requirements for stockholder nominations to our Board or for stockholder proposals that can be acted on at stockholder meetings; and • limit who may call stockholder meetings. We are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15 % or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time. We presently do not intend to pay cash dividends on our common stock. We have never paid cash dividends in the past, and we currently anticipate that no cash dividends will be paid on the common stock in the foreseeable future. ~~Furthermore, our Loan and Security Agreement with Oxford currently prohibits our issuance of cash dividends.~~ This could make an investment in our common stock inappropriate for some investors, and may serve to narrow our potential sources of additional capital. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of our business. If securities and / or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely, or if our results of operations do not meet their expectations, our stock price and trading volume could decline. The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline. General Risk Factors Increased information technology security threats and more sophisticated and targeted computer crime could pose a risk to our systems, networks, and products. Increased global information technology security

threats and more sophisticated and targeted computer crime pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data and communications. While we attempt to mitigate these risks by employing a number of measures, including employee refreshers, monitoring of our networks and systems, and maintenance of backup and protective systems, our systems, networks and products remain potentially vulnerable to advanced persistent threats. Depending on their nature and scope, such threats could potentially lead to the compromising of confidential information and communications, improper use of our systems and networks, manipulation and destruction of data, defective products, production downtimes and operational disruptions, which in turn could adversely affect our reputation, competitiveness and results of operations.