Risk Factors Comparison 2025-04-15 to 2024-04-11 Form: 10-K

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

Investing in our securities involves a high degree of risk. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under " Special Note Regarding Forward- Looking Statements, " you should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report, including the accompanying financial statements and related notes, and in the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " If any of the following events or developments described as risks were to occur, either alone or taken together, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our securities could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. RISKS RELATED TO OUR BUSINESS Risks Related to Our Financial Condition We have a limited operating history, have incurred significant losses since our inception and anticipate incurring increasing expenses and continuing losses for the foreseeable future. ~~Our independent registered public accountants and management have expressed substantial doubt as to our ability to continue as a going concern.~~ We are a commercial- stage medical device and Phase I clinical- stage pharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have incurred significant losses since inception, including net losses of $ ~~59~~ **30** . 0 million and $ ~~47~~ **59** . ~~2~~ **4** million for the years ended December 31, **2024 and** 2023 ~~, and 2022~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~248~~ **279** . ~~4~~ **5** million. We anticipate incurring **increased sales** ~~increasing research and development~~ and general and administrative expenses related to our operations and transition into a public company for the foreseeable future. Losses will likely continue and may increase in the future as we continue to incur significant expenses related to drug development. We may find that these efforts are more expensive than we currently anticipate or that these efforts may not result in revenues, which would further increase our losses. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by clinical- stage pharmaceutical companies. If we are unable to achieve and / or sustain profitability, or if we are unable to achieve the growth that we expect from these efforts, it could have a material adverse effect on our business, financial condition or results of operations. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. ~~In~~ **Our need for** ~~addition~~ **additional capital raises** ~~, the Report of Independent Registered Public Accounting Firm to our December 31, 2023, financial statements includes an explanatory paragraph that expressed~~ substantial doubt about our ability to continue as a going concern ~~. Additionally, our management has independently determined that there is substantial doubt about our ability to continue as a going concern because we have incurred significant operating losses and expect to continue incurring losses for the foreseeable future. Our financial statements were prepared assuming that we will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty. Without additional financing and based on our sales, operations and research and development plans, our management estimates that our existing cash and cash equivalents as of December 31, 2023, will be insufficient to fund our projected liquidity requirements for the next 12 months, creating substantial doubt about our ability to continue as a going concern, and we may be unable to realize assets and discharge liabilities in the ordinary course of operations. If we are unable to obtain sufficient funding, we may be forced to delay, scale back, or eliminate some or all of our research and development activities, our financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. Future financial statements may include similar qualifications about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern; investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. The Dynavax Agreement, entered into by Legacy TriSalus in connection with its purchase of nelitolimod, requires us to make potentially significant payments to Dynavax before we will have regulatory approval of nelitolimod and be able to generate revenue from sales of nelitolimod. Pursuant to the Dynavax Agreement, as of the date of this Annual Report, we have paid Dynavax $ 12 million to date and we may be required to pay Dynavax up to an additional $ 158 million upon the achievement of certain development and regulatory milestones with respect to nelitolimod. We will also be required to pay up to $ 80 million upon achieving certain commercial milestones once sales of nelitolimod have begun. The Dynavax Agreement also obligates us to pay royalties based on potential future net sales of products containing nelitolimod compound on a product- by- product and country- by- country basis during the applicable royalty term. Such royalties are subject to reduction by up to 50 % in certain circumstances. Our failure to satisfy these payment obligations or other obligations under the Dynavax Agreement could result in penalties or litigation, which could have a material adverse effect on our business, financial condition, and results of operations~~ . Until we are able to generate significant revenues or achieve profitability through product sales, we will require substantial additional capital to finance our operations and continue development of our product candidates. We cannot be certain that such additional financing will be available on terms favorable to us, or at all, which could limit our ability to grow and jeopardize our ability to continue our business operations. **This Annual Report includes disclosures regarding management' s assessment of our ability to continue as a going concern as our current liquidity position and recurring losses from operations since inception and negative cash flows from operating activities raise substantial doubt about our ability to continue as a going concern. As of December 31, 2024, we had $ 8. 5 million in cash and cash equivalents.**

Based on our sales, operations, and research and development plans, we expect that our existing cash and cash equivalents ~~as of December 31, 2023,~~ will **not** be sufficient to fund operations ~~into~~ **for at least the next 12 months from the issuance date of this Annual Report. As a result,** ~~the~~ **there** ~~second quarter of 2024~~ **is substantial doubt about our ability to continue as a going concern** . We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in the commercialization of TriNav, **and** clinical trials and other development, manufacturing and regulatory activities for TriNav, nelitolimod **,** and our other product candidates, and discovery research and development. Based on our history of losses, we do not expect that we will be able to fund our longer- term capital and liquidity needs through our cash balances ~~and ,~~ operating cash flow **, and the proceeds from the OrbiMed Credit Agreement** alone. Until we can generate a sufficient amount of revenue, we will need to finance our operations through strategic alliance and licensing arrangements and / or public or private debt and equity financings. We **anticipate needing** ~~expect to need~~ to obtain substantial additional funding in connection with our continuing operations and planned activities ~~, including to continue the clinical development of, and seek regulatory approval for, nelitolimod in any indication,~~ to expand our business, to respond to competitive pressure and to make acquisitions. The amount of capital we will need may change depending on, among other things, the success of our efforts to grow revenue, our efforts to continue to effectively manage expenses, the results of our research and development and clinical trials for product candidates, and costs arising from seeking regulatory approvals. We may not succeed in raising additional funds in a timely manner. The timing of our need for additional funds will depend on many factors, which are difficult to predict or may be outside of our control, including **to continue the clinical development of, and seek regulatory approval for, nelitolimod in any indication. These factors include** : ◦ the revenue received from sales of TriNav; ◦ the costs and timing of research and development programs, including for additional Pressure- Enabled Drug Delivery (“ PEDD ”) devices; ◦ **our ability to access the remaining available loan amount under our OrbiMed Credit Agreement if and when needed;** ◦ the scope, progress, results, resources, time and costs of preclinical development, laboratory testing and clinical trials for our current and future product candidates; ◦ the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims; ◦ our ability to establish collaborations on favorable terms, if at all; ◦ the costs, timing and outcome of the regulatory review and approval of nelitolimod and any future product candidate; ◦ the timing of any milestone payments or royalties due to Dynavax; and ◦ the costs of operating as a public company. If our estimates and predictions relating to any of these factors are incorrect, we may need to modify our business plans. Conducting preclinical testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales for nelitolimod or any of our product candidates. In addition, nelitolimod and any future product candidates, if approved, may not achieve commercial success. Our ability to raise additional capital in the equity and debt markets, should we choose to do so, will depend upon many factors, including but not limited to, the market demand for our Common Stock, which itself is subject to a number of development and business risks and uncertainties, as well as investor perception of our creditworthiness and prospects. It will also depend on a number of factors, including market conditions, interest rates, our operating performance and our credit rating. If we are unable to raise funds on acceptable terms, we may not be able to execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements. This may seriously harm our business, financial condition and results of operations. If we are not able to continue operations, investors may suffer a complete loss of their investments in our securities. If we raise additional funds through future issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of Common Stock. ~~Any~~ **Subject to limited exception, we are prohibited from incurring indebtedness without the prior written consent of OrbiMed pursuant to the OrbiMed Credit Agreement. Regardless, any** debt financing that we may secure in the future could involve significant fixed payment obligations and restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. We may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when needed, we may need to delay, reduce the scope of or put on hold one or more research and development programs or commercialization efforts while we seek strategic alternatives, and our ability to continue to support our business growth and to respond to business challenges and opportunities could be significantly impaired. We may also need to seek collaborators for nelitolimod and any future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to nelitolimod and any future product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition, and results of operations and cause the price of Common Stock to decline. Further, our ability to raise additional capital **and the interest rate of our term loans under the OrbiMed Credit Agreement** may be adversely impacted by potential worsening global economic conditions, and the continued disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from geopolitical events, including the wars in Ukraine and the Middle East, and disruptions to the U. S. banking system due to bank failures ~~, particularly in light of the recent events that have occurred with respect to Silicon Valley Bank, Signature Bank, and First Republic Bank~~ . 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, have in the past and may in the future lead to market- wide liquidity problems. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy and business development efforts, which could jeopardize our ability to continue our business operations. Our future capital needs may require us to sell additional equity or debt securities that may dilute our stockholders, adversely affect the market price of our Common Stock or

introduce covenants that may restrict our operations. We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, such offerings may reduce the market price of the Common Stock, and the terms may include a preference on liquidating distributions or a preference on dividend payments ~~liquidation~~ or other preferences that adversely affect the rights of existing stockholders. Thus, existing holders of our Common Stock bear the risk of our future offerings reducing the market price of our Common Stock and diluting their shareholdings in us. For instance, in October 2023, we entered into a standby equity purchase agreement (the " SEPA ") with YA II PN, LTD., a Cayman Islands exempt limited partnership (" Yorkville "), whereby we have the right, but not the obligation, to sell to Yorkville up to $ 30. 0 million of our Common Stock at our request, subject to terms and conditions specified in the SEPA. We have, and in the future may continue to, sell shares of our Common stock to Yorkville under the SEPA. In addition, the **OrbiMed Credit Agreement requires us to make** ~~incurrence of indebtedness would result in increased fixed or variable payment~~ **payments** ~~obligations~~ **of interest** and ~~could involve certain~~ **principal and subject us to a number of** restrictive covenants, ~~such as~~ **including among others,** limitations on our ability to incur additional debt **; create liens and encumbrances; merge** , ~~limitations on~~ **dissolve, merge, dissolve, liquidate** ~~our~~ **or** ~~ability to acquire~~ **consolidate; make acquisitions, investments, advances or loans; dispose of or transfer assets; pay dividends or make other payments in respect of** ~~or~~ **our capital stock; amend certain material documents; redeem or repurchase certain debt; engage in certain transactions with our affiliates; enter into certain restrictive agreements; and** license intellectual property rights ~~and other operating restrictions that could adversely impact our ability to conduct our business, including grants of security interests in our intellectual property~~ . If we raise additional capital through future collaborations, strategic alliances or third- party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. Because our decision to issue additional equity or debt securities in any future offering or to enter into any strategic partnership or licensing arrangement will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, nature or success of our future capital raising efforts or partnership and licensing arrangements. In addition, a significant decline in the trading price of our Common Stock could potentially impact our ability to use equity securities as consideration in acquisitions. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, or grant rights to develop and market products or product candidates that we would otherwise develop and market ourselves **. We may not be able to generate sufficient cash to service our indebtedness or borrow additional funds pursuant to our Loan Facility. We have entered into the OrbiMed Credit Agreement, pursuant to which we may borrow up to $ 50. 0 million in senior secured term debt. Our obligations under the OrbiMed Credit Agreement are secured by substantially all of our assets. We are subject to a number of affirmative and restrictive covenants pursuant to the OrbiMed Credit Agreement, which limit or restrict our ability to, among others (subject to certain qualifications and exceptions): create liens and encumbrances; incur additional indebtedness; merge, dissolve, liquidate or consolidate; make acquisitions, investments, advances or loans; dispose of or transfer assets; pay dividends or make other payments in respect of our capital stock; amend certain material documents; redeem or repurchase certain debt; engage in certain transactions with our affiliates; and enter into certain restrictive agreements. In addition, we are required to maintain at least $ 5. 0 million of unrestricted cash and cash equivalents at all times (which requirement will increase to $ 10. 0 million at all times after March 31, 2025). Our obligations under the OrbiMed Credit Agreement are subject to acceleration upon the occurrence of an event of default (subject to applicable notice and grace periods). We are currently in compliance with the OrbiMed Credit Agreement covenants; however, we currently expect that we expect that we will need to raise additional capital to remain in compliance with the minimum cash threshold. If we are unable to achieve certain milestones, generate sufficient revenue and maintain certain minimum cash threshold, we may fall out of compliance with these covenants, which could constitute an event of default. We may also enter into other debt agreements in the future which may contain similar or more restrictive terms. Our ability to make scheduled monthly payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Failure to comply with the conditions of or covenants in the OrbiMed Credit Agreement could result in an event of default, which could result in an acceleration of amounts due under the OrbiMed Credit Agreement. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and OrbiMed could seek to enforce security interests in the collateral securing such indebtedness, which would materially harm our business and our stock price. In addition, the OrbiMed Credit Agreement provides up to $ 15. 0 million will be made available on or prior to December 31, 2025, subject to certain revenue requirements. If we are unable to achieve the revenue requirements by the applicable dates, we would be unable to borrow additional funds pursuant to the Loan Facility, which could negatively impact our ability to fund our operations** . We may issue additional Common Stock from time to time under our equity incentive plans. Any such issuances would dilute the interest of our stockholders and likely present other risks. We may issue additional Common Stock from time to time under our equity

incentive plans. Common Stock reserved for future issuance under our equity incentive plans will become eligible for sale in the public market once those shares are issued, subject to provisions relating to time- based and performance- based vesting conditions, lock- up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. We have filed a registration statement on Form S- 8 under the Securities Act to register additional shares we may issue pursuant to our 2023 Equity Incentive Plan (the " 2023 Plan ") and 2023 Employee Stock Purchase Plan. In addition, we may file one or more registration statements on Form S- 8 under the Securities Act to register additional Common Stock or securities convertible into or exchangeable for Common Stock issued pursuant to our equity incentive plans. Any future Form S- 8 registration statements will automatically become effective upon filing. Accordingly, Common Stock registered under such registration statements may be immediately available for sale in the open market. **Any acquisitions, strategic investments, entries into new businesses, joint ventures, divestitures, and other transactions could fail to achieve strategic objectives, disrupt our ongoing operations, result in operating difficulties, liabilities and expenses, harm our business, or negatively impact our results of operations. We may evaluate and consider strategic transactions, combinations, acquisitions, dispositions, joint ventures or similar transactions. These transactions could be material to our financial condition and results of operations if consummated.** If we ~~engage~~ **are able to identify an appropriate business opportunity, we may not be successful** in ~~future acquisitions~~ **negotiating favorable terms and /** or **consummating the transaction and, even if we do consummate such a transaction, we may be unable to obtain the benefits or avoid the difficulties and risks of such transaction. Any** strategic ~~partnerships~~ **transaction** , ~~this may increase~~ **combination, acquisition, disposition, joint venture** ~~our~~ **or** ~~capital requirements~~ **similar transaction will involve risks encountered in business relationships** , ~~dilute~~ **including: • difficulties in assimilating and integrating the operations, personnel, systems, data, technologies, products and services of the acquired business; • inability of the acquired technologies, products** ~~our~~ **or** ~~stockholders if we issue equity securities~~ **businesses to achieve expected levels of revenue** , ~~cause~~ profitability,productivity or other benefits;• difficulties in retaining,training,motivating and integrating key personnel;• diversion of management' s time and resources from our normal daily operations;• difficulties in successfully incorporating licensed or acquired technology and rights into our operations;• difficulties in maintaining uniform standards,controls,procedures,and policies within the combined organizations;• difficulties in retaining relationships with customers,employees,and suppliers of the acquired business;• risks of entering markets in which we have no or limited prior experience;• regulatory risks,including remaining in good standing with existing regulatory bodies or receiving any necessary pre- closing or post- closing approvals,as well as being subject to new regulators with oversight over an acquired business;• assumption of contractual obligations that contain terms that are not beneficial to us ~~to incur debt or assume contingent liabilities~~ , **require** ~~and subject~~ us to ~~other risks. We may evaluate various acquisitions and strategic partnerships, including licensing~~ **license** or **waive** ~~acquiring complementary products,~~ intellectual property rights, ~~technologies,~~ or ~~businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: • increased~~ **increase our liability** ~~operating expenses and cash requirements~~ ; • ~~the assumption~~ **failure to successfully further develop any acquired product candidates or technology; • liability** ~~or for occurrence~~ **activities** of ~~additional indebtedness~~ **the acquired** or ~~contingent~~ **disposed of business before the acquisition or disposition, including patent and trademark infringement claims, violations of laws, regulatory actions, commercial disputes, tax liabilities, assumed debt and other known and unknown** liabilities; • **difficulty in separating assets and replacing shared services; • potential disruptions to our ongoing businesses; and • unexpected costs and unknown risks and liabilities associated with** the ~~issuance of~~ **specific transaction. We may not make any strategic transactions, combinations, acquisitions, dispositions, joint ventures** ~~our~~ **or** similar transactions,or any future transactions,combinations,acquisitions,dispositions,joint ventures or similar transactions may not be successful,may not benefit our business strategy,may not generate sufficient revenue to offset the associated costs,or may not otherwise result in the intended benefits.It may take us longer than expected to fully realize the anticipated benefits and synergies of these transactions and those benefits and synergies may ultimately be smaller than anticipated or may not be realized at all,which could adversely affect our business and operating results.Any strategic transactions,combinations,acquisitions,dispositions,joint ventures or similar transactions may also require us to issue additional ~~equity~~ equity securities ~~; • assimilation~~ **, spend our cash, or incur debt (and increase our interest expense), liabilities, and amortization expenses related to intangible assets or write- offs of goodwill, which could adversely affect our results** of operations ~~, intellectual property~~ and **the interests of holders of our indebtedness and dilute the economic and voting rights of our stockholders. In addition, we cannot assure you that any future acquisition of new businesses,** products ~~of an acquired company~~ , ~~including difficulties associated with integration; • the diversion of our management' s attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership; • retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or~~ product candidates **or** technologies will lead to the successful integration of any products,product candidates or technologies acquired with our existing operations or the successful development of new or enhanced products or that any new or enhanced products,if developed,will achieve market acceptance or prove to be profitable.Further,we may also choose to divest certain businesses or product lines that no longer fit with our strategic objectives.If we decide to sell assets or a business,we may have difficulty obtaining terms acceptable to us in a timely manner,or at all.Additionally,the terms of such potential transactions may expose us to ongoing obligations ~~and~~ and ~~related~~ **liabilities. The Dynavax Agreement, entered into by Legacy TriSalus in connection with its purchase of nelitolimod, requires us to make potentially significant payments to Dynavax before we will have** regulatory ~~approvals~~ **approval** ~~;~~ **of nelitolimod** and **be able** ~~• our inability~~ to generate revenue from **sales of nelitolimod. Pursuant to the Dynavax Agreement, as of the date of this Annual Report on Form 10- K, we have paid Dynavax $ 12. 0 million to date and we may be** ~~acquired~~ **required** ~~technology~~ **to pay Dynavax up to** ~~and~~ **an** ~~/ or~~ **additional $ 158. 0 million upon the achievement of certain development and regulatory milestones with respect to nelitolimod. We will also be**

required to pay up to $ 80. 0 million upon achieving certain commercial milestones once sales of nelitolimod have begun. The Dynavax Agreement also obligates us to pay royalties based on potential future net sales of products **containing nelitolimod compound** ~~sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions, we may incur large one-~~ **on a product** ~~time expenses~~ **by- product** and ~~acquire intangible assets that~~ **country- by- country basis during the applicable royalty term. Such royalties are subject to reduction by up to 50 % in certain circumstances. Our failure to satisfy these payment obligations or other obligations under the Dynavax Agreement** could result in **penalties or litigation** ~~significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities~~, which could **have a material adverse effect on** ~~impair our ability to grow or obtain access to technology or products that may be important to the development of~~ our business **, financial condition, and results of operations**. Risks Related to TriNav Our revenue is primarily generated from sales of our TriNav device and we are therefore highly dependent on it for our success. Failure to achieve continued market acceptance of TriNav for any reason will harm our business and future prospects. We began selling TriNav in 2020 in the United States, and sales of TriNav ~~accounted~~ -- **account** for ~~substantially~~ **primarily** all of **our** revenue ~~for the years ended December 31, 2023,~~ and **will** ~~2022. Sales of TriNav are expected to~~ continue to account for primarily all of our revenue going forward. Our ability to execute our growth strategy and become profitable will therefore depend upon the adoption of TriNav by physicians and hospitals, among others **, and for various conditions where PEDD may be applicable, including liver cancer, multinodular goiters, locally advanced pancreatic cancer, UFEs and prostate embolization**. TriNav is a relatively new drug delivery platform designed to overcome the barriers of the high pressure tumor microenvironment. As a result, physician awareness of TriNav, and experience with TriNav, is limited. A number of factors that are outside of our control may contribute to fluctuations in our financial results, including: • physician experience and hospital demand for our products and the extent of adoption of TriNav, including the rate at which physicians recommend TriNav for use on their patients; • delays in, or failure to supply product, component and material deliveries by our third- party suppliers; • positive or negative media coverage, or public, patient and / or physician perception, of TriNav or competing products and procedures; • any safety or effectiveness concerns that arise regarding TriNav; • the extent of reimbursement by **the Centers for Medicare & Medicaid Services ("** CMS **")** for purchases of TriNav; and • introduction of new products or procedures for delivering drugs into the tumor microenvironment that compete with TriNav. There is no assurance that TriNav will achieve broad market acceptance among physicians and hospitals **or in the conditions for which PEDD maybe applicable**. Any failure of TriNav to satisfy physician or hospital demand or to achieve meaningful market acceptance will harm our business and future prospects. Further, to the extent broad market acceptance is achieved in the future, there is no assurance that such acceptance will be sustained. Our business is dependent upon the continued adoption of TriNav by hospitals and physicians. Our future growth and profitability largely depend on our ability to increase physician awareness and adoption of TriNav **for the different conditions for which PEDD may be applicable** and on the willingness of physicians to recommend the device to more of their patients. Physicians may not use our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our product provides a safe and effective treatment alternative for drug delivery. Even if we are able to raise awareness and increase adoption of TriNav among physicians, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select TriNav for recommendation to patients for a variety of reasons, including: • Long- standing relationships with competing companies and distributors that sell competitive products; • Competitive response and negative selling efforts from providers of alternative catheter products; • Perceived liability risk generally associated with the use of new products and procedures; • Lack of sufficient clinical evidence, including long- term data, supporting the clinical benefits of TriNav **in the different conditions for which PEDD may be applicable**; • Reluctance to change to or use new products and procedures; and • Time commitment and skill development that may be required to gain familiarity and proficiency with TriNav. Physicians play a significant role in determining the course of a patient' s treatment and, as a result, the type of treatment that will be recommended or provided to a patient. We focus our sales, marketing, and education efforts primarily on interventional radiologists with the goal of educating these physicians regarding the patient population that we believe would benefit from TriNav. However, we cannot assure you that we will achieve broad education or market acceptance among these practitioners. For example, if treating physicians are not made aware of TriNav, they may not treat patients using our product, and those patients may instead not seek treatment at all or may be treated with alternative products or procedures. In addition, some physicians may choose to utilize TriNav on only a subset of their total patient population or may not adopt TriNav at all. If a physician experiences an adverse event in one or more of their TriNav patients or if any issues with the safety or efficacy of TriNav develop, physicians may not continue offering TriNav as a drug delivery method at the same rate or at all. If we are not able to effectively demonstrate that TriNav is beneficial in a broad range of patients, adoption of TriNav will be limited and may not occur as rapidly as we anticipate, which would have a material adverse effect on our business, financial condition, and results of operations. We cannot assure you that TriNav will achieve broad market acceptance among hospitals and physicians. Any failure of TriNav to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations. In addition, the medical device industry' s interactions and relationships with health care providers, including physicians and hospitals are under increasing scrutiny by the U. S Department of Health and Human Services Office of the Inspector General (" OIG "), the Department of Justice (" DOJ "), state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with health care providers, including physicians and hospitals, or an investigation into our compliance by the OIG, DOJ, state attorneys general or other government agencies, could significantly harm our business. In most cases, before physicians can use our products for the first time, our products must be approved for use by a hospital' s new product or value analysis committee, or the staff of a hospital or health system. Following such approval, we may be required to enter into purchase contracts with

such hospital or health system. Such approvals or requirements to enter into a purchase contract could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals, enter into purchase contracts, or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations. Any change to TriNav' s reimbursement status that reduces our level of reimbursement could cause TriNav sales to materially decline and impede market adoption. **In December 2023** ~~We presently benefit from various reimbursement codes in the United States~~ , ~~including the following: •~~ **CMS granted a New Technology** Healthcare Common Procedure Coding System Code (" HCPCS") ~~: C1982; and • Current Procedural Terminology~~ for **both** ~~physicians to support reimbursement for physician- rendered healthcare services Codes: 37242 Mapping~~ **mapping** and **therapeutic** ~~37243 Treatment. In December 2023, CMS granted a New Technology HCPCS for~~ procedures involving TriNav. This ~~new~~ code, HCPCS C9797, has been assigned to the Ambulatory Payment Classification (" APC") 5194- Level 4 Endovascular Procedures **.The code became effective on January 1,2024,and may be reported by hospital outpatient departments and ambulatory surgical centers.Effective April 1,2025,TriNav received a second unique and permanent HCPCS code from CMS,C8004,which has been assigned to APC 5193 (Level 3 Endovascular Procedures).This new code provides reimbursement clarity for mapping procedures conducted prior to TARE.Although CMS approved a reimbursement amount increase for 2025,there can be no assurance that continuing reimbursement will be available at similar reimbursement rates or at all.** Any reduction in the amount of the reimbursement for TriNav will negatively impact the revenue we are able to generate from the sale of TriNav and may hinder our ability to recoup our total investment in TriNav notwithstanding regulatory approval of the product.If we are unable to maintain coverage and profitable payment rates from hospital budgets or government- funded and private purchasers for TriNav or any future products,we may sell fewer units or need to sell them at a lower price.Such changes in revenues would have a material adverse effect on our operating results and our overall financial condition.We currently have a limited marketing,sales and distribution organization.If we are unable to successfully grow our marketing,sales and distribution capabilities,then our product revenues related to TriNav,our results of operations and financial condition will suffer.We currently have limited in- house sales and marketing capabilities ~~.Until January 1,2023,we contracted with a limited number of third- party distributors for a significant portion of our commercial sales of TriNav~~ .Although we continue to further develop an in- house marketing organization and sales force with technical expertise and supporting distribution capabilities to commercialize TriNav,which will require significant capital expenditures,management resources and time,we may be unable to accurately predict the future level of demand for TriNav that will be generated by our existing or potential customers,or the future demand for our medical device products by these customers or new customers.We will also have to compete with other pharmaceutical and biotechnology companies to recruit,hire,train and retain marketing and sales personnel.We may not be able to build an effective sales and marketing organization with supporting distribution capabilities in the United States,the European Union (" EU ") or other key global markets in compliance with applicable legal requirements.Any failure or delay in the development of our internal sales,marketing and distribution capabilities would adversely impact our revenues,results of operations and financial condition ~~.Further,if we decide to re- enter into arrangements with third parties to perform sales,marketing,and distribution services,our product revenues related to TriNav may be lower than if we were to market,sell and distribute TriNav ourselves.We also would face competition in our search for third parties to assist with the sales,marketing and distribution efforts of TriNav~~ .In addition,we have an agreement with a partner in China for the distribution and commercialization of TriNav,if approved in China.Foreign organizations may be subject to U.S.legislation,including the proposed BIOSECURE Act,sanctions,trade restrictions and other foreign regulatory requirements which could have an adverse effect on our ability to expand certain foreign jurisdictions.Increases in costs,disruption of supply or shortage of materials could harm our business.We manufacture TriNav internally,and certain materials necessary to produce our products are sourced from a limited number of suppliers.Any disruption in the supply of materials from such suppliers could disrupt production of our products until such time as a different supplier is fully qualified.As a result,we may experience an increase in costs or inability to meet customer demand.Furthermore,shortages or increased demand of such materials and other economic conditions,like inflation,may cause us to experience significant increases in the cost of materials.In the case of TriNav,substantial increases in the prices for materials used in our production would increase our operating costs and could reduce our margins if we cannot recoup any such increased costs through increased product pricing.Any attempts to increase product prices in response to increased material costs could result in cancellations of product orders and therefore materially and adversely affect our brand,business,prospects and results of operations.Risks Related to Nelitolimod and Product Development We are early in our pharmaceutical development efforts **for** ~~and we have only one pharmaceutical product candidate,~~ nelitolimod, **and if** ~~in early clinical development.If~~ we are unable to advance our product candidates,including nelitolimod ~~,~~ in clinical development for any reason (including due to lack of funding),obtain regulatory approval and ultimately commercialize our product candidates,or experience significant delays in doing so,our business,results of operations,financial condition and prospects may be materially adversely affected.We are in the early stages of our development efforts and have only one product candidate,nelitolimod,in early clinical development.We have initiated Phase 1 and Phase 1b clinical trials for **nelitolimod** ~~this product candidate~~ ,each of which are focused on a different target indication,specifically ~~:~~ **UMLM,ICC and HCC,and pancreatic cancer.We expect that any continued investigation for ICC and HCC will only continue through IITs.Based on the changing landscape for second line treatment of** uveal melanoma, ~~intrahepatic cholangiocarcinoma~~ **we do not intend to proceed to Phase II trials for that indication on our own,but we are looking for potential partners to advance that indication.Our Phase I PERIO- 03 clinical trial in pancreatic cancer is enrolled** and ~~hepatocellular carcinoma~~ **we anticipate data from the study will be available by the end of 2025,depending on when treatment is completed** .We will need to progress ~~any early product candidates~~ **the pancreatic carcinoma indication** through IND- enabling studies and submit Investigational New Drug applications (" INDs ") to the FDA prior to initiating their clinical development.Our ability to generate product revenues from our ~~pharmaceutical~~ **product**

~~candidates~~ **candidate** ,which we do not expect will occur for several years,if ever,will depend heavily on the successful development and eventual commercialization of our product ~~candidates~~ **candidate** .The success of ~~these~~ **this** product ~~candidates~~ **candidate** will depend on several factors,including the following:◦ successful enrollment in clinical trials and completion of clinical trials and preclinical studies with favorable results;◦ clearance of INDs by the FDA or similar regulatory filings by comparable foreign regulatory authorities for the conduct of clinical trials of our product ~~candidates~~ **candidate** and our proposed design of future clinical trials;◦ demonstrating the safety and efficacy in the proposed indications for use of our product ~~candidates~~ **candidate** to the satisfaction of applicable regulatory authorities;◦ receipt of marketing approvals from applicable regulatory authorities,including New Drug Applications (“ NDAs ”) from the FDA and maintaining such approvals;◦ making arrangements with third- party manufacturers for,or establishing,clinical and commercial manufacturing capabilities;◦ establishing sales,marketing and distribution capabilities and launching commercial sales of our product ~~candidates~~ **candidate** ,if and when approved,whether alone or in collaboration with others;◦ establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product ~~candidates~~ **candidate** ;◦ maintaining an acceptable safety profile of our products following approval;and ◦ building and maintaining an organization of people who can successfully develop our product ~~candidates~~ **candidate** .The success of our business depends in part on the successful development,regulatory approval,and commercialization of our product candidate,nelitolimod,as well as any other future product candidates,which may never occur.We have not yet succeeded in,and we may not succeed in,obtaining marketing approval for nelitolimod.If we are unable to develop,or obtain regulatory approval for,or,if approved,successfully commercialize our product candidates,we may not be able to generate any revenue from our pharmaceutical development efforts and this may have a material adverse effect on our business,results of operations,financial condition and prospects.Clinical trials of our product candidates or potential product candidates may fail to produce results necessary to support regulatory clearance or authorization.We incur substantial expense for,and devote significant time to,clinical trials but cannot be certain that the trials will ever result in commercial gains.We may experience significant setbacks in clinical trials,even after earlier clinical trials showed promising results,and failure can occur at any time during the clinical development process.Our products may produce undesirable adverse effects that could cause us,institutional review boards (“ IRBs ”) or regulatory authorities to interrupt,delay or halt clinical trials.We,IRBs,the FDA,or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks.Our clinical trials may produce negative or inconclusive results or may demonstrate a lack of effect of our product candidates.Additionally,the FDA may disagree with our interpretation of the data from our pilot studies and clinical trials,or may find the clinical trial design,conduct or results inadequate to demonstrate safety or effectiveness,and may require us to pursue additional clinical trials,which could further delay the clearance or authorization of our product candidates.If we are unable to demonstrate the safety and effectiveness of product candidates in our clinical trials,we will be unable to obtain the regulatory clearances or authorizations we need to commercialize new products.Interim,“ topline ” and preliminary data from clinical trials of our product candidates may change as more patient data becomes available and are subject to confirmation,audit,and verification procedures that could result in material changes in the final data.From time to time,we may publish interim,topline or preliminary data from our clinical trials.Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available.Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published.As a result,interim and preliminary data should be viewed with caution until the final data is available.Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.Clinical development is a lengthy and expensive process with an uncertain outcome.In addition,results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.Failure can occur at any stage of clinical development.Clinical testing is expensive and can take many years to complete,and outcomes are inherently uncertain.Failure can occur at any time during the clinical trial process and may result from a multitude of factors both within and outside our control,including flaws in formulation,adverse safety or efficacy profiles and flaws in trial design,among others.To obtain the requisite regulatory approvals or clearances to market and sell any of our product candidates,we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication.The results of preclinical studies and early clinical trials of nelitolimod and any future drug candidates may not be predictive of the results of later- stage clinical trials,making it impossible to predict when or if any of our product candidates will prove safe or effective in humans or receive regulatory approval or clearance.The results generated to date in preclinical studies for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results.Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier- stage clinical trials.In later- stage clinical trials,we will likely be subject to more rigorous statistical analyses than in completed earlier- stage clinical trials.Several companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles,notwithstanding promising results in earlier trials,and we cannot be certain that we will not face similar setbacks. **Changing treatment landscapes may also diminish the opportunities for our product candidates leading to termination of their development in general or for certain indications.** Moreover,preclinical and clinical data are often susceptible to varying interpretations and analyses,and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval or clearance of these product candidates.In some instances,there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors,including changes in clinical trial procedures set forth in protocols,differences in the size and type of the patient populations,adherence to the dosing regimen and other clinical trial protocols,and the rate of dropout among clinical trial participants.If the trials result in negative or inconclusive results,we or our collaborators or partners may decide,or regulators

may require them,to discontinue trials of our drug candidates or conduct additional clinical trials or preclinical studies.In addition,data obtained from trials and studies are susceptible to varying interpretations,and regulators may not interpret our data as favorably as we do,which may delay,limit or prevent regulatory approval.For these reasons,our future clinical trials may not be successful.If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates,the development timeline and regulatory approval or clearance and commercialization prospects for our product candidates,and,correspondingly,our business and financial prospects,would be materially and adversely affected.Also,we cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule,if at all.We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons,including challenges resulting from ~~COVID- 19,~~ labor shortages ~~,~~and global supply chain interruptions.Any inability to timely and successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to achieve regulatory and commercialization milestones.In addition,if we make manufacturing or formulation changes to our product candidates,we may need to conduct additional testing to bridge our modified product candidate to earlier versions.Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals or clearances.Delays in clinical trials are common and have many causes,and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence future product sales.We may also find it difficult to enroll patients in our clinical trials,which could delay or prevent the development of our product candidates.We may experience delays in clinical trials of our drug candidates.Planned clinical trials may not begin on time,have an effective design,enroll a sufficient number of patients or be completed on schedule,if at all.Our clinical trials have been and can be delayed for a variety of reasons,including:• inability to raise or delays in raising funding necessary to initiate or continue a trial;• delays in obtaining regulatory approval to commence a trial;• delays in reaching agreement with the FDA on final trial design;• imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;• delays in reaching agreement on acceptable terms with prospective contract manufacturing organizations (“ CMOs ”),or contract research organizations (“ CROs ”),and clinical trial sites,or failure by such CMOs to complete the manufacturing of clinical trial materials or CROs to follow and carry out the clinical study protocol at each site in accordance with the terms of our agreements with them;• delays in obtaining required IRB,approval at each site;• difficulties or delays in having patients’ complete participation in a trial or return for post- treatment follow- up;• clinical sites electing to terminate their participation in one of our clinical trials,which would likely have a detrimental effect on subject enrollment;• time required to add new clinical sites;or • delays by prospective CMOs to produce and deliver sufficient supply of clinical trial materials.If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons,our development costs may increase,our regulatory approval process could be delayed and our ability to commercialize and commence sales of our drug candidates could be materially harmed,which could have a material adverse effect on our business.In addition,identifying and qualifying patients to participate in clinical trials of our drug candidates is critical to our success.The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our drug candidates as well as completion of required follow- up periods.We may not be able to identify,recruit and enroll a sufficient number of patients,or those with required or desired characteristics or to complete our clinical trials in a timely manner.Patient enrollment is and completion of the trials are affected by a variety of factors,including:• severity and prevalence of the disease under investigation;• design of the trial protocol;• size of the patient population;• eligibility criteria for the trial in question;• perceived risks and benefits of the drug candidate under trial;• proximity and availability of clinical trial sites for prospective patients;• availability of competing therapies and clinical trials;• efforts to facilitate timely enrollment in clinical trials;• patient referral practices of physicians;and • ability to monitor patients adequately during and after treatment. ~~Nelitolimod relies on oligonucleotide~~ **Use of toll- like receptor (** TLR **)** ~~agonists~~ - **agonist,including nelitolimod,may negatively impact the immune system** .Serious adverse event data relating to TLR agonists may require us to reduce the scope of or discontinue certain of our pre- clinical or clinical activities.Nelitolimod **,an investigational agent in development,** is ~~composed,in part,of~~ **a toll- like receptor 9 (** TLR9 **)** agonist ~~CpG oligonucleotides~~ **which is believed to bind to the TLR9 receptors found on suppressive immune cells including myeloid- derived suppressor cells,antigen- presenting immune cells and other immune cells.TLRs play a key role in the innate immune system and create a bridge to adaptive immunity.It is believed that activating TLR9 primes immune cells to promote anti- tumor T- cells** .If nelitolimod or any of our future product candidates in clinical trials or similar products from competitors produce serious adverse event data,we may be required to delay,discontinue,or modify many of our clinical trials or our clinical trial strategy.If a safety risk based on mechanism of action or the molecular structure were identified,it may hinder our ability to develop our product candidates or enter into potential collaboration or commercial arrangements.Rare diseases and a numerical imbalance in cardiac adverse events have been observed in patients in our clinical trials.If adverse event data are found to apply to our TLR agonist and / or inhibitor technology as a whole,we may be required to significantly reduce the scope of or discontinue certain of our pre- clinical or clinical activities ~~.Our long- term prospects are dependent on the success of our development- stage products including nelitolimod,which depend on regulatory approval.Failure to maintain or obtain regulatory approvals would materially and adversely impact us and our business prospects.Our long- term prospects are dependent on nelitolimod,currently our sole development- stage immune- oncology product candidate,and early- stage development is inherently risky.Even if we have early indications of success in clinical development,in order to be able to market nelitolimod in the United States,we must obtain approval from the FDA,and corresponding applications to foreign regulatory agencies must be approved by those agencies before we may sell the product in respective geographic areas.Obtaining FDA marketing approval and corresponding foreign applications is highly uncertain and we may fail to obtain approval,or might obtain approval in a more limited indication than sought.The FDA review process is extensive,lengthy,expensive and uncertain,and the FDA or foreign regulatory agencies may delay,limit or deny approval of our application for many reasons,including:whether the data from our clinical trials or the development program are satisfactory to~~

~~the FDA or foreign regulatory agency;disagreement with the number,design,size,conduct or implementation of our clinical trials or proposed post- marketing study,or a conclusion that the data fails to meet statistical or clinical significance or safety requirements;acceptability of data generated at our clinical trial sites that are monitored by third- party CROs;and deficiencies in our manufacturing processes or facilities or those of our third- party contract manufacturers and suppliers,if any.In the event that we determine to commercialize nelitolimod outside the United States,such as in Europe,whether we can do so successfully will depend upon us receiving regulatory approval,which can be costly and time- consuming,and there is a risk that one or more regulatory bodies may require that we conduct additional clinical trials and / or take other measures which will take time and require us to incur significant additional expense.In addition,there is the risk that we may not receive approval in one or more jurisdictions.In addition,we obtain guidance from regulatory authorities on certain aspects of our clinical development activities and seek to comply with written guidelines provided by such authorities.These discussions and written guidelines are not binding obligations on the part of the regulatory authorities and the regulatory authorities may require additional patient data or studies to be conducted.Regulatory authorities may revise or retract previous guidance during the course of a clinical trial or after the completion of the trial.The authorities may also disqualify a clinical trial from consideration in support of approval of a potential product if they deem the guidelines have not been met.The FDA or foreign regulatory agencies may determine our clinical trials or other data regarding safety,efficacy or consistency of manufacture or compliance with GMP regulations are insufficient for regulatory approval.Failure to maintain or obtain regulatory approvals would materially and adversely impact us and our business prospects .~~Even if we obtain regulatory approval for our product candidates,the products may not gain market acceptance among physicians,patients,hospitals,cancer treatment centers and others in the medical community,which could materially adversely impact our business,results of operations and financial condition.Our sole pharmaceutical product candidate,nelitolimod,may never be approved for marketing as a potential cancer treatment.To the extent nelitolimod is approved for marketing as a potential cancer treatment,it may not become broadly accepted by physicians,patients,hospitals,cancer treatment centers and others in the medical community.Various factors will influence whether nelitolimod is accepted in the market,including:• the clinical indications for which nelitolimod is approved;• physicians,hospitals,cancer treatment centers and patients considering nelitolimod as a safe and effective treatment;• the potential and perceived advantages of nelitolimod over alternative treatments;• our ability to demonstrate the advantages of nelitolimod over other cancer medicines;• the prevalence and severity of any side effects;• the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;• product labeling or product insert requirements of the FDA or other regulatory authorities;• limitations or warnings contained in the labeling approved by the FDA;• the timing of market introduction of nelitolimod as well as competitive products;• the cost of treatment in relation to alternative treatments;• the availability of adequate coverage,reimbursement and pricing by third- party payors and government authorities;• the willingness of patients to pay out- of- pocket in the absence of coverage by third- party payors and government authorities;• relative convenience and ease of administration,including as compared to alternative treatments and competitive therapies;and • the effectiveness of our sales and marketing efforts.If nelitolimod is approved by the FDA but fails to achieve market acceptance among physicians,patients,hospitals,cancer treatment centers or others in the medical community,our business and prospects will be adversely affected.Even if nelitolimod achieves market acceptance,it may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than nelitolimod,are more cost- effective or render nelitolimod obsolete.In addition,although nelitolimod differs in certain ways from other approaches,serious adverse events or deaths **in other clinical trials involving precision medicines,even if not ultimately attributable to our product candidates,could result in increased government regulation,unfavorable public perception and publicity,potential regulatory delays in the testing or licensing of our product candidates,stricter labeling requirements for those product candidates that are licensed,and a decrease in demand for any such product candidates.If our products do not gain market acceptance among physicians,patients,hospitals,cancer treatment centers and others in the medical community,this could materially adversely impact our business,results of operations and financial condition.Risks Related to Our Business and Industry Changes in existing third- party coverage or our inability to secure and maintain favorable reimbursement may impact our ability to sell our products,which would materially and adversely impact our business,results of operations,financial condition and prospects.Maintaining and growing sales of TriNav,and any future product candidates,depends,in part,on the availability of coverage and adequate reimbursement from third- party payors,including government programs such as Medicare and Medicaid,private insurance plans and managed care programs.The process for determining whether a third- party payor will provide coverage for a product or procedure may be separate from the process for establishing the reimbursement rate that such a payor will pay for the product or procedure.A payor' s decision to provide coverage for a product or procedure does not imply that an adequate reimbursement rate will be approved.Further,one payor' s determination to provide coverage for a product or procedure does not assure that other payors will also provide such coverage.Adequate third- party reimbursement may not be available to enable us to achieve profitability.We may be unable to sell our products on a profitable basis if third- party payors deny coverage or reduce any existing levels of payment,or if our costs of production increase faster than increases in reimbursement levels.For example,in December 2023,CMS granted a New Technology HCPCS for procedures involving TriNav** . The new code became effective on January 1, 2024, and may be reported by hospital outpatient departments and ambulatory surgical centers, but there can be no assurance that continuing reimbursement will be available at similar reimbursement rates or at all. Any reduction in the amount of the..... similar reimbursement rates or at all. If TriNav does not receive or maintain adequate reimbursement, this would materially and adversely impact our business, results of operations, financial conditions, and prospects. Additionally, the reimbursement process is complex and can involve lengthy delays. Also, third- party payors may reject, in whole or in part, requests for reimbursement based on determinations that certain amounts are not reimbursable under plan coverage, that services provided were not medically necessary, that additional

supporting documentation is necessary, or for other reasons. Retroactive adjustments by third- party payors may be difficult or cost- prohibitive to appeal, and such changes could materially reduce the actual amount we receive. Delays and uncertainties in the reimbursement process may be out of our control and could have a material adverse effect on our business, prospects, results of operations and financial condition. Moreover, the reimbursement by third- party payors for our product and the amount that we may receive in payment for our products may be materially and adversely affected by factors we do not control, including federal or state regulatory or legislative changes, and cost- containment decisions and changes in reimbursement schedules of third- party payors or product purchasers (such as hospitals). Lack of reimbursement or any reduction or elimination of these payments could have a material adverse effect on our business, prospects, results of operations and financial condition. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the procedures using our products will be reimbursed at a cost- effective level. Additionally, we cannot be certain that third- party payors using a methodology that sets amounts based on the type of procedure performed, such as those utilized by government programs and in many privately managed care systems, will view the cost of our products to be justified so as to incorporate such costs into the overall cost of the procedure. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to achieve profitability. Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third- party payors in the future. The business and industry in which we participate are highly competitive. If we are unable to compete effectively, we will not be able to establish our products in the marketplace or maintain or grow our products' market share in the marketplace, and as a result, our business and results of operations will be adversely impacted. The biopharmaceutical and medical device industries are characterized by intense competition and rapid innovation. Our competitors may be able to develop other devices or drugs that are able to achieve similar or better results. Potential competitors for TriNav and nelitolimod include major multinational medical device and pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of these competitors have substantially greater financial, technical, and other resources than we do, such as larger research and development staff, experienced marketing and manufacturing organizations, well- established sales forces, and name recognition. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than nelitolimod or may develop proprietary technologies or secure patent protection that we may need for the development of our drug delivery technologies and products or product candidates. The availability and price, and in the case of nelitolimod, if approved, its FDA- approved labeling versus that of ~~competitors of~~ our competitors' products could limit the demand and the price we are able to charge for TriNav and nelitolimod, if approved. We may not be able to implement our business plan if the acceptance of TriNav or nelitolimod is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment, or if physicians switch to other new drug or biologic products or drug delivery systems or choose to reserve TriNav and / or nelitolimod for use in limited circumstances. For additional information regarding our competition, see the section title" Industry and Competition." We may, in the future, enter into material collaborations, in- licensing arrangements, joint ventures, or strategic alliances with third parties that may not result in the development of commercially viable products or the generation of significant or any future revenues. Alternatively, part of our strategy is to enter into such kinds of relationships with third parties involving our products and product candidates, and we may not be able to do so on acceptable terms or at all. In the ordinary course of our business, we may enter into collaborations, in- licensing arrangements, joint ventures, or strategic alliances to develop and / or commercialize our products or product candidates and / or to pursue new markets. Proposing, negotiating, and implementing collaborations, in- licensing arrangements, joint ventures, and strategic alliances may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure or complete any such transactions or arrangements in a timely manner, on a cost- effective basis, on acceptable terms, or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues or otherwise achieve their goals and could be terminated prior to developing any products. Additionally, we may not be in a position to exercise sole decision- making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self- interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or

may need to purchase such rights at a premium. Our business and growth strategy depend on the continued ability of TriNav to remain a preferred product among a community of established, board- certified physicians and other provider specialists and to expand such community. If we are unable to do so, our future growth would be limited and our business would be harmed. Our success is dependent upon the continued ability of TriNav to remain a preferred product among a community of independent, established, board- certified physicians and other provider specialists who choose to use TriNav in their medical practice. In any particular market, the hospitals that purchase TriNav for use by these providers could demand higher payments or take other actions that could result in higher costs or difficulty meeting regulatory or accreditation requirements. Our ability to develop and maintain satisfactory relationships with these providers also may be negatively impacted by other factors not associated with us, such as changes in Medicare and / or Medicaid reimbursement levels and other pressures on healthcare providers and consolidation activity among hospitals, physician groups and healthcare providers. The failure to maintain or to secure new contracts with the hospitals may result in a loss of or inability to grow our customer base, higher costs and / or healthcare provider community disruptions, any of which could harm our business. We generally do not have long- term contractual commitments from our customers, and our customers may choose not to enter into new agreements with us. We generally do not have long- term contractual commitments with our customers. Our TriNav customers can terminate many of our consignment agreements with or without cause, in some cases subject only to 30 days' prior notice in the case of termination without cause. Although a substantial majority of our revenue is typically generated from existing customers, our engagements with our customers are typically for orders that are singular in nature. Large consignment orders may involve multiple deliveries or stages, and a customer may choose not to replace inventory with TriNav devices or may cancel or delay additional planned orders. Even if we successfully deliver on contracted orders and maintain close relationships with our customers, a number of factors outside of our control could cause the loss of or reduction in business or revenue from our existing customers. The loss or diminution in business from any of our major customers could have a material adverse effect on our business, financial condition, results of operations and prospects. The ability of our customers to terminate agreements exacerbates the uncertainty of our future revenue. We may not be able to replace any customer that elects to terminate or not renew its contract with us. We may be unable to effectively manage our growth or achieve anticipated growth. The success of our future operating activities will depend upon our ability to expand our support system to meet the demands of our growing business. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the ~~areas~~ **area** of sales and marketing ~~, research, drug development and regulatory affairs~~ . Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. We will be required to manage multiple relationships with various customers, clinical investigators, manufacturers and suppliers, consultants and other third parties. This expansion and these expanded relationships will require us to significantly improve or replace our existing managerial, operational and financial systems, procedures and controls; to improve the coordination between our various corporate functions; and to manage, train, motivate and maintain a growing employee base. The time and costs to effectuate these steps may significantly strain our management personnel, systems and resources, particularly given the limited amount of financial resources and skilled employees that may be available at the time. We may not be able to institute, in a timely manner or at all, the improvements to our managerial, operational and financial systems, procedures and controls necessary to support our anticipated increased levels of operations and to coordinate our various corporate functions, or that we will be able to properly manage, train, motivate and retain our anticipated increased employee base. Any failure by our management to effectively anticipate, implement, and manage changes required to sustain our growth would have a material adverse effect on our business, financial condition, and results of operations. We cannot assure you that we will be able to successfully operate acquired businesses, if any, become profitable in the future, or effectively manage any other change. We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could adversely affect our business. Our future performance depends to a large extent on the continued services of members of our current management including, in particular, our Chief Executive Officer ~~, Chief Medical Officer~~ and Chief Financial Officer. If any of these key executive officers were to leave us, we would be forced to expend significant time and money in the pursuit of a replacement, which would result in both a delay in the implementation of our business plan and the diversion of limited working capital. The unique knowledge and expertise of these individuals would be difficult to replace. In the event that we lose the continued services of such key personnel for any reason, this could have a material adverse effect on our business, operations and prospects. In addition, we will be required over the longer- term to hire highly skilled managerial, scientific and administrative personnel to fully implement our business plan and growth strategies. Due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific, technical and managerial personnel. If we cannot attract and retain such personnel, we will be unable to develop our product candidates and achieve regulatory clearance for them, which would have a material adverse effect on our business, financial condition, and results of operations. As of ~~March 5~~ **December 31** , 2024, we had approximately ~~112~~ **110** full- time employees, ~~ten~~ **six** of whom hold advanced degrees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the ~~areas~~ **area** of sales and marketing ~~, research, drug development and regulatory affairs~~ . Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, in a timely manner or at all. In particular, we have experienced a very competitive hiring environment. Many of the other biotechnology and medical device companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we have to offer. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity incentive awards that vest over time. The value to employees of stock options or other equity awards that vest over time may be

significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams are at- will employees and may terminate their employment with us on short notice. We do not maintain " key man " insurance policies on the lives of these individuals or the lives of any of our other employees. Given the stage of our programs and our plans to expand operations, our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior personnel across the organization. Workforce shortages may continue to negatively impact our operations. Workforce shortages have resulted in staffing challenges experienced by us and by third parties that we utilize, including but not limited to manufacturing and testing organizations, CROs and clinical trial sites. If these challenges continue for any period of time, our anticipated timing of clinical trials and product development may be delayed and our product inventory may not meet demand. If we fail to promote, protect, and maintain our brand in a cost- effective manner, we may lose market share and our ability to commercialize our products and revenues will suffer. Our ability to further develop our business depends on our ability to build a strong and trusted brand. We are in the process of building our brand, and once achieved, we believe that developing, protecting, and maintaining awareness of our brand in a cost- effective manner will be critical to continuing to develop our business. Successful promotion of our brand will entail broadening our brand among physicians and hospitals and will depend largely on the effectiveness of our marketing efforts and the experience of physicians who use our products and product candidates in treating their patients. Our efforts to build our brand have involved significant expense, and we expect to increase our marketing spend in the near term. These brand promotion activities may not result in increased revenue and, even if they do, any increases may not offset the expenses incurred. Additionally, the successful protection and maintenance of our brand will depend on our ability to obtain, maintain, protect and enforce trademark and other intellectual property protection for our brand. If we fail to successfully promote, protect and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote, protect and maintain our brand, we may be unable to broaden the use of our products and product candidates among physicians and hospitals, which would have an adverse effect on our business, financial condition and results of operations. The medical device and drug development industries are characterized by rapid, continuous innovation, and if we cannot keep pace with rapid innovation in those industries, our products and product candidates will become less competitive and our ability to commercialize our products and revenues will suffer. The medical device and drug development industries are highly competitive and characterized by rapid and significant change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete or less competitive. Many of our current and potential competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Larger competitors may have substantially larger sales and marketing operations than we have or plan to have and may have greater name recognition. This may allow those competitors to spend more time with potential customers and to focus on a larger number of potential customers, which would give them a significant advantage over the sales and marketing team we would use in making sales. Larger competitors may also have broader product lines, which enable them to offer customers bundled purchase contracts and quantity discounts. These competitors may have more experience than we have in research and development, marketing, manufacturing, preclinical testing, conducting clinical studies, obtaining FDA and foreign regulatory approvals or certifications and marketing approved or certified products. Our competitors may discover technologies and techniques, or enter into partnerships and collaborations, to develop competing products that are more effective or less costly than our products or the products we may develop. There can be no assurance that other companies will not succeed in developing or marketing products that are more effective than our products or product candidates or that would render our products or product candidates obsolete or noncompetitive. Academic institutions, government agencies, and other public and private research organizations may seek patent protection regarding potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors. Our competitors may be better equipped than we are to respond to competitive pressures. Competition will likely intensify. Additionally, many healthcare provider systems are consolidating to create new companies with greater market power, and we expect that to continue. As the healthcare provider systems consolidate, competition among suppliers to healthcare provider systems will become more intense. Healthcare provider systems may try to use their market power to negotiate price concessions or reductions for our products. If we reduce our prices because of consolidation in the healthcare industry, our revenue will decrease and our results of operations and financial condition will suffer. The manufacturing of our product candidates may require outsourced, custom manufacturing, and we may encounter difficulties in production, particularly with respect to formulation, process development or scaling up of our manufacturing capabilities. If our third- party manufacturers or suppliers encounter such difficulties, our ability to provide supply of product candidates for preclinical studies, clinical trials or products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. In the course of developing our product candidates, we expect that various aspects of the development program, such as manufacturing methods, may be altered along the way to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned preclinical studies or future clinical trials. If either we or any third- party we rely on for materials used in the production of our product candidates is adversely affected by ongoing supply chain constraints, we and our third- party manufacturers may be unable to timely manufacture product candidates for our clinical trials. Although we are working to develop commercially viable manufacturing processes, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale up or formulation, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. Any of these challenges could delay completion of preclinical studies or clinical

trials, require bridging studies or trials, or the repetition of one or more studies or trials, increase development costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects. We currently rely on, and may in the future rely on, third- party contractors, including certain sole- source suppliers and manufacturers, to supply and manufacture preclinical, clinical and commercial drug supplies for nelitolimod and any future product candidates. We do not currently have the internal infrastructure to supply or manufacture preclinical, clinical or commercial quantities of our drug candidate, nelitolimod. While we have a supply of nelitolimod sufficient for our ongoing clinical trials, we do not currently have a supplier for nelitolimod. If we are not able to establish a reliable supplier for nelitolimod before our supply is exhausted, our clinical trials may be delayed. We may be unable to establish agreements and validate third- party manufacturers and suppliers or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers and suppliers entails additional risks, including, but not limited to: • reliance on the third party for sufficient quantity and quality; • the possible breach of the manufacturing or supply agreement by the third party; • failure to manufacture or supply nelitolimod according to our specifications, schedule or at all; • the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or comparator not being properly identified; • misappropriation of our proprietary information, including our trade secrets and know- how; • the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; • the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions; and • the reliance on the third party for regulatory compliance, quality assurance and safety reporting. Thus, our current and anticipated future dependence upon others for the manufacture or supply of nelitolimod or other product candidates and materials may adversely affect our development timeline, our future profit margins or our ability to commercialize nelitolimod or any future product candidates that receive marketing approval on a timely and competitive basis. We may rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. We may also have sole- source suppliers for one or more of our other product candidates. Some of the active pharmaceutical ingredients (“ APIs ”) and other substances and materials used in our product candidates are currently available only from one or a limited number of domestic or foreign suppliers and foreign manufacturers and certain of our finished product candidates are manufactured by one or a limited number of contract manufacturers. In the event an existing supplier or manufacturer fails to supply or manufacture, as applicable, product or product candidate on a timely basis or in the requested amount, fails to meet regulatory requirements or our specifications, becomes unavailable through business interruption or financial insolvency or loses regulatory status as an approved source, or if we or our manufacturers are unable to renew current supply agreements when such agreements expire and we do not have a second supplier, we likely would incur added costs and delays in identifying or qualifying replacement suppliers, manufacturers and materials and there can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. In certain cases, we may be required to get regulatory approval to use alternative suppliers and manufacturers, and this process of approval could delay the production of our products or development of product candidates indefinitely. We and our manufacturers do not currently maintain inventory of these APIs and other substances and materials. Any interruption in the supply of an API or other substance or material or in the manufacture of a finished product could have a material adverse effect on our business, financial condition, operating results and prospects. Although we are ultimately responsible for ensuring compliance with regulatory requirements such as current Good Manufacturing Practices (“ cGMPs ”), we are dependent on our contract suppliers and manufacturers for day- to- day compliance with cGMPs for production. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. Our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If our contract suppliers or manufacturers fail to achieve and maintain compliance with applicable laws and regulatory requirements, our business could be adversely affected in a number of ways, and cause, among other things: • an inability to initiate or continue clinical trials of our product candidates under development; • delay in submitting regulatory applications, or receiving regulatory approvals, for our product candidates; • third- party manufacturing facilities or our own facilities to be subjected to additional inspections by regulatory authorities; • requirements to cease distribution or to recall batches of our product candidates; • suspension of manufacturing of our products or product candidates; • revocation of obtained approvals; and • inability to meet commercial demands for our products or product candidates in the event of approval. Further, if the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws and regulatory requirements, or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates and could entail higher costs or result in us being unable to effectively commercialize our approved products on a timely basis, or at all. We expect to continue to depend on third- party contract suppliers and manufacturers for the foreseeable future, but supply and manufacturing arrangements do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. We and our contract suppliers and manufacturers may attempt to improve production processes, certain aspects of which are complex and unique, and we may encounter difficulties with new or existing processes. While we attempt to build in certain contractual obligations on such third- party suppliers and manufacturers, we may not be able to ensure that such third parties comply with these obligations. Depending on the extent of any difficulties encountered, we could experience an interruption in clinical or commercial supply, with the result that the development, regulatory approval or commercialization of our products or product candidates may be delayed or interrupted. Our risk management processes and procedures may not be effective. While we have dedicated resources to develop risk management processes and procedures intended to identify, measure, monitor and control the types of risk we are subject to, including liquidity risk, strategic risk,

operational risk, cybersecurity risk, healthcare regulatory compliance risk, product liability risk, and reputational risk, those procedures may not be effective. Risk is inherent in our business, and therefore, despite our efforts to manage risk, there can be no assurance that we will not sustain unexpected losses. We could incur substantial losses and our business operations could be disrupted to the extent our business model, operational processes, control functions, technological capabilities, risk analyses, and business / product knowledge do not adequately identify and manage potential risks associated with our business operations and strategic initiatives. There also may be risks that exist, or that develop in the future, that we have not appropriately anticipated, identified or mitigated, including when processes are changed or new products are introduced. If our risk management framework does not effectively identify and control our risks, we could suffer unexpected losses or be adversely affected, which could have a material adverse effect on our business, financial condition, and results of operations. If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we rely may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, " process ") proprietary, confidential, and sensitive data, including personal data (such as anonymized health- related data in connection with our clinical trials), intellectual property, trade secrets, business data, sensitive third- party data, business plans, transactions, financial information and patient data. As a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber- attacks, malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, which could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as a fake and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (credential stuffing attacks), credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications and electrical failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. In addition, our reliance on third- parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks and other threats to our business operations. We may rely on third- parties and third- party technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. We ~~may~~ also rely on third- parties to provide other products, services, parts, or otherwise to operate our business, including clinical trial sites and investigators, contractors, manufacturers, suppliers, and consultants. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third- parties upon which we rely experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third parties upon which rely fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or in the third parties upon which rely supply chains have not been compromised. While we have implemented security measures designed to protect against security incident, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties upon which we rely). We ~~may~~ **have** not **and may not in the future** , however, detect and remediate all such vulnerabilities on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities, which could be exploited and resulted in a security incident. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third

parties upon which we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon which we rely) to provide our services. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations ~~may~~ **have** ~~require~~ **required** us to implement and maintain specific security measures or industry- standard or reasonable security measures to protect our information technology systems and sensitive data. Additionally, applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon which we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, including government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm (including but not limited to damage to our patient, partner, or employee relationships); monetary fund diversions; interruptions in our operations (including availability of data and interruptions to our clinical trial operations); financial loss; delay in the development and commercialization of our products and product candidates; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Natural or man- made disasters and other similar events may significantly disrupt our business, and negatively impact our business, financial condition and results of operations. Our ability to make, move and sell products in coordination with our suppliers, manufacturers and business partners is critical to our success. Damage or disruption to our collective supply, manufacturing or distribution capabilities resulting from weather, any potential effects of climate change, natural disasters, pandemics or other outbreaks of contagious diseases, fire, explosion, cyber- attacks, terrorism, strikes, repairs or enhancements at facilities manufacturing or delivering TriNav or other reasons could impair our ability to manufacture, sell or timely deliver TriNav to customers and patients. Further, such damage or disruption to the supply, manufacturing, or trial sites of nelitolimod could impair our ability to complete our clinical trials on a timely basis, if at all. We rely on a limited number of third- party suppliers and manufacturers. Adverse events affecting such suppliers or manufacturers may limit our ability to obtain the materials they supply or manufacture for us, or alternatives at competitive prices, or at all. Competitors can be affected differently by weather conditions and natural disasters depending on the location of their suppliers and operations. Failure to take adequate steps to reduce the likelihood or mitigate the potential impact of such events, or to effectively manage such events if they occur, particularly when materials are sourced from a single location or supplier or produced by a single manufacturer, could adversely affect our business, financial condition, results of operations and / or require additional resources to restore our supply chain or manufacturing capabilities, as applicable. Any acquisitions, strategic investments, entries..... us to ongoing obligations and liabilities. Risks Related to Our Legal and Regulatory Environment We are subject to numerous complex regulatory requirements, and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business. The research, pre- clinical testing, clinical trials, manufacturing, marketing and distribution of medical devices, human drugs and biologics and combination products are subject to regulation by numerous governmental authorities in the United States and other jurisdictions, if we desire to export the resulting products to such other jurisdictions. These regulations govern or affect the testing, manufacture, safety, effectiveness, labeling, storage, record- keeping, approval or clearance, distribution, advertising and promotion of product candidates, as well as safe working conditions. In some cases, the FDA requirements have increased the amount of time and resources necessary to develop new products and bring them to market in the United States. The FDA and foreign regulatory authorities have substantial discretion to require additional testing, to delay or withhold registration and marketing approval or clearance and to otherwise preclude distribution and sale of a product. In addition, regulatory approval or clearance could impose limitations on the indicated or intended uses for which product candidates may be marketed, and impose post- approval requirements. Our failure to obtain approval or clearance, significant delays in the approval or clearance process, or our failure to maintain approval or clearance in any jurisdiction will prevent us from selling any applicable products in that jurisdiction. We would not be able to realize revenues for those new products in any jurisdiction where we do not have approval or clearance. Even after a product candidate has been approved **or cleared** , the FDA and comparable governmental authorities subject such product to continuing review and regulatory requirements including, for example, the reporting of safety issues or adverse events associated with use of an approved drug or cleared or approved device. These authorities may, in certain circumstances, require us to conduct and report the results of certain clinical studies or trials and to commit to voluntarily conducting additional clinical trials. Developments following regulatory approval or clearance may adversely affect sales of our products. Failure to comply with, or changes to applicable regulatory requirements may result in a variety of consequences, including the following: • restrictions on our products or the manufacturing processes of such products; • warning letters, untitled letters and cyber letters; • withdrawal of a product from the market; • voluntary or mandatory recall of a product; • fines; • suspension or withdrawal of regulatory approvals or clearances for a product; • suspension of any ongoing clinical trials; • refusal to permit the import or export of our products; • refusal to **clear or** approve pending applications or supplements to **cleared or** approved applications that we submit; requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization; • denial of permission to file an application or supplement in a jurisdiction; • debarment, exclusion from participation in federal

healthcare programs, exclusion or debarment from government contracting, consent decrees, or corporate integrity agreements; • seizure or detention of products; and • injunctions or the imposition of civil or criminal penalties against us. More stringent oversight by the FDA and other agencies in recent years has resulted in increased enforcement activity, which increases our compliance risk. To the extent that ~~we or~~ our partners **or we** do not perform particular regulated functions themselves but contract out to third parties, including contract manufacturers, contract research organizations, clinical trial sites, and laboratories, ~~we or~~ our partners **or we** may be held responsible for such third parties' failure to follow the applicable regulatory requirements. The complexity of a combination product that includes a drug and a medical device presents additional, unique development and regulatory challenges, which may adversely impact our development plans and our ability to obtain regulatory approval or clearance of our product candidates. We may decide to pursue marketing authorization for a combination product comprised of drug candidates and medical devices. A combination product includes, among other possibilities, a combination of a drug and device intended to be used together, according to their proposed labeling where both are required to achieve the intended use, indication or effect. Developing and obtaining regulatory approval or clearance for combination products pose unique challenges because they involve components that are regulated by the FDA pursuant to different regulatory frameworks and by different FDA centers. As a result, such products raise regulatory, policy and review management challenges. For example, because divisions from both FDA' s Center for Drug Evaluation and Research and FDA' s Center for Devices and Radiological Health must review submissions concerning product candidates that are combination products comprised of drug and devices, the regulatory review and approval for these products may be lengthened. In addition, differences in regulatory pathways for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees and post- approval modifications. Similarly, the device components of our product candidates will require any necessary approvals or clearances or other marketing authorizations or certifications in other jurisdictions, which may prove challenging to obtain. We intend to use the FDA' s expedited drug development programs for nelitolimod but may not be able to achieve expedited development or approval for this product candidate. The FDA has established various expedited drug development programs to facilitate more rapid and efficient development, review and approval of certain types of drugs. Such programs include fast track designation, breakthrough therapy designation, accelerated approval, and priority review. We intend to use one or more expedited drug development programs for nelitolimod. The FDA has broad discretion on whether or not to admit a drug candidate for these programs, so even if we believe a particular product candidate is eligible for an expedited drug development program, we cannot assure you that the FDA would agree. Even if any of our product candidates is admitted to any of the expedited drug development programs, we may not experience a faster development process, review or approval compared to conventional FDA approval timelines, and the FDA may still decline to approve such product candidates. Fast track designation is designed to facilitate the development and expedite the review of therapies for serious conditions that fill an unmet medical need. Programs with fast track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. If any of our product candidates receive fast track designation but do not continue to meet the criteria for fast track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply or due to other issues, we will not receive the benefits associated with the fast track program. Fast track designation alone does not guarantee qualification for the FDA' s priority review procedures. FDA may award breakthrough therapy designation to a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Designation as a breakthrough therapy is within the discretion of the FDA. Even if one or more of our product candidates qualify as breakthrough therapies pursuant to FDA standards, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek breakthrough therapy designation for one or more of our current or future product candidates, there can be no assurance that we will receive breakthrough therapy designation. If any of our programs or product candidates receive fast track or breakthrough therapy designation by the FDA or similar designations by other regulatory authorities, there is no assurance that we will receive any benefits from such programs or that we will continue to meet the criteria to maintain such designation. Even if we obtain such designations, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A fast track or breakthrough therapy designation does not ensure that a product candidate will receive marketing approval or that approval will be granted within any particular time frame. In addition, the FDA may withdraw any such designation if it believes that the designation is no longer supported by data from our clinical development program upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of nelitolimod or any future product candidates. Any marketing approval we or our collaborators ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. ~~Even if we receive orphan drug designation for any of our product candidates, we may be unable to maintain the benefits associated with such designation, including the potential for market exclusivity.~~

Regulatory authorities in some jurisdictions, including the United States and the EU, may also designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually 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, the EMA' s Committee for Orphan Medicinal Products evaluates 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 five in 10, 000 persons in the EU. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers, and it may entitle the therapeutic to exclusivity. Regulatory authorities may not grant our requests for orphan designation or may require submission of additional data before making such determination. Even if we receive orphan drug designation for any of our product candidates, there is no guarantee that it will obtain approval or orphan drug exclusivity for such product candidates. Even if we obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect the product candidates from competition because different therapies can be approved for the same condition and the same therapy could be approved for different conditions. Even after an orphan drug is approved, the FDA can subsequently approve a different drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the disease for which it received orphan designation. On January 24, 2023, the FDA announced its intention to apply its existing regulations and long- standing approach to grant orphan drug exclusivity based on the indications for which the drug is approved rather than granting the exclusivity for the entire rare disease or condition that was the subject of the orphan drug designation, in response to the U. S. Court of Appeals for the Eleventh Circuit' s September 30, 2021, decision in Catalyst P harms., Inc. v. Becerra. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Further, under the Inflation Reduction Act of 2022 (" IRA "), orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA' s Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known. Disruptions at the FDA, SEC and other government agencies (e. g., CMS) caused by funding shortages or global health concerns could hinder our ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices, drugs or biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States government has shut down several times, certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs , it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Separately, in response to the COVID- 19 pandemic, the FDA had to postpone inspections of foreign and domestic manufacturing facilities and products. While such inspections have resumed, the FDA may use remote interactive evaluations where in- person inspections are not feasible or may defer action due to factors including travel restrictions. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities , it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Accordingly, if we or any future collaborators experience delays in obtaining approval or clearance or if we or they fail to obtain approval or clearance of nelitolimod or any future product candidates, the commercial prospects for these product candidates may be harmed, and our ability to generate revenues will be materially impaired. Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval or clearance process is expensive, time- consuming and uncertain and may prevent us from obtaining approvals or clearances for the commercialization of nelitolimod or any future product candidates. If we or any future collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals or clearances, we or they will not be able to commercialize nelitolimod, and our ability to generate revenue will be materially impaired. The activities associated with nelitolimod or other product candidates' development and commercialization, including testing, manufacturing, safety, efficacy, record keeping, labeling, storage, approval or clearance, advertising, promotion, sale and distribution, export and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States. Additionally, in order to commercialize, develop, market and sell our products in the

EU, Canada, the United Kingdom, China or other countries and many other jurisdictions, we or our third- party collaborators must obtain separate marketing approvals or clearances and comply with numerous and varying regulatory requirements for comparable regulatory authorities in these other countries. Failure to obtain marketing approval or clearance for nelitolimod or any future product candidates will prevent us from commercializing them. We have not received approval to market nelitolimod from regulatory authorities in any jurisdiction. We have limited experience in the designing of clinical trials, in obtaining authorization and in conducting clinical trials in various countries and expect to rely on third- party CROs to assist us in this process. Securing marketing approval or clearance requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to the various regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Nelitolimod or any future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or clearance or prevent or limit commercial use. The success of our product candidates will depend on several additional factors, including: ◦ successful completion of preclinical studies; ◦ successful initiation of, patient enrollment in, and completion of clinical trials that demonstrate their safety and efficacy; ◦ receiving marketing approvals or clearances from applicable regulatory authorities; ◦ obtaining, maintaining, protecting and enforcing patent, trade secret and other intellectual property rights and regulatory exclusivity for our product candidates; ◦ completing any post- marketing studies required by applicable regulatory authorities; ◦ making and maintaining arrangements with third- party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates; ◦ establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; ◦ the prevalence and severity of adverse events experienced with our product candidates; ◦ acceptance of our product candidates by patients, the medical community and third- party payors; ◦ a continued acceptable safety profile following approval or clearance; ◦ obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates; ◦ competing effectively with other cancer therapies, including with respect to the sales and marketing of our product candidates, if approved; ◦ obtaining licenses to any third- party intellectual property we deem necessary or desirable; and ◦ obtaining any necessary third- party agreements to register nelitolimod as part of a combination therapy. Many of these factors are beyond our control, including the time needed to adequately complete preclinical studies, clinical testing and the regulatory submission process, our ability to obtain and protect intellectual property rights and changes in the competitive landscape. It is possible that none of our product candidates will ever obtain regulatory approval or clearance, even if we expend substantial time and resources seeking such approval or clearance. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We or any future third- party collaborators may not obtain approvals or clearances from regulatory authorities outside the United States on a timely basis, if at all. Approvals or clearances by the FDA does not ensure approval or clearance by regulatory authorities in other countries or jurisdictions, and approval or clearance by one regulatory authority outside the United States does not ensure approval or clearance by regulatory authorities in other countries or jurisdictions or by the FDA. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or clearance or, if approved, commercialize our product candidates, which would materially harm our business, financial condition, results of operations and prospects. ~~We may in the future develop product candidates in combination with other therapies and that may expose us to additional risks We may develop future product candidates for use in combination with one or more currently approved therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our products being removed from the market or being less successful commercially. We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell our product candidates we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or similar foreign regulatory authorities do not approve or revoke the approval of these other drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs that we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates.~~ Even if we obtain regulatory approval or clearance for nelitolimod or any future product candidates, such product candidates will remain subject to ongoing regulatory oversight. Even if we obtain regulatory approval or clearance for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record- keeping. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP regulations and GCPs, for any clinical trials that we conduct post- approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals or clearances that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval or clearance, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, that may require surveillance requirements regarding monitoring the safety and efficacy of the product candidate. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. If we receive marketing approval or clearance for any future product candidates we may develop, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent

with the approved label. However, if we are found to have promoted such off- label uses, we may become subject to significant liability. The FDA may also require a Risk Evaluation and Mitigation Strategies (" REMS ") as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA' s and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval or clearance of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval or clearance that we may have obtained and we may not achieve or sustain profitability. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co- marketers fails to comply with regulatory requirements, the regulators could take various actions. These include: ◦ issuing warning or untitled letters; ◦ seeking an injunction or imposing civil or criminal penalties or monetary fines; ◦ suspension or imposition of restrictions on operations, including product manufacturing; ◦ seizure or detention of products, refusal to permit the import or export of products or request that we initiate a product recall; ◦ suspension or withdrawal of our marketing authorizations; ◦ suspension of any ongoing clinical trials; ◦ refusal to approve pending applications or supplements to applications submitted by us; or ◦ requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could harm our business, financial condition, results of operations and prospects. In particular for TriNav and the pancreatic retrograde venous infusion (" PRVI ") device and any future medical device product candidate, we and our third- party suppliers are required to comply with the FDA' s Quality System Regulation (" QSR "). These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we or our manufacturers fail to adhere to QSR requirements in the United States, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations. In addition, the FDA assesses compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the enforcement actions listed above. Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. If any of our product candidates receives marketing approval or clearance and we or others later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the product could be compromised. Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives regulatory approval or clearance, and we or others later discover that such product candidates are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including: ◦ withdrawal or limitation by regulatory authorities of approvals or clearances of such product; ◦ seizure of the product by regulatory authorities; ◦ recall of the product; ◦ restrictions on the marketing of the product or the manufacturing process for any component thereof; ◦ requirement by regulatory authorities of additional warnings on the label, such as a " black box " warning or contraindication; ◦ requirements that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients; ◦ commitment to expensive additional safety studies prior to approval or clearance or post-marketing studies required by regulatory authorities of such product; ◦ adverse impact on the product' s competitiveness; ◦ initiation of regulatory investigations and government enforcement actions; ◦ initiation of legal action against us to hold us liable for harm caused to patients; and ◦ harm to our reputation and resulting harm to physician or patient acceptance of our products Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could harm our business, financial condition, results of operations and prospects. Healthcare reform and other governmental and private payor initiatives may have an adverse effect upon, and could prevent, the commercial success of our products or product candidates. In the U. S. and in certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably, such as the Patient Protection and Affordable Care Act, as amended by the Health Care and Education ~~Affordability~~ Reconciliation Act of 2010, or collectively the Affordable Care Act (" ACA "). Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect that there will be additional challenges and amendments to the ACA in the future. For example, on June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (" IRA ") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by

significantly lowering the beneficiary maximum out- of- pocket cost and creating a newly established manufacturer discount program. Other legislative changes have been proposed and adopted in the U. S. since the ACA was enacted. **These changes** ~~In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach the required goals, thereby triggering the legislation' s automatic reduction to several government programs. This includes~~ **include** aggregate reductions ~~of~~ **to** Medicare payments to providers of 2 % per fiscal year ~~that~~ **pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments,** will remain in effect ~~through~~ **until** 2032 unless additional congressional action is taken **.** . There has been increasing legislative and enforcement interest in the U. S. with respect to prescription- pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the U. S. Department of Health and Human Services (" HHS ") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single- source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~take~~ **took** effect progressively starting in fiscal year 2023. On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list~~ **agreed- upon reimbursement prices** of the first ten drugs that **were** ~~will be~~ subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges **. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare drug price negotiation program** . In response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services, or CMS, Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on ~~December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act. On~~ December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework. We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on reimbursement price that we receive for any cleared, authorized, or approved device, or any of our product candidates in the future, if approved. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory clearance, authorization, or approval and that may affect our overall financial condition and ability to develop product candidates. **Additional health reform measures may continue and affect our business in unknown ways, particularly given the recent change in administration. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration' s executive order that directed HHS to establishing an AI task force and developing a strategic plan, and directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.** If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates that we may develop may lose any regulatory clearance, authorization, or approval that may have been obtained and we may not achieve or sustain profitability. TriNav and the PRVI device must be manufactured in accordance with federal and foreign regulations, and we or any of our suppliers or third- party manufacturers could be forced to recall the products or terminate production if we fail to comply with these regulations. The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, component failures, unapproved or improper use of our products, or inadequate disclosure of risks or other information relating to the use of our products can lead to injury or other serious adverse events. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies

or defects in design or manufacture. For the FDA, the authority to require a recall must be based on a finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our international distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or another third- country competent authority. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or another third- country competent authority. If the FDA disagrees with our determinations, the FDA could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report recalls. We are also required to follow detailed recordkeeping requirements for all firm- initiated medical device corrections and removals. If treatment guidelines for the cancer indications that we are targeting change or the standard of care evolves, we may need to redesign our preclinical or clinical trials of, or seek new marketing authorization from, the FDA for any approved products. If treatment guidelines for the cancer indications that we are targeting change or the standard of care evolves, We may need to redesign TriNav, the PRVI device or any product candidates and seek new clearances or approvals from the FDA for any approved products. Our 510 (k) clearances from the FDA for TriNav, TriNav Large and the PRVI device are based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of TriNav and the PRVI device could be diminished, and our business could suffer. Competition by other forms of cancer treatment, for example, the development of new and more efficacious systemic therapies, could reduce the use of regional therapy as a standard of care in certain indications. Changes in treatment guidelines or standard of care may also impact product coverage and / or reimbursement by ~~payers~~ **payors** ~~. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delays. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval or clearance and commercialization, it is common that various aspects of the development activities, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause nelitolimod or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, including comparability testing, to bridge earlier clinical data obtained from nelitolimod produced under earlier manufacturing methods or formulations, and regulatory authorities may disagree on the interpretation of results from this testing. This could delay the completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of nelitolimod or any future product candidates and jeopardize our ability to commence sales and generate revenue~~ . Our relationships with customers, hospitals, physicians, and third- party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security 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 United States and elsewhere, will play a primary role in the recommendation of TriNav and the PRVI device and prescription of any product candidates for which we obtain marketing approval or clearance. Our current and future arrangements with healthcare professionals, principal investigators, consultants, hospitals, customers and third- party payors subject us to various federal and state fraud and abuse laws, data privacy and security laws, transparency laws and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute TriNav and the PRVI device, and any other any future products candidates once they have obtained marketing authorization. Restrictions under applicable federal and state healthcare laws and regulations, include the following: • The federal Anti- Kickback Statute, which prohibits, among other things, a person or entity from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease order, arranging for or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, by a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, a violation of the Anti- Kickback Statute can form the basis for a violation of the federal False Claims Act (discussed below); • Federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, which provides for civil whistleblower or qui tam actions, that impose penalties against individuals or entities for knowingly presenting or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a referral made in violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • The Health Insurance Portability and Accountability Act (" HIPAA ") which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific

intent to violate it in order to have committed a violation; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“ HITECH ”), and their implementing regulations, which impose obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses as well as their business associates and subcontractors that perform certain services involving the use or disclosure of individually identifiable health information; • The federal transparency requirements known as the federal Physician Payments Sunshine Act, created as part of ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’ s Health Insurance Program to report annually to the CMS information related to payments and other transfers of value made by that entity to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and • Analogous local, state and foreign laws and regulations, such as state anti- kickback and false claims laws that may apply to healthcare items or services reimbursed by third- party payors, including private insurers. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations. If the physicians or other providers or entities with whom we do, or expect to do, business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have a material adverse effect on our ability to compete in the marketplace. We could be subject to litigation that could have an adverse effect on our business and operating results. We are, from time to time, involved in litigation. The numerous operating hazards inherent in our business increase our exposure to litigation, which may involve, among other things, contract disputes, personal injury, environmental, employment, warranty and product liability claims, tax and securities litigation, patent infringement and other intellectual property claims and litigation that arises in the ordinary course of business. Our management cannot predict with certainty the outcome or effect of any claim or other litigation matter. Litigation may have an adverse effect on us because of potential negative outcomes such as monetary damages or restrictions on future operations, the costs associated with defending the lawsuits, the diversion of management’ s resources and other factors. Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop. We are developing additional sizes of, and uses for, the TriNav device. Our **products and** product candidates **are** ~~may be~~ used in connection with medical procedures in which it is important that those products function with precision and accuracy. If our existing TriNav device or our product candidates, if approved, do not function as designed, or are designed improperly, we may be forced by regulatory agencies to withdraw such products from the market. In addition, the use of our product candidates in clinical trials, the **use and possible misuse of our TriNav device in medical procedures, the** sale of any products **and any product candidates** for which we obtain marketing approval, and other liability risks that are inherent in the testing, manufacturing, marketing and sale of medical devices exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs, which may not be covered by insurance. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition and results of operations. In addition, regardless of merit or eventual outcome, product liability claims may result in: ◦ impairment of our business reputation and significant negative media attention; ◦ withdrawal of participants from our clinical trials; ◦ injury to our reputation; ◦ initiation of investigations by regulators; ◦ significant costs to defend the related litigation and related litigation; ◦ distraction of management’ s attention from our primary business; ◦ substantial monetary awards to patients or other claimants; ◦ inability to commercialize a product candidate; ◦ product recalls, withdrawals or labeling, marketing or promotional restrictions; ◦ exhaustion of any available insurance and our capital resources, and the inability to commercialize any product candidate; ◦ decreased demand for ~~a~~ **our products and any** product candidate ~~, if~~ **that is** approved for commercial sale; and ◦ loss of revenue. Although we currently carry clinical trial insurance and product liability insurance which we believe to be reasonable, such insurance may not be adequate to cover all liability that we may incur. An inability to renew our policies or to obtain sufficient insurance at an acceptable cost could prevent or inhibit the commercialization of pharmaceutical products that we develop, alone or with collaborators. We ~~may be~~ **and the third parties with whom we work are** subject to stringent and evolving U. S. and foreign laws, regulations, and rules, contractual obligations, policies and other obligations related to data privacy and security. Our **(or the third parties with whom we work)** actual or perceived failure to comply with such

obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences. In the ordinary course of business, we process sensitive data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, HIPAA as amended by HITECH imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In the past few years, numerous states ~~- including California, Virginia, Colorado, Connecticut, and Utah -~~ have passed comprehensive privacy laws which impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ~~, as amended by the California Privacy Rights Act of 2020 (" CPRA "), (collectively, "~~ CCPA ") applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines ~~of up to $ 7, 500 per intentional violation~~ and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data maintained about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and may increase legal risk and compliance costs to us and the third parties upon which we rely. Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the EU' s General Data Protection Regulation (" EU GDPR ") imposes strict requirements for processing personal data, and, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 **. 0** million Euros or 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross- border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (" EEA ") and the United Kingdom (" UK ") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt **or have already adopted** similarly stringent ~~interpretations of their~~ data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we could satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, we could face significant adverse consequences. In addition to data privacy and security laws, we **are** ~~may be~~ contractually subject to industry standards adopted by industry groups and **we are, and** may become **in the future** subject to such obligations in the future. We ~~may~~ **are** also ~~be~~ bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self- regulatory principles, regarding data privacy and security. ~~If~~ **Regulators in the United States are increasingly scrutinizing these statements and if** these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, **misleading** or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on which we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- action claims) and mass arbitration demands; additional reporting requirements and / or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in

bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. Changes in tax law and differences in interpretation of tax laws and regulations may adversely impact our financial statements. We operate in multiple jurisdictions and are subject to tax laws and regulations of the U. S. federal, state and local and non- U. S. governments. U. S. federal, state and local and non- U. S. tax laws and regulations are complex and subject to change and varying interpretations. For instance, the IRA imposes, among other rules, a 15 % minimum tax on the book income of certain large corporations and a 1 % excise tax on certain corporate stock repurchases. U. S. federal, state and local and non- U. S. tax authorities may interpret tax laws and regulations differently than we do and challenge tax positions that we have taken. This may result in differences in the treatment of revenues, deductions, credits and / or differences in the timing of these items. The differences in treatment may result in payment of additional taxes, interest or penalties that could have an adverse effect on our financial condition and results of operations. Further, future changes to U. S. federal, state and local and non- U. S. tax laws and regulations could increase our tax obligations in jurisdictions where we do business or require us to change the manner in which we conduct some aspects of our business. Our ability to use our net operating loss carryforwards and certain other tax attributes is limited. We have incurred losses during our history. Unused federal net operating losses (“ NOLs ”) for taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under current law, federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ ownership change, ” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period, the corporation’ s ability to use its pre- change NOLs and other pre- change tax attributes (such as research tax credits) to offset its post- change income or taxes may be limited. We have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. **For example, California recently imposed limits on the usability of California state NOL carryforwards and certain state tax credits in tax years beginning after 2023 and before 2027.** These factors could limit our ability to use our NOLs and other tax attributes, which could adversely affect our future cash flows or results of operations. Risks Related to Our Intellectual Property Failure to obtain, adequately protect, maintain or enforce our intellectual property rights could substantially harm our business and results of operations. Our success depends in part on our ability to obtain and maintain protection for our owned and in- licensed intellectual property rights and proprietary technology. We rely on a combination of patents, trademarks, trade secret protection and confidentiality agreements, including in- licenses of intellectual property rights of others, to protect our current or future platform technologies, products, product candidates, methods used to manufacture our current or future product candidates and methods for treating patients using our current or future product candidates. We own or in- license patents and patent applications relating to our platform technologies, products and product candidates. There is no guarantee that any patents covering our platform technologies or product candidates will issue from the patent applications we own, in- license or may file in the future, or, if they do, that the issued claims will provide adequate protection for our platform technologies or product candidates, or any meaningful competitive advantage. Further, there cannot be any assurance that such patents issued will not be infringed, designed around, invalidated by third parties or effectively prevent others from commercializing competitive technologies, products or product candidates. The patent prosecution process is expensive, complex and time- consuming. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in- license may fail to result in issued patents, and, even if patents are issued, such patents may not cover our current or future technologies or product candidates in the United States or in other countries or provide sufficient protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We do not have exclusive control over the preparation, filing and prosecution of patent applications under certain of our in- license agreements, and we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents that we out- licenses to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Even if our owned or in- licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non- infringing manner. Further, although we make reasonable efforts to ensure patentability of our inventions, we cannot guarantee that all of the potentially relevant prior art relating to our owned or in-licensed patents and patent applications has been found. For example, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published

until 18 months after filing, and in some cases not at all. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our product candidates, or the use of our technologies. We thus cannot know with certainty whether we or our licensors were the first to file for patent protection of such inventions. In addition, the United States Patent and Trademark Office (" USPTO ") might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. There is no assurance that all potentially relevant prior art relating to our owned or in- licensed patent applications has been found. For this reason, and because there is no guarantee that any prior art search is correct and comprehensive, we may be unaware of prior art that could be used to invalidate an issued patent or to prevent our owned or in- licensed patent applications from issuing as patents. Invalidation of any of our patent rights, including in- licensed patent rights, could materially harm our business. Moreover, the patent positions of biotechnology and medical device companies like us are generally uncertain because they may involve complex legal and factual considerations that have, in recent years, been the subject of legal development and change. The relevant patent laws and their interpretation, both inside and outside of the United States, are also uncertain. Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our platform technology or product candidates and could affect the value of such intellectual property. Our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe, misappropriate or otherwise violate our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our platform technology, product candidates, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our owned or licensed pending patent applications or with respect to any patent applications we may file or license in the future, nor can we be sure that any patents that may be granted to us or our licensors in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Additionally, third parties, including our former employees and collaborators, may challenge the ownership or inventorship of our patent rights to claim that they are entitled to ownership and inventorship interest, and we may not be successful in defending against such claims. However, we are not currently facing any such challenges. Moreover, issued patents do not guarantee the right to practice our technology in relation to the commercialization of our products. Issued patents only allow us to block — in some cases — potential competitors from practicing the claimed inventions of the issued patents. The issuance, scope, validity, enforceability and commercial value of our pending patent rights are uncertain. The standards applied by the USPTO and foreign patent offices in granting patents are not always certain and moreover, are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in patents. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned or in- licensed patent applications or narrow the scope of any patent protection we may obtain from our owned or in- licensed patent applications. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Further, patents and other intellectual property rights in the pharmaceutical, biotechnology and medical device space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and any future product candidates and practicing our proprietary technology, and any issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our products, product candidates and any future product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors or other parties with similar technology. Additionally, our competitors may initiate legal proceedings, such as declaratory judgment actions in federal court or reexaminations or an inter partes review at the USPTO in an attempt to invalidate or narrow the scope of our patents. However, we are not currently facing any such proceedings. Furthermore, our competitors or other parties may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our products, product candidates and any future product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product candidate may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides. Even if patents do successfully issue from our owned or in- licensed patent application, and even if such patents cover our current or any future products or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any current or future products or product candidates that we may develop. Likewise, if patent applications we own or have in- licensed with respect to our development programs and current or future products or product candidates fail to issue, if their breadth or strength is threatened, or if they fail to provide meaningful exclusivity, other companies could be dissuaded from collaborating with us to develop current or future products or product candidates. Lack of valid and enforceable patent protection could threaten our ability to commercialize current or future products and could prevent us from maintaining exclusivity with respect to the invention or feature claimed in the patent applications. Any failure to obtain or any loss of patent protection could have a material adverse impact on our business and ability to achieve profitability may be unable to prevent competitors from entering the market with a product that is similar or identical to any of our products or current or potential future product candidates or from utilizing technologies similar to those in our products or current product candidates. The filing of a patent application or the issuance of a patent is not conclusive as to our ownership, inventorship, scope, patentability, validity or enforceability. Issued

patents and patent applications may be challenged in the courts and in the patent office in the United States and abroad. For example, our patent applications or patent applications filed by our licensors, or any patents that grant therefrom, may be challenged through third- party submissions, opposition or derivation proceedings. By further example, any issued patents that may result from our owned or in- licensed patent applications may be challenged through reexamination, inter partes review or post- grant review proceedings before the USPTO, or in declaratory judgment actions or counterclaims. An adverse determination in any such submission, proceeding or litigation could prevent the issuance of, reduce the scope of, invalidate or render unenforceable our owned or in- licensed patent rights, result in the loss of exclusivity, limit our ability to stop others from using or commercializing similar or identical products and product candidates, or allow third parties to compete directly with us without payment to us. In addition, if the breadth or strength of protection provided by any patents that might result from our owned or in- licensed patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, we currently co- own certain patents and patent applications with third parties and may in the future co- own additional patents and patent applications with third parties. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such patents or patent application, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co- owners to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects and financial conditions. Our in- licensed patent rights may be subject to a reservation of rights by one or more third parties, such as the U. S. government. In addition, our rights in such inventions may be subject to certain requirements to manufacture product candidates embodying such inventions in the United States. Any exercise by the U. S. government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. The expiration or loss of patent protection may adversely affect our future revenues. We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of our products and product candidates. In particular, patent protection is important in the development and eventual commercialization of our product candidates. Patents covering our product candidates normally provide market exclusivity, which is important in order to improve the probability that our product candidates are able to become profitable. Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the U. S. and other countries with respect to our products and product candidates. The patent positions of biotechnology and medical device companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the U. S. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our products and product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our products and product candidates may be impaired. As of ~~April 3~~ **December 31**, 2024, we owned at least ~~122~~ **79** registered patents. Our issued U. S. patents expire between ~~2024~~ **2030** and 2040. All of our solely- owned granted U. S. and foreign patents that relate to composition of matter for nelitolimod ~~will expire~~ **expired** in December 2023. Upon expiration of the patents covering nelitolimod, third parties, including other biopharmaceutical companies, will be able to obtain or use nelitolimod other than to the extent we have other patent protection ~~, including through our method of use patents for pressure controlled therapeutic delivery~~. In addition, certain of our patents relating to the use of TriNav will expire beginning in 2031, with additional patents relating to TriNav expiring in 2036 and 2038. While we are seeking additional patent coverage, there can be no assurances that such additional patent protection will be granted, or **,** if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. We also intend to apply for orphan drug designation and orphan designation **for nelitolimod** in the U. S. and EU, respectively, which, if granted, would extend the **regulatory** exclusivity period beyond the initial five years of regulatory exclusivity **for a New Chemical Entity (" NCE")** from the date of approval in the U. S. and beyond the eight years of data exclusivity from the date of approval in Europe; however, there can be no assurance that we will ever obtain approval or orphan drug exclusivity for such product candidates. Without patent protection of our product candidates, we may be open to competition from generic versions of such **products** ~~methods and compositions~~. As of ~~April 3~~ **December 31**, 2024, we have at least ~~69~~ **88** pending ~~patent applications and four U. S. provisional~~ patent applications. We do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology and drugs, in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. Even if we are successful in obtaining a patent, patents have a limited lifespan. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection of our product candidates, we may be open to competition from generic versions of such **drug products** ~~methods and compositions~~. There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to

our product candidates. Furthermore, as our issued patents expire, the risk that competitors may be able to circumvent our remaining patents by developing similar or alternate technologies or products in a non- infringing manner is increased. If we do not obtain protection under the Hatch- Waxman Amendments by extending the patent term, our business may be harmed. Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our products and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension, or PTE, under the Drug Price Competition and Patent Term Restoration Act of 1984 (the " Hatch-Waxman Amendments "). The Hatch- Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time- period or the scope of patent protection afforded could be less than we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following expiration of our regulatory exclusivity and our patent expiration, and launch their product earlier than might otherwise be the case. We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business. Filing, prosecuting and defending patents covering our products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does and novel formulations of existing drugs and manufacturing processes may not be patentable in certain jurisdictions. Further, future licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products or product candidates and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and medical device products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while it intends to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products and product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our products and product candidates in all of our expected significant foreign markets. Additionally, the requirements for patentability may differ in certain countries. Generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensees or any future licensors to engage in complex, lengthy and costly litigation or other proceedings. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensees or any future licensors may have limited remedies if patents are infringed or if we and our licensees or any future licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights in some regions of the world may be inadequate to obtain a significant commercial advantage from our intellectual property. We may be subject to claims that we or our employees, consultants, contractors or advisors have infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership

of what we regard as our own intellectual property. Many of the contributors to our intellectual property, including patents and applications, were previously employed at universities or other biotechnology, pharmaceutical or medical device companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information, know- how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our business. In addition, while we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. To the extent that we fail to obtain such assignments, such assignments do not contain a self- executing assignment of intellectual property rights, or if such assignments are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our products or product candidates. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. Our business model may require reliance on third parties and the need to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed, and if we are unable to protect the confidentiality of our trade secrets, the value of our intellectual property could be materially adversely affected and our business would be harmed. In addition to seeking patents for some of our products and product candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, in seeking to develop and maintain a competitive position. Because we rely on third parties to manufacture our product candidates and we may collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, corporate collaborators, outside scientific collaborators, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know- how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Since our inception, we have sought to contract with manufacturers to supply commercial quantities of pharmaceutical formulations. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers and suppliers. We believe that these disclosures, while necessary for our business, may result in the attempt by potential manufacturers and suppliers to improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing and supplier rights. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed. Trade secrets and know- how can be difficult to protect as trade secrets and know- how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If we fail to prevent material disclosure of the know- how, trade secrets and other intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us. We may not be able to prevent misappropriation of our trade secrets or other proprietary and confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may seek to market generic versions of nelitolimod or any other product candidate for which we may in the future obtain approval by submitting abbreviated new drug applications (" ANDAs") or biosimilar applications to the FDA or new products that use our approved products as the reference listed drug **or biologic** , in each case where our competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with nelitolimod and any future product candidates we may develop. In these circumstances, we may need to defend or assert our

patents, by means including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if patents are valid and enforceable, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Furthermore, as our issued patents expire, the risk that competitors may be able to circumvent our remaining patents by developing similar or alternate technologies or products in a non- infringing manner is increased. Additionally, competitors could purchase TriNav or our other products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. We ~~have in the past been, and~~ may ~~in the future~~ be ~~,~~ subject to claims challenging the inventorship or ownership of our patents and other intellectual property. The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability, and our owned and licensed patents have in the past been, and in the future may be, challenged in the courts or patent offices in the United States and abroad. **We** ~~For example, in October 2017, an individual filed a suit against Legacy TriSalus in the United States District Court, District of Colorado asserting joint inventorship of six patents assigned to Legacy TriSalus. The individual sought to be added as a co- inventor and co- owner of the patents in question. A stipulated dismissal order was entered in June 2021 with the court dismissing the plaintiff' s case with prejudice. In the future, we~~ may face ~~similar or other~~ challenges by third parties, former employees or collaborators with respect to ownership interest in the patents and intellectual property that we own or license at the time. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our products or product candidates. While it is our policy to require employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as Legacy- TriSalus owned. To the extent that we license intellectual property from a third party, such licensors may face similar obstacles. In addition, we have not updated the records in certain foreign patent offices to reflect our ownership of certain **expired** foreign patents relating to nelitolimod, but have recorded our ownership for at least the ~~unexpired~~ -- **expired** foreign patents acquired from Dynavax relating to composition of matter for nelitolimod in Australia, Canada, Austria, Germany, Denmark, Estonia, the UK, Hong Kong, Ireland, Luxembourg, Portugal, New Zealand, and Singapore. Failure to update such ownership may result in a purchaser potentially acquiring rights in such patents that are adverse to our interests. Litigation may be necessary to defend against any claims challenging inventorship or ownership and such litigation may be costly. If we fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our products and product candidates. To the extent undertaken, we cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of our products and product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, certain United States patent applications can remain confidential until patents issue. Therefore, patent applications covering our products and product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our products and product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products and product candidates. We may incorrectly determine that our products or product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our products or product candidates that are held to be infringing. We might, if possible, also be forced to redesign products or product candidates so that we no longer infringe the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors. Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. Disputes may arise between us and any of these counterparties regarding intellectual property rights that are subject to such agreements, including, but not limited to: • the scope of rights granted under the 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 agreement; • our right to sublicense patent and other rights to third parties; • 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; • our right to transfer or assign our license; and • the effects of termination. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. If we fail to comply with our obligations under any agreements, we may be required to pay damages and could lose intellectual property rights that are necessary or useful for developing and protecting our product candidates. Dynavax has represented to us that we were given all intellectual property rights related to nelitolimod pursuant to the Dynavax Agreement. Pursuant to the Dynavax Agreement, we are obligated to pay up to $ 250 **. 0** million upon the achievement of certain development, regulatory, and commercial milestones and low double- digit royalties based on potential future net sales of products containing the nelitolimod compound. Additionally, we are responsible for prosecution and maintenance of the acquired patents with obligations to keep Dynavax reasonably informed of the status thereof. Any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any such material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and any licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology. Intellectual property rights do not necessarily address all potential threats to our business. Once granted, patents may remain open to opposition, interference, re- examination, post- grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative: • others may be able to make formulations that are similar to our product candidates or other formulations but that are not covered by the claims of our patents that we own or have exclusively licensed; • the patents of third parties may have an adverse effect on our business; • we or any current or future strategic partners and / or collaborators might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own; • we or any of our current or future strategic partners and / or collaborators might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we may own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; • patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product; • our competitors might conduct research and development activities in the United States and in other countries that provide a safe harbor from patent infringement claims for such activities, as well in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our existing or intended commercial markets; • third parties performing manufacturing or testing for us using our product candidates could use the intellectual property of others without obtaining a proper license; • we may not develop additional proprietary technologies that are patentable; • the patents of others may have an adverse effect on our business; and • we may choose not to file a patent application for certain technologies, trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects. ~~The validity, scope and enforceability of any of our patents can be challenged by third parties and any lawsuits to protect or enforce our patents could be expensive, time consuming and unsuccessful. Competitors or other third parties may infringe our patents or the patents of any party from whom we may license patents from in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In a patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or of any of our future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In addition, to the extent that we have to file patent litigation in a federal court against a U. S. patent holder, we would be required to initiate the proceeding in the state of incorporation or residency of such entity. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain product candidates or aspects of the TriNav or other technology. Such a loss of patent protection could compromise our ability to pursue our business strategy. Interference~~

proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone, with our licensees, or with any of our future licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the USPTO or other foreign patent offices, or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our products or product candidates without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future products or product candidates. If one of our product candidates is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non- infringement. For example, if a third party submits an application under Section 505 (b) (2) or an ANDA, for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA' s publication Approved Drug Products with Therapeutic Equivalence Evaluations, which we refer to as the Orange Book, with respect to our New Drug Application (" NDA ") for the applicable approved product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the third party' s generic drug. A certification that the new drug will not infringe the Orange Book- listed patents for the applicable approved product candidate, or that such patents are invalid or unenforceable, is called a " paragraph IV certification. " If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us within 20 days once the third party' s ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party' s ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45- day period, the third party' s ANDA will not be subject to the 30- month stay of FDA approval. Moreover, a third party may challenge the current patents, or patents that may be issued in the future, within our portfolio which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our product candidates. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our product candidates, we will not be entitled to the 30- month stay of FDA approval upon the filing of an ANDA for a generic drug containing the applicable product candidate. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time- consuming, may divert our management' s attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our product candidates.

If we do not obtain protection under the Hatch- Waxman Amendments by obtaining data exclusivity, our business may be harmed. Our commercial success will largely depend on our ability to retain with respect to TriNav and other device technologies, and obtain with respect to nelitolimod and other product candidates, market exclusivity in the United States and other countries. Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, certain of our product candidates may be eligible for marketing exclusivity. The Federal Food, Drug and Cosmetic Act provides a five- year period of non- patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA or Section 505 (b) (2) NDA for a new chemical entity, or NCE. An NCE is a drug that contains no active moiety (the molecule or ion responsible for the action of the drug substance) that has been approved by FDA in any other NDA submitted under section 505 (b) of the FDC Act. During the five- year NCE exclusivity period, the FDA may not ~~accept for review or~~ approve an abbreviated new drug application, or ANDA, or a Section 505 (b) (2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a paragraph IV certification of patent invalidity, unenforceability, or non- infringement to one of the patents listed in the Orange Book, with the FDA by the innovator NDA holder. The FDC Act also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations for a previously- approved active moiety, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages, dosage forms or strengths of an existing drug. This three- year exclusivity covers only the conditions associated with the new clinical investigations and prohibits the FDA from approving an ANDA, or a Section 505 (b) (2) NDA submitted by another company with overlapping conditions associated with the new clinical investigations for the three- year period. Three- year exclusivity does not prohibit the FDA from approving ANDAs for

drugs containing the original conditions of use, i. e., original indications. If we are unable to obtain such marketing exclusivity for our product candidates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our approval to obtain approval of competing products and launch their product earlier than might otherwise be the case. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We rely on trademarks as one means to distinguish any of our products or product candidates that are approved for marketing from the products of our competitors. TriNav ® and Pressure- Enabled Drug Delivery ™ (PEDD ™) are our trademarks and, in the United States, our trademarks may be challenged, infringed, circumvented or declared descriptive or generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively. Risks Related **to** the Ownership of Our Securities We have limited experience operating as a United States public company and may not be able to adequately develop and implement the governance, compliance, risk management and control infrastructure and culture required for a public company, including compliance with the Sarbanes Oxley Act. We have limited experience operating as a United States public company. Certain of our executive officers lack experience in managing a United States public company, which makes their ability to comply with applicable laws, rules and regulations uncertain. Our failure to comply with all laws, rules and regulations applicable to United States public companies could subject us and our management to regulatory scrutiny or sanction, which could harm our reputation and share price. We have limited experience preparing and filing periodic or other reports with the SEC or complying with the other requirements of United States federal securities laws applicable to public companies. We also have limited experience establishing and maintaining the disclosure controls and procedures and internal controls over financial reporting applicable to a public company in the United States, including the Sarbanes- Oxley Act. Although we are in the process of developing and implementing our governance, compliance, risk management and control framework and culture required for a public company, we may not be able to meet the requisite standards expected by the SEC and / or our investors. We may also encounter errors, mistakes and lapses in processes and controls resulting in failures to meet the requisite standards expected of a public company. As a United States public reporting company, we incur significant legal, accounting, insurance, compliance, and other expenses. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. Compliance with reporting, internal control over financial reporting and corporate governance obligations requires members of our management and our finance and accounting staff to divert time and resources from other responsibilities to ensure these new regulatory requirements are fulfilled. If we fail to adequately implement the required governance and control framework, we could be at greater risk of failing to comply with the rules or requirements associated with being a public company. Such failure could result in the loss of investor confidence, could harm our reputation, and cause the market price of our securities to decline. Other challenges in complying with these regulatory requirements may arise because we may not be able to complete our evaluation of compliance and any required remediation in a timely fashion. Furthermore, any current or future controls may be considered as inadequate due to changes or increased complexity in regulations, our operating environment or other reasons. Due to inadequate governance and internal control policies, misstatements or omissions due to error or fraud may occur and may not be detected, which could result in failures to make required filings in a timely manner and make filings containing incorrect or misleading information. Any of these outcomes could result in SEC enforcement actions, monetary fines or other penalties, as well as damage to our reputation, business, financial condition, operating results and share price. We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management now devotes substantial time to new compliance initiatives and corporate governance practices. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes- Oxley Act, which could result in sanctions or other penalties that would adversely impact our business. As a public company, and particularly after we are no longer an " emerging growth company, " we incur significant legal, accounting, and other expenses that we did not incur as a private company, including costs resulting from public company reporting obligations under the Securities Act and the Exchange Act, and regulations regarding corporate governance practices. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the rules of the SEC, the listing requirements of the Nasdaq Stock Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have begun to hire additional accounting, finance, and other personnel in connection with becoming a public company, and our management and other personnel devotes a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to

disclosure and governance practices. We cannot predict or estimate the amount of additional costs we will incur as a result of becoming a public company or the timing of such costs. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the Board or committees of the Board or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms. Pursuant to Sarbanes- Oxley Act Section 404, we are required to furnish a report by our management on our internal control over financial reporting. In order to continue to maintain effective internal controls to support growth and public company requirements, we will need additional financial personnel, systems and resources. However, while we remain an emerging growth company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of the Sarbanes- Oxley Act within the prescribed period, we are engaged in a process to enhance our documentation and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal control over financial reporting is effective as required by Sarbanes- Oxley Act Section 404. Our management has identified material weaknesses and, in the future, our management may identify one or more material weaknesses, which could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Our management has identified material weaknesses in its internal control over financial reporting and we may identify additional material weaknesses in the future. If we fail to remediate the material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, it may adversely affect our ability to accurately and timely report our financial results, and may adversely affect investor confidence and business operations. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the financial statements would not be prevented or detected on a timely basis. In connection with our audited consolidated financial statements for the years ended December 31, ~~2022~~ **2024** and ~~December 31,~~ 2023, management identified material weaknesses in its internal control over financial reporting with respect **to** (i) ~~to~~ a lack of sufficient number of trained resources with the appropriate skills and knowledge and with assigned responsibilities and accountability for the design and operation of internal controls over financial reporting **, patent** ~~; accounting for~~ costs ~~associated with the SEPA~~ , ~~patents and the Business Combination; and~~ certain R & D accruals **, certain general accruals, accounting for leases under ASC 842, accounting for revenue, and accounting for significant transactions, including costs associated with the SEPA, the Exchange Warrants, accounting for the OrbiMed Credit Agreement, including the Initial Commitment Amount and the related derivative financial instruments,** ; (ii) ~~to~~ **inadequate controls over accounting and financial reporting for the Business Combination; (iii)** inadequate internal controls over the valuation of **derivative financial instruments, including** the warrant and tranche rights and obligations and liabilities resulting from the series B- 2 preferred stock financing; and **the Revenue Base Redemption liability associated with the Initial Commitment Amount;** (~~iii~~ **iv**) inadequate controls of the conversion of data from our legacy ~~equity~~ **stock- based compensation** management system to our new system and assumptions used to calculate fair value of certain equity awards **; and (v) inadequate security management internal controls over certain IT applications supporting financial reporting, related to segregation of privileged IT user rights and to monitor elevated user activity** ; each described in more detail under the heading Part II — Item 9A. Controls and Procedures elsewhere in this Annual Report. Our management developed a remediation plan, and we are taking steps to remediate each of the material weaknesses described above. The remediation plan included hiring four additional trained resources with requisite experience with complicated accounting issues, designing and enforcing processes that ensure adequate segregation of duties within the finance function and adequately reviewing the assumptions and inputs to accounting estimates and engaging outside expert consultants as needed. As of ~~December 31, 2023~~ **the date of this filing** , we have hired all of the additional trained resources with such requisite experience. The material weaknesses will be considered remediated when our management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are **operating** ~~effective~~ **effectively** . Our management will continue to monitor the effectiveness of the remediation plan and will make the changes it determines to be appropriate. Although our management intends to complete this remediation process as quickly as practicable, it cannot at this time estimate how long it will take, and initiatives may not prove to be successful in remediating the material weaknesses. Furthermore, we cannot assure you that the remediation measures taken to date, and the actions we may take in the future, will be sufficient to remediate the control deficiencies that led to the material weaknesses in our internal controls over financial reporting described above or that we will prevent or avoid potential future material weaknesses. Further, additional weaknesses in our disclosure controls and internal controls over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in material errors in our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to the listing requirements of Nasdaq, investors may lose confidence in our financial reporting and our stock price may decline as a result. In addition, we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities as well as stockholder litigation which would require additional financial and management resources, and investors may lose confidence in our financial reporting and our stock price may decline as a result. As a result, our ability to obtain financing, or financing on

favorable terms, could be materially and adversely affected, which in turn, could materially and adversely affect our business, financial condition and the market value of our securities and require us to incur additional costs to improve our internal control systems and procedures. In addition, perceptions of us among customers, partners, investors, securities analysts and others could also be adversely affected. If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired. As a public company, we are required to comply with the requirements of the Sarbanes- Oxley Act, including, among other things, maintaining effective disclosure controls and procedures and internal control over financial reporting. We continue to develop and refine our disclosure controls and other procedures that are designed to ensure that the information we are required to disclose in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our management, including our principal executive and financial officers. We may, however, be unable to meet the time periods specified in the SEC rules and forms. For example, prior to the filing of ~~this~~ **the** Annual Report **on Form 10- K for the year ending December 31, 2023** , we filed a Form 12b- 25 (Notification of Late Filing) with the SEC to avail ourselves of a 15- day extension to file ~~this~~ **the** Annual Report **on Form 10- K** . The need for the extension was primarily due to the calculation of non- cash stock compensation caused by data errors associated with a transition to a new service provider in 2023. We must continue to improve our internal control over financial reporting. Our management will be required to make a formal assessment of the effectiveness of our internal control over financial reporting pursuant to Sarbanes- Oxley Act Section 404 (a), and we may in the future be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with these requirements within the prescribed time period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. There is a risk that we will not be able to conclude, within the prescribed time period or at all, that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes- Oxley Act. Any failure to implement and maintain effective disclosure controls and procedures and internal control over financial reporting, including the identification of one or more material weaknesses, could cause investors to lose confidence in the accuracy and completeness of our financial statements and reports, which would likely adversely affect the market price of our Common Stock. In addition, we could be subject to sanctions or investigations by the stock exchange on which our Common Stock is listed, the SEC and other regulatory authorities. The price of our securities has been and may continue to be volatile. The price of our securities has been and may continue to be volatile. From August 11, 2023, the date following the Business Combination, through ~~April 3~~ **December 31** , 2024, our common stock price has fluctuated from a low of $ 3. ~~62~~ **60** to a high of $ 12. 00 per share, and the price of our ~~Public~~ **publicly traded** ~~Warrants~~ **warrants** ~~has~~ **have** fluctuated from a low of $ 0. 12 to a high of $ ~~1~~ **2** . ~~19~~ **18** per ~~Public Warrant~~ **warrant** . The price of our Common Stock and ~~Public~~ **publicly traded** ~~Warrants~~ **warrants** may continue to fluctuate in the future due to a variety of factors, including, without limitation: • the volume and timing of sales of TriNav or other products; • the introduction of new products or product enhancements by us or others in our industry; • the timing and results of clinical trials of any of our product candidates; • regulatory actions with respect to our product candidates or our competitors' products and product candidates; • the success of existing or new competitive products or technologies; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; • establishment or termination of collaborations for our product candidates or development programs; • failure or discontinuation of any of our development programs; • results of clinical trials of product candidates of our competitors; • regulatory or legal developments in the United States and other countries **, including as a result of tariffs** ; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the level of expenses related to any of our product candidates or development programs; • the results of our efforts to discover, develop, acquire or in- license additional product candidates or products; • actual or anticipated changes in estimates as to financial results or development timelines; • actual or anticipated fluctuations in our quarterly or annual operating results; • publication of research reports by securities analysts about us or our competitors or our industry; • the public' s reaction to our press releases, our other public announcements and our filings with the SEC; • our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; • additions and departures of key personnel; • changes in laws and regulations affecting our business; • commencement of, or involvement in, litigation **or government investigations** involving us; • changes in our capital structure, such as future issuances of securities or the incurrence of **(or inability to incur)** additional debt; • the volume of shares of Common Stock available for public sale; • general economic and political conditions, such as recessions, interest rates, social, political and economic risks and acts of war or terrorism; and • that the information we are required to disclose in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our management, including our principal executive and financial officers. These market and industry factors may materially reduce the market price of our securities regardless of our operating performance. It is also possible that an active trading market will not be sustained. Any of these effects would make it difficult to sell our securities at an attractive price or at all. We may be unable to maintain the listing of our securities on Nasdaq in the future. We cannot guarantee that our securities will continue to be listed on Nasdaq. If we fail to meet the requirements of the applicable listing rules, such failure may result in a suspension of the trading of our shares or delisting in the future. This may further result in legal or regulatory proceedings, fines and other penalties, legal liability for us, the inability for our stockholders to trade their shares and negatively impact our share price,

reputation, operations and financial position, as well as our ability to conduct future fundraising activities. If Nasdaq delists our securities and we are not able to list our securities on another national securities exchange, we expect that our securities could be quoted on an over- the- counter market. If this were to occur, we could face significant material adverse consequences, including: ◦ a limited availability of market quotations for our securities; ◦ reduced liquidity for our securities; ◦ a limited amount of news and analyst coverage for the company; and ◦ a decreased ability to issue additional securities or obtain additional financing in the future. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, higher interest rates and uncertainty about economic stability **, including as a result of actual or threatened tariffs** . For example, the **recent implementation** ~~COVID- 19 pandemic resulted in widespread unemployment, economic slowdown~~ and **threat of tariffs have created** extreme volatility in the **global** capital markets **, disrupted global supply chains and may materially and adversely impact the cost of goods** . ~~Similarly~~ **As a further example** , Russia' s ongoing incursion of Ukraine has created extreme volatility in the global capital markets and disrupted global supply chain and energy markets; it is possible that ~~the war~~ **wars** in the Middle East may have similar effects ~~. There have also recently been disruptions to the U. S. banking system due to bank failures, such as those that have occurred with respect to Silicon Valley Bank, Signature Bank, and First Republic Bank~~ . Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of **economic policies,** political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates **or tariffs** can adversely affect us by increasing our ~~costs, including labor and employee benefit~~ costs. In addition, higher inflation could also increase customers' operating costs, which could result in reduced budgets for customers and potentially less demand for our products and services. ~~Any significant increases~~ **These factors can individually or** in **the aggregate** ~~inflation and related increase in interest rates could~~ have a material adverse effect on our business, results of operations and financial condition. If our operating and financial performance in any given period does not meet the guidance provided to the public or the expectations of investment analysts, the market price of Common Stock may decline. We may, but are not obligated to, provide public guidance on our expected operating and financial results for future periods. Any such guidance will consist of forward- looking statements, subject to the risks and uncertainties described in this filing and in our public filings and public statements. The ability to provide this public guidance, and the ability to accurately forecast our results of operations, will be impacted by a number of factors, many of which are out of our control. Actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic or regulatory uncertainty. If, in the future, our operating or financial results for a particular period do not meet any guidance provided or the expectations of investment analysts, or if we reduce our guidance for future periods, the market price of Common Stock may decline as well. Even if we issue public guidance, there can be no assurance that we will continue to do so in the future. We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of our securities. This risk is especially relevant for us because life sciences companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and our resources, which could harm our business. Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our securities. Securities research analysts may establish and publish their own periodic projections of us. These projections may vary widely and may not accurately predict the results that we actually achieve. Our share price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline. While we expect research analyst coverage to continue, if analysts cease to continue coverage of us, the market price and volume for our securities could be adversely affected. Sales of our securities or the perception of such sales, by us or our ~~equityholders~~ **equity holders** , in the public market or otherwise, could cause the market price for our securities to decline. The sale of our Common Stock in the public market or otherwise, or the perception that such sales could occur, could harm the prevailing market price of our Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of our Common Stock may cause the market price of our securities to drop significantly, even if our business is doing well. **Specifically, we** ~~Certain of our equityholders acquired securities at prices that are significantly less than the current trading price of our Common Stock. We~~ have filed a **number of resale** registration ~~statement~~ **statements** ~~(~~ **covering** the ~~" Resale~~ **resale of** ~~S- 1") relating to the offer and sale from time to time by certain equityholders or~~ **our** ~~their permitted transferees of (i) up to 52, 536, 549 shares of Common Stock consisting of (a) up to 25, 237, 094 shares of~~ Common Stock that **is outstanding or that may be** ~~are issuable upon the conversion of the 4, 015, 002 PIPE Shares,~~ issued **and become outstanding** at ~~a price of $ 10. 00 per share, (b) up to 4, 062, 500 Founder Shares originally issued in a private placement to~~ the **election** ~~Sponsor prior to MTAC' s initial public offering at a price~~ of **the holder** ~~approximately $ 0. 006 per share, including 3, 125, 000 Founder Shares subject to vesting and forfeiture, (c) up to 1, 452, 965 shares~~ of **such security** ~~Common Stock issuable~~ upon exercise **or** ~~of the Assumed Options initially granted by Legacy TriSalus, at a weighted average price of $ 2. 51 per share, (d) up to 86, 148 shares of Common Stock issuable upon the settlement of Assumed RSUs that were initially granted by Legacy TriSalus, (e) up to 4, 933, 333 shares of Common Stock issuable upon exercise of the Private Placement Warrants at a price of $ 11. 50 per share and (f) up to 8, 281, 779 shares of Common Stock that are issuable upon the exercise of the Public Warrants at a price of $ 11. 50 per share and (ii) up to 5, 933, 333 warrants consisting of (a) up to 4, 933, 333 Private Placement Warrants and (b) up to 1, 000, 000~~

~~Conversion~~ **conversion thereof** ~~Warrants (together with the Public warrants and the Private Placement Warrants, the" Warrants"). Defined terms used in this discussion that are not defined in this Annual Report shall have the meaning provided to such term in the Resale S- 1~~. Our stockholders will be able to sell all of their securities held for so long as ~~the~~ **they remain registered for** ~~Resale~~ **resale** ~~S- 1~~ **on an effective registration statement or if the sale** is **otherwise exempt from** ~~in effect, subject to certain lock- up restrictions~~ **registration** . ~~Such restrictions began at~~ **This is more relevant now given all** the ~~closing~~ **conversion** of the **preferred** ~~Business Combination and end on the earliest of (i) August 10, 2024; (ii) the first day after the date on which the closing price of the Common Stock equals or exceeds $ 12. 00 per share (as adjusted for~~ stock ~~splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within any 30- trading day period commencing at least 150 days after the date of the Closing; or (iii) the date on which we complete a liquidation, merger, capital stock exchange, reorganization or other similar transaction that results in all of our public stockholders having the right to exchange their Common Stock for cash, securities or other property~~. Certain of our selling securityholders acquired the Common Stock at prices that are significantly lower than the current trading price of our Common Stock. Even if the trading price of our Common Stock falls to or significantly below the current trading price, certain of our securityholders may still have an incentive to sell and profit due to the nominal purchase prices paid by such selling securityholders, which are significantly lower than the purchase prices they paid. Our Warrants are exercisable for Common Stock, the exercise of which would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders. ~~Our 8~~ **Following the closing of the offer and Consent Solicitation on July 1** , ~~281~~ **2024** , ~~779~~ **there were approximately 1, 751, 825** Public Warrants to purchase an aggregate of ~~8~~ **1** , ~~281~~ **751** , ~~779~~ **825** shares of Common Stock, 4, ~~933~~ **428** , ~~333~~ **648** Private Placement Warrants to purchase an aggregate of 4, ~~933~~ **428** , ~~333~~ **648** shares of Common Stock and 1, 000, 000 Conversion Warrants to purchase an aggregate of 1, 000, 000 shares **of Common Stock. The Private Placement Warrants and Conversion Warrants became exercisable on September 10, 2023, in accordance with the terms of the Warrant Agreement. The Initial OrbiMed Warrant for 130, 805 share** of Common Stock became exercisable on ~~September 10~~ **April 30** , ~~2023~~ **2024** ~~, in accordance with the terms of that certain warrant agreement, dated December 17, 2020, by and between us and Continental Stock Transfer & Trust Company, as warrant agent (the " Warrant Agreement ")~~. The exercise price of the **remaining SPAC** Warrants is $ 11. 50 per share, or approximately $ ~~164~~ **82** . ~~0~~ **6** million in the aggregate, assuming none of the **SPAC** Warrants are exercised through " cashless " exercise. **The exercise price of the Initial OrbiMed Warrant was initially $ 9. 5562 per share, or approximately $ 1. 25 million in the aggregate, assuming none of the Initial OrbiMed Warrant is exercised through a" cashless" exercise. For the year ended December 31, 2024, the exercise price was adjusted pursuant to the terms of the Initial OrbiMed Warrant to $ 9. 3722 per share, or approximately $ 1. 23 million in the aggregate, assuming none of the Initial OrbiMed Warrant is exercised through a" cashless" exercise.** We have the unilateral right to reduce the exercise price of the **SPAC** Warrants, and may do so as a means of raising capital **. Additionally, pursuant to the Warrant Amendment, we have the unilateral right to force conversion of the remaining 1, 751, 825 Public Warrants in exchange for 0. 27 shares of Common Stock per Public Warrant** . There is no guaranty that the warrant holders will exercise their ~~options~~ **Warrants** at the current exercise price or any reduced exercise price. We believe the likelihood that warrant holders will exercise their Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Common Stock. So long as the trading price for our Common Stock is less than $ 11. 50 per share (or, if the exercise price is lowered, such lower exercise price), meaning the **SPAC** Warrants are " out of the money, " we believe holders of our **SPAC** Warrants that were issued will be unlikely to exercise their **SPAC** ~~warrants~~ **Warrants** on a cash basis. **Similarly, if the trading price of our Common Stock is below $ 9. 3722, meaning the Initial OrbiMed Warrant would be " out of the money, " we believe OrbiMed would be unlikely to exercise the Initial OrbiMed Warrant on a cash basis. Additionally, the Initial OrbiMed Warrant, as shown above, is subject to customary price- based anti- dilution protections, such that, in certain circumstances, if we issue shares of our common stock below the current exercise price of the Initial OrbiMed Warrant, including through sales under the SEPA, the exercise price of the Initial OrbiMed Warrant will be adjusted downward based on such issuance. As a result, if there are any such adjustments, the amount of proceeds we receive from the exercise of the Initial OrbiMed Warrant will be less than $ 1. 24 million in the aggregate.** On ~~April 3~~ **December 31** , 2024, the reported sales price of our Common Stock was $ ~~9~~ **5** . ~~78~~ **01** per share and the last reported sales price of our Public Warrants was $ 1. ~~04~~ **10** per warrant, both of which are lower than the exercise price of the Warrants. To the extent such Warrants are exercised **, or we force the conversion of the Public Warrants** , additional Common Stock will be issued, which will result in dilution to the holders of Common Stock and will increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of Common Stock. We are an emerging growth company as well as a smaller reporting company within the meaning of the Securities Act and, if we take advantage of certain exemptions from disclosure requirements available to " emerging growth companies, " our securities may be less attractive to investors and it may be more difficult to compare our performance with other public companies. We qualify as an emerging growth company under SEC rules. As an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These provisions include: (1) presenting only two years of audited financial statements; (2) presenting only two years of related selected financial data and " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure; (3) an exemption from compliance with the auditor attestation requirement in the assessment of internal control over financial reporting pursuant to Section 404 of Sarbanes- Oxley; (4) not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; (5) reduced disclosure obligations regarding executive compensation arrangements in periodic reports, registration statements, and proxy statements; and (6) exemptions from the

requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide will be different than the information that is available with respect to other public companies that are not emerging growth companies. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for the Common Stock, and its market price may be more volatile. We will remain an emerging growth company until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of MTAC' s initial public offering (i. e., December 31, 2025), (b) in which we have total annual gross revenue of at least $ 1. 235 billion or (c) in which we are deemed to be a " large accelerated filer " under the rules of the SEC, which means the market value of our common equity that is held by non- affiliates exceeds $ 700 **. 0** million as of the end of the prior fiscal year' s second fiscal quarter; and (2) the date on which we will have issued more than $ 1. 0 billion in non- convertible debt securities during the prior three- year period. Additionally, we qualify as a " smaller reporting company " as defined in Item 10 (f) (1) of Regulation S- K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our Common Stock held by non- affiliates exceeds $ 250 **. 0** million as of the end of that year' s second fiscal quarter, or (2) our annual revenues exceeded $ 100 **. 0** million during such completed fiscal year and the market value of Common Stock held by non- affiliates equals or exceeds $ 700 **. 0** million as of the end of that year' s second fiscal quarter. To the extent that we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible. Our Warrants may not be exercised at all or may be exercised on a cashless basis and we may not receive any cash proceeds from the exercise of the Warrants. The exercise price of the Warrants may be higher than the prevailing market price of the underlying shares of Common Stock. The exercise price of the Warrants is subject to market conditions and may not be advantageous if the prevailing market price of the underlying shares of Common Stock is lower than the exercise price. The cash proceeds associated with the exercise of Warrants to purchase our Common Stock ~~and the subsequent resale of that Common Stock~~ are contingent upon our stock price. The value of our Common Stock will fluctuate and may not align with the exercise price of the Warrants at any given time. As of ~~April 3~~ **March 31** , ~~2024~~ **2025** , the last reported sales price of our Common Stock was $ ~~9~~ **5** . ~~78~~ **38** per share. So long as the trading price of our Common Stock is less than $ 11. 50, meaning the **SPAC** Warrants are " out of the money, " meaning the exercise price is higher than the market price of our Common Stock, we believe that holders of the **SPAC** Warrants are unlikely to choose to exercise their **SPAC** Warrants **. Similarly, so long as the trading price for our Common Stock is less than $ 9. 3722, meaning the Initial OrbiMed Warrant is " out of the money, " we believe OrbiMed would be unlikely to exercise the Initial OrbiMed Warrant** . As a result, we may not receive any proceeds from the exercise of the Warrants. Furthermore, to the extent that the Private Placement Warrants ~~or ,~~ Conversion **Warrants, or Initial OrbiMed** Warrants are exercised on a " cashless basis, " we will not receive cash upon their exercise. A cashless exercise allows holders of such Warrants to convert the warrants into shares of our Common Stock without the need for a cash payment. Instead of paying cash upon exercise, the warrant holder would receive a reduced number of shares based on a predetermined formula. As a result, the number of shares issued through a cashless exercise will be lower than if the Private Placement Warrants ~~or ,~~ Conversion **Warrants, or Initial OrbiMed** Warrants were exercised on a cash basis. The Public Warrants may only be exercised for cash provided there is then an effective registration statement registering the shares of Common Stock issuable upon the exercise of such warrants. If there is not a then- effective registration statement, then such Public Warrants may be exercised on a " cashless basis, " pursuant to an available exemption from registration under the Securities Act. Anti- takeover provisions contained in our Certificate of Incorporation and Bylaws, as well as provisions of Delaware law, could limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable. Our Certificate of Incorporation and Bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the Board or taking other corporate actions, including effecting changes in our management. We are also subject to anti- takeover provisions under Delaware law, which could delay or prevent a change of control. Together these provisions may discourage transactions that otherwise could involve the payment of a premium over prevailing market prices for our securities. These provisions include: • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • a classified board of directors with three- year staggered terms, which could delay the ability of stockholders to change the membership of a majority of the Board; • the right of the Board to elect a director to fill a vacancy created by the expansion of the Board or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on the Board; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • the requirement that a special meeting of stockholders may only be called by a majority of the Board, the chairperson of the Board, or our chief executive officer which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; • the ability of the Board to issue shares of preferred stock, including " blank check " preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer; • limitation of the liability of, and the indemnification of, our directors and officers; • the ability of the Board to amend our Bylaws, which may allow the Board to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the Bylaws to facilitate an unsolicited takeover attempt; and • advance notice procedures with which stockholders must comply to nominate candidates to the Board or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in the Board, and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the potential acquirer' s own slate of directors or otherwise attempting to obtain control of us.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control of us or changes in our Board and our management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the General Corporation Law of the State of Delaware (the " DGCL "), which prevents some stockholders who hold more than 15 % of our outstanding Common Stock from engaging in certain business combinations without approval of the holders of substantially all of our Common Stock. Any provision of our Certificate of Incorporation and Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for stockholders to receive a premium for their shares of Common Stock and could also affect the price that some investors are willing to pay for Common Stock. Our Certificate of Incorporation designates the Delaware Court of Chancery or Delaware state or United States federal district courts as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit such stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, other employees or other stockholders. Our Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for state law claims for (i) any derivative claim or cause of action brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, other employees or stockholders, us or our stockholder; (iii) any action against us or any of our current or former directors, officers or other employees asserting a claim arising pursuant to any provision of the DGCL, our Certificate of Incorporation or Bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or Bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction on the Delaware Court of Chancery; and (vi) any action asserting a claim against us or any of our current or former directors, officers or other employees governed by the internal affairs doctrine or otherwise related to our internal affairs. The foregoing provisions will not apply to any claims as to which the Delaware Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of such court, which is rested in the exclusive jurisdiction of a court or forum other than such court. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules or regulations promulgated thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such Securities Act claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring, holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the forum provisions in our Certificate of Incorporation. Although we believe these exclusive forum provisions will benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. Furthermore, investors cannot waive compliance with the federal securities laws and rules and regulations promulgated thereunder. Our Certificate of Incorporation, to the extent permitted by applicable law, contains provisions renouncing our interest and expectation to participate in certain corporate opportunities identified or presented to our non- employee directors or stockholders. Our officers and directors and their respective affiliates may hold, and may, from time to time in the future, acquire interests in or provide advice to businesses that directly or indirectly compete with certain areas of our business. Our Certificate of Incorporation provides that we renounce, to the fullest extent permitted by Delaware or other applicable law, any expectancy that any of our non- employee directors, stockholders or the affiliates of such stockholders will offer any corporate opportunity of which such director or stockholder may become aware to us except with respect to a corporate opportunity that was offered to a director solely in his or her capacity as our director and (i) such opportunity is one we are legally and contractually permitted to undertake and (ii) the director is permitted to refer that opportunity to us without violating any legal obligation. As a result, these arrangements could adversely affect our business, results of operations, financial condition or prospects if attractive business opportunities are allocated to any of our non- employee directors, stockholders or the affiliates of such stockholders instead of to us.