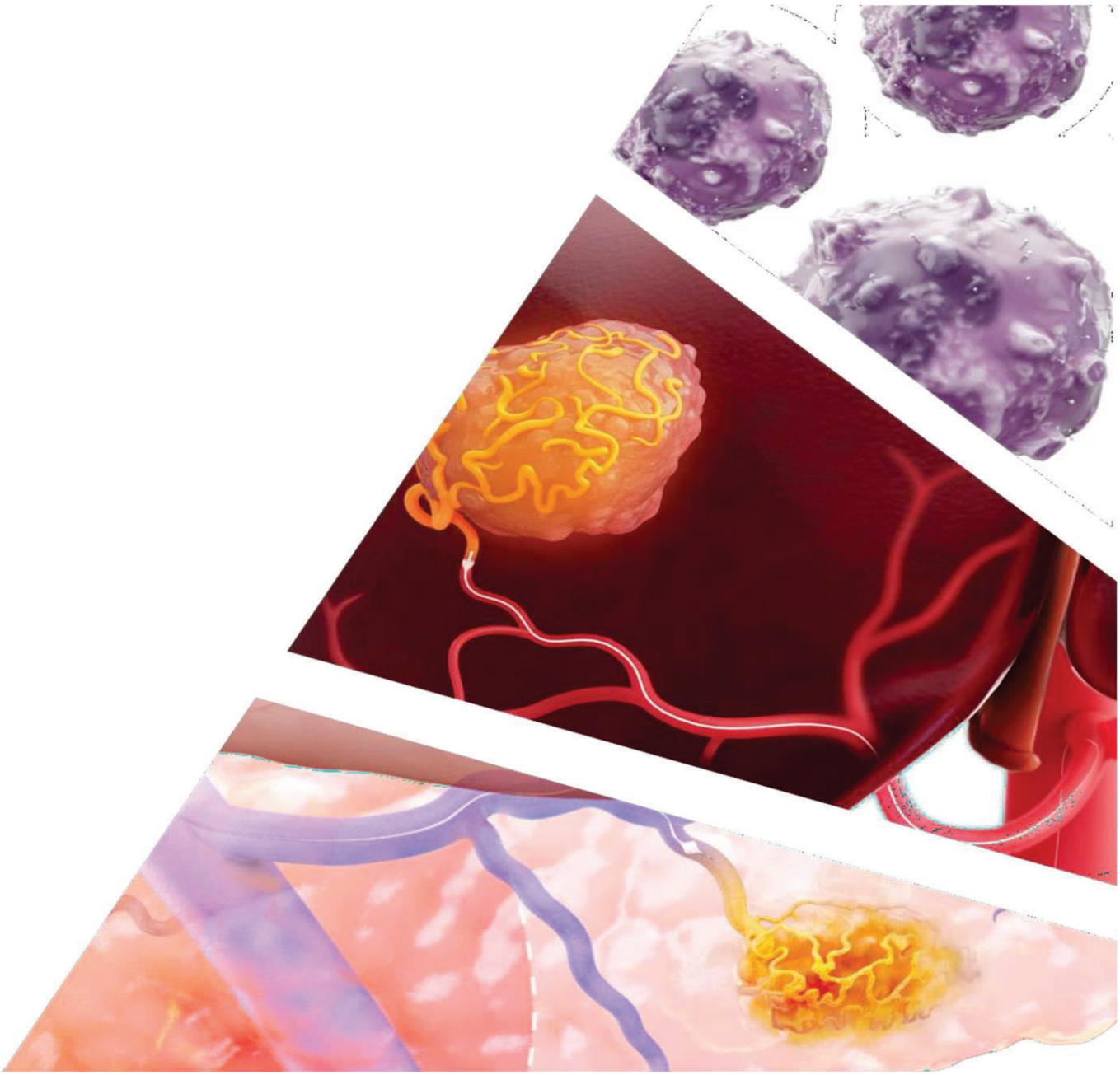
TriSalus LIFE SCIENCES®

ANNUAL REPORT

2023



A Letter from Mary Szela

Dear Fellow Shareholders,

As we look back on our first year as a public company, I am pleased to report that 2023 was a significant year of advancement for TriSalus Life Sciences.

We reached several important milestones that propelled our company forward and reaffirmed our dedication to providing sustainable growth and long-term value to our shareholders.

The team at TriSalus is comprised of individuals who are passionately focused on improving outcomes for patients with liver and pancreatic cancer. Our innovative platform combines our FDA-cleared Pressure-Enabled Drug Delivery technology with Nelitolimod, an investigational immunotherapeutic TLR9 agonist that activates the immune system in liver and pancreatic tumors. This dual approach is designed to address specific barriers in these organs that hinder patients from fully benefitting from immunotherapy advances.

Throughout the year, we achieved notable successes that underscore our commitment to our mission and our shareholders:

- Full year revenues of $18.5 million, up 49% over prior year
- Gross Margin improvement from 82% to 86% for the year.
- Received assignment of a new APC from the Center for Medicare and Medicaid Services (CMS) to ensure ongoing reimbursement for TriNav via assignment of a new HCPCS code.
- Real-world data published on TriNav system demonstrates significant improvement in the delivery of therapeutics to liver tumors for patients with higher disease burden.
- Received 510k clearance for TriNav Large and TriGuide systems.
- Completed enrollment of one hundred patients in several phase 1 clinical trials in uveal melanoma liver metastases, hepatocellular cancer, intrahepatic cholangiocarcinoma, and pancreatic cancer. Data is maturing, and we plan to analyze data from all three clinical trials in the second half of 2024 to determine the next steps.
- Initiated first-in-man clinical trial of our novel pancreatic infusion technology, (510k cleared), plus nelitolimod, to demonstrate safety and efficacy.

Looking ahead, we remain steadfast in our mission to redefine standards of care and transform the lives of patients battling liver and pancreatic cancer. With a clear focus on innovation, collaboration, and excellence, we are poised to navigate the evolving healthcare landscape and deliver sustained value to our shareholders.

Thank you for your unwavering support as we continue our journey to make a meaningful difference in the lives of our patients.

Kind Regards,

Mary Szela
Chief Executive Officer
TriSalus Life Sciences, Inc.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ____ to ____

Commission file number 001-39813

TRISALUS LIFE SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**85-3009869**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
6272 W 91st Ave Westminster, CO Telephone: (303) 442-1222	**80031**
(Address of Principal Executive Offices)	(Zip Code)

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value	**TLSI**	**Nasdaq Global Market**
Warrants, each whole warrant exercisable for one share of registrant's common stock at an exercise price of $11.50 per share	**TLSIW**	**Nasdaq Global Market**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the Registrant was approximately $11,645,271 as of June 30, 2023 (the last trading day of the registrant's most recently completed second quarter), based on the closing price of $10.48 as reported on the Nasdaq Global Market on such date. Shares of the registrant's common stock held by executive officers, directors, and the registrant's affiliates have been excluded from this calculation. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

APPLICABLE ONLY TO CORPORATE ISSUERS:

The registrant had outstanding 26,758,295 shares of common stock as of April 3, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Table of Contents

INTRODUCTORY NOTE

TriSalus Life Sciences, Inc., a Delaware corporation (the "Company", "TriSalus", "we", "us"), formerly known as MedTech Acquisition Corp. (“MTAC”), was originally incorporated in the State of Delaware on September 11, 2020, as a special purpose acquisition company formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or other similar business combination with one or more target businesses or entities. On August 10, 2023 (the “Closing Date”), we consummated the transactions contemplated by the Agreement and Plan of Merger, dated as of November 11, 2022, as amended by that certain First Amendment to Agreement and Plan of Merger, dated as of April 4, 2023, the Second Amendment to Agreement and Plan of Merger, dated as of May 13, 2023, and the Third Amendment to Agreement and Plan of Merger, dated as of July 5, 2023 (as amended, the “Merger Agreement”), by and between MTAC, MTAC Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of MTAC (“Merger Sub”) and TriSalus Operating Life Sciences, Inc. (formerly known as TriSalus Life Sciences, Inc.), a Delaware corporation (“Legacy TriSalus”), whereby Merger Sub merged with and into Legacy TriSalus with the separate corporate existence of Merger Sub ceasing (the “Merger” and, together with the other transactions contemplated by the Merger Agreement, the “Business Combination”) and TriSalus Life Sciences, Inc. becoming the surviving company. The closing of the Business Combination is herein referred to as "the Closing." In connection with the consummation of the Merger, on August 10, 2023, Legacy TriSalus changed its name from TriSalus Life Sciences, Inc. to TriSalus Operating Life Sciences, Inc., and MTAC changed its name to TriSalus Life Sciences, Inc.

Unless the context indicates otherwise, references in this Annual Report on Form 10-K for the year ending December 31, 2023, ("Annual Report") to the “Company,” “TriSalus,” “we,” “us,” “our” and similar terms refer to TriSalus Life Sciences, Inc. (f/k/a MedTech Acquisition Corp.) and its consolidated subsidiaries (including Legacy TriSalus). References to “MTAC” refer to the predecessor company prior to the consummation of the Business Combination.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). This includes, without limitation, statements regarding the financial position, business strategy and the plans and objectives of management for future operations. These statements constitute projections, forecasts and forward-looking statements, and are not guarantees of performance. We have based these forward-looking statements on our current expectations and projections about future events. Any statements that refer to projections, forecasts or other characterizations of future events or circumstances are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “outlook,” “believes,” “expects,” “potential,” “continues,” “may,” “will,” “should,” “could,” “seeks,” “approximately,” “predicts,” “intends,” “plans,” “estimates,” “anticipates” or the negative version of these words or other comparable words or phrases.

These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions about us that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. Except as otherwise required by applicable law, we disclaim any duty to update any forward-looking statements, all of which are expressly qualified by the statements in this section, to reflect events or circumstances after the date of this Annual Report.

We caution you that these forward-looking statements are subject to numerous risks and uncertainties, most of which are difficult to predict and many of which are beyond our control. Some factors that could cause actual results to differ include:

- our ability to recognize the anticipated benefits of the Business Combination (see Note 3 to the consolidated financial statements accompanying this Annual Report for more information about the Business Combination);
- our ability to maintain the listing of our securities on the Nasdaq Global Market, and the potential liquidity and trading of such securities;
- changes in applicable laws or regulations;
- our ability to raise financing in the future;
- our ability to retain or recruit, or changes required in, our officers, key employees or directors;
- our ability to successfully commercialize any product candidates that we successfully develop and that are approved by applicable regulatory authorities;
- our expectations for the timing and results of data from clinical trials and regulatory approval applications;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our business, operations and financial performance including:
- our history of operating losses and expectations of significant expenses and continuing losses for the foreseeable future;
- our ability to execute our business strategy, including the growth potential of the markets for our products and our ability to serve those markets;
- our ability to grow market share in our existing markets or any new markets we may enter;
- our ability to develop and maintain our brand and reputation;
- our ability to partner with other companies;
- the size of the addressable markets for our product candidates;
- our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- our ability to manage our growth effectively;

- the outcome of any legal proceedings that may be instituted against us; and
- unfavorable conditions in our industry, the global economy or global supply chain, including financial and credit market fluctuations, international trade relations, pandemics, political turmoil, natural catastrophes, warfare and terrorist attacks.

Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Should one or more of the risks or uncertainties described in this Annual Report occur, or should underlying assumptions prove incorrect, actual results and plans could differ materially from those expressed in any forward-looking statements. For a further discussion of these and other factors that could cause our future results, performance or transactions to differ significantly from those expressed in any forward-looking statement, please see the section titled "Risk Factors."

Except to the extent required by applicable law, we are under no obligation (and expressly disclaim any such obligation) to update or revise their forward-looking statements whether as a result of new information, future events, or otherwise. You should read this Annual Report completely and with the understanding that our actual future results, levels of activity and performance as well as other events and circumstances may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

RISK FACTOR SUMMARY

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found in the more detailed discussion in Item 1A in this Annual Report, and the below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should carefully consider the risks and uncertainties described herein as part of your evaluation of an investment in our securities:

- 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.
- The Asset Purchase Agreement, dated July 31, 2020, TriSalus Operating Life Sciences, Inc. (formerly known as TriSalus Life Sciences, Inc.) entered into with Dynavax Technologies Corporation ("Dynavax") in connection with the 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.
- 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.
- 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.
- TriNav is currently subject to an uncertain reimbursement environment, and any change to TriNav's reimbursement status that reduces our level of reimbursement could cause TriNav sales to materially decline and impede market adoption.
- 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 are early in our pharmaceutical development efforts and we have only one pharmaceutical product candidate, nelitolimod, 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.
- 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.

- Changes in existing third-party coverage or our inability to maintain and secure 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.
- 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.
- 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 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.
- Failure to obtain, adequately protect, maintain or enforce our intellectual property rights could substantially harm our business and results of operations.
- The expiration or loss of patent protection may adversely affect our future revenues.
- 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.
- 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.
- The price of our securities has been and may continue to be volatile.

Part I

Item 1. Business

Overview

We are a growing, oncology focused medical technology business bringing disruptive drug delivery technology with the goal of improving therapeutic delivery to liver and pancreatic tumors. Additionally, we are exploring the integration of our technology with our investigational immunotherapeutic, nelitolimod, a class C Toll-like receptor 9 agonist, for a range of liver and pancreatic indications. Our ultimate goal is to transform the treatment paradigm for patients battling liver and pancreatic tumors. We have developed an innovative organ-specific platform that is designed to overcome two of the most significant challenges that prevent optimal delivery and performance of therapeutics in these difficult-to-treat diseases: (i) high intratumoral pressure caused by tumor growth and collapsed vasculature restricting the delivery of oncology therapeutics and (ii) the immunosuppressive properties of liver and pancreatic tumor immune cells. By systematically addressing these barriers, we aim to improve response to therapies and to enable improved patient outcomes.

Background

Liver and pancreatic cancers are among the world's most lethal diseases. Depending on the disease stage, many patients have no curative treatment options and have poor outcomes, with 5-year survival rates ranging from 8-20% for patients with advanced disease. While immunotherapy represents one of the greatest advancements in cancer treatment over the past 50 years, patients with primary or secondary tumors in the liver or pancreas are less likely to respond to treatment relative to most other cancer types that do not involve these sites of disease. These patients need new treatment options designed to address the unique challenges specific to liver and pancreatic tumors that limit the success of immunotherapy.

We have developed a platform approach to address the unique challenges of treating tumors in the liver and pancreas by integrating our innovative drug delivery technology with our investigational immunotherapeutic agent, nelitolimod, formerly known as SD-101, with the goal of overcoming the two primary barriers that inhibit treatment success: intratumoral pressure and immunosuppression, both of which limit therapeutic delivery and efficacy.

PEDD & TriNav- Device Business with Potential for Growth:

Our delivery method — Pressure-Enabled Drug Delivery (PEDD™) ("PEDD") — modulates pressure and flow within blood vessels to improve intravascular therapeutic delivery into tumors and is designed to increase the likelihood of tumor response in comparison to conventional delivery technologies. Our on-market, 510(k) cleared PEDD device, the TriNav Infusion System ("TriNav") is currently being used for a number of interventional radiology procedures, most commonly transarterial radioembolization ("TARE") and transarterial chemoembolization ("TACE") in patients with either primary liver cancer and in patients with liver metastases. TriNav is a highly innovative, novel technology, FDA-cleared drug delivery device that has undergone peer-reviewed studies at multiple clinical sites. The PEDD method has now been used in over 18,000 procedures, primarily TACE and TARE. TriNav achieved $18.5 million in revenue in 2023 with fourth quarter growth of 77% vs. the previous year.

We also have developed a separate 510(k) cleared PEDD device for infusions into the pancreas (Pancreatic Retrograde Venous Infusion (PRVI) device) to treat pancreatic tumors. TriSalus developed a novel way to access the pancreas via the venous vasculature where the vessels are larger, easier to access and PRVI is designed to address many of the limitations inherent to arterial infusions in the pancreas. The PRVI device is currently being studied in a clinical trial for nelitolimod delivery into pancreatic tumors. Although FDA-cleared, the PRVI device has not yet been commercialized and commercial sale is not anticipated before 2025.

We are currently studying the ability of nelitolimod, an investigational class C toll-like receptor 9 ("TLR9") agonist, to reactivate the immune system within the liver and pancreas by broadly reprogramming immune cells and reducing myeloid derived suppressor cells ("MDSCs"), cells which cause immunosuppression, to enable more durable responses to immune checkpoint inhibitors ("CPIs"), thereby improving patient outcomes.

Nelitolimod has previously been shown in both clinical and non-clinical studies to broadly induce interferon production, dendritic cell activation, and B cell activation. Through pre-clinical experiments and early clinical experience in patients with liver and pancreatic tumors, we have demonstrated that nelitolimod reduces MDSCs, which are important mediators of immunosuppression in these tumor types, while recruiting T cells which are the target of CPIs.

We believe that the combination of PEDD with nelitolimod creates a platform approach with the potential to address common therapeutic barriers across numerous cancer indications affecting the liver and pancreas and that this approach

could provide a meaningful benefit to patients. There is also the potential that this platform may not only enable CPIs, but other classes of immunotherapy as well, such as cell therapeutics.

Currently we are completing phase 1 clinical trials for four indications, in leading academic oncology centers across the United States ("U.S."). In these trials, PEDD devices are used to administer our investigational immunotherapy candidate, nelitolimod, through a regional intravascular approach for patients with liver and pancreatic tumors. We believe this approach will maximize TLR9 stimulation within the liver and pancreas and eliminate immunosuppressive cells to broadly reprogram the tumor microenvironment ("TME") with the goal of enabling improved efficacy of systemic immunotherapies like CPIs or cell therapy while maintaining a tolerable safety profile. We are currently evaluating data from these trials and determining which indication we intend to advance.

Overcoming Barriers to Effective Drug Delivery with PEDD

Systemic delivery of cancer therapeutics presents two critical challenges for patients with liver tumors. First, based on the normal distribution of cardiac output, the liver will receive only a small fraction of the dose. Second, intratumoral solid stresses compress the interior of the tumor and deform blood vessels, inhibiting therapeutic delivery into the tumor tissue. In particular, vessel leakiness together with vascular compression causes elevated interstitial fluid pressure that hinders delivery of therapeutic agents and limits efficacy. The end result of these factors creates barriers to the systemic administration of chemotherapeutic agents and nanomedicines to tumors, reducing treatment efficacy.

PEDD Delivery Technology is a technological solution to this intratumoral pressure barrier that can enable more effective delivery of therapeutic agents to liver and pancreatic tumors. PEDD devices are engineered to overcome high intratumoral pressure through creation of a favorable pressure gradient, causing increased blood flow to the tumor while constricting blood flow to normal tissue minimizing systemic exposure and decreasing toxicity.

The unique valve on the PEDD device, referred to as SmartValve, works in sync with the cardiac cycle and preserves more than 70% of forward blood flow with a pulsative response (vs. total occlusion) due to its intermittently occlusive design. This physiologically and traumatically increases local vascular pressure at the target location close to the tumor, infusing therapeutics into resistive tumor vessels to enable deeper perfusion and to improve therapeutic delivery. The SmartValve also provides a fixed centro-luminal catheter position, unlike a standard microcatheter where the position of the catheter is in a random, off-centered position. This more reproducible catheter positioning has been associated with a more homogeneous particle distribution in an *in vivo* hepatic arterial model. The SmartValve has also been shown to reduce or eliminate reflux and has been shown in clinical studies to reduce delivery of therapeutics to non-target tissues.

In independent clinical studies, the PEDD method of delivery has demonstrated the ability to overcome the infusion barriers of the TME and to improve therapeutic delivery. Additionally, in a recent large Health Economics and Outcome Research ("HEOR") study, (a 300 million patient dataset covering over 98% of US patients), capturing real-world safety and clinical outcomes for TriNav in its launch phase (2020-2022), demonstrated that TriNav patients, despite a higher baseline disease burden and clinical complexity, showed overall clinical results that were comparable to patients with a lower disease burden. The study also demonstrated that:

- In TACE procedures, interventional radiologists were able to deliver significantly more chemotherapeutic to the tumor when using TriNav vs. the amount delivered using standard catheters, a critical treatment goal.
- TriNav patients had fewer 30-day inpatient visits post-procedure vs. non-TriNav patients in matched cohort comparison.
- TriNav HCC patients were more likely to have a liver transplant in matched cohort comparison.
- TriNav TARE patients with liver metastases had fewer clinical complications post-procedure vs. non-TriNav patients in matched cohort comparison.
    - TriNav TARE patients with liver metastases had lower rates of post-procedure fatigue vs. non-TriNav patients.

The results from this HEOR study suggests that TriNav is preferentially selected to treat patients with higher burden of disease than patients treated with standard catheters, yet these patients show comparable results post-treatment when compared to patients with lower disease burden. In matched cohort comparisons, TriNav patients showed meaningful trends towards better outcomes, including an increased rate of liver transplant. These results also demonstrate how real-world data complement traditional clinical trials to provide a more robust and timely understanding of the benefits realized by patients. TriSalus is committed to updating this data set continuously, and to continue reinforcing the benefit TriNav and the PEDD approach have been shown to provide to patients, providers, and payers.

Treatment of Liver Tumors with Transarterial Radioembolization (TARE)

TARE is an image guided, locoregional therapy that involves hepatic artery embolization with intra-arterial infusion of Yttrium-90 ("^{90}Y") microspheres for treatment of hepatocellular cancer as well as patients with certain metastatic liver cancers. The aim of the treatment is to target tumor cells with a high dose of radiation while limiting exposure to healthy tissue.

The PEDD approach is designed to provide a reliable method to maximize the tumor to normal liver ratio ("T/N ratio"). PEDD devices are designed to not only increase therapeutic delivery to target tumors but also to provide anti-reflux protection to minimize off-target delivery of radioactive micro spheres and the potential complications associated with undesired normal tissue exposure. A pilot study of a PEDD catheter not only demonstrated reduced hepatic nontarget embolization but also found a significant increase in tumor deposition of ^{99m}Tc-MAA by a factor of 1.68 (range 1.33 to 1.90, $p < 0.05$). Another study at the Saint Luc University Hospital and King Albert II Cancer Institute in Brussels, Belgium confirmed the superiority of PEDD devices in improving tumor deposition in liver radioembolization with resin microspheres.

In patients undergoing TARE, augmenting the T/N ratio for the delivery of therapeutic micro spheres has the potential to increase therapeutic response as a direct positive relationship between absorbed dose and tumor response. In addition to the potential for improved response, an increased T/N ratio reduces radiation exposure to normal liver parenchyma and reduces the risk of associated liver toxicity.

Treatment of Liver Tumors with Transarterial Chemoembolization (TACE)

TACE is an image-guided, locoregional therapy that involves hepatic artery embolization with intra-arterial infusion of a chemotherapeutic agent and is used most commonly for treatment of HCC and hepatic metastases of colorectal and neuroendocrine tumors in the U.S. As with TARE, the goal of TACE procedures is to deliver chemotherapeutic agents (in either an emulsion or as part of a drug-eluting bead system) with the goal of complete tumor coverage while avoiding delivery of therapeutic or embolic beads to normal tissue.

This goal of increasing tumor perfusion while reducing delivery to normal tissue may be achieved with the PEDD method using the 510(k) FDA-cleared TriNav device. TriNav alters downstream hepatic arterial blood pressure and may reduce resistance in tumor microvascular. In clinical studies, the use of PEDD devices for delivery of drug-coated micro spheres to treat HCC has demonstrated improved microsphere deposition, tumor necrosis, and imaging response compared to delivery with conventional end-hole catheters. PEDD devices have also been demonstrated, in multiple independent clinical studies, to increase delivery of chemotherapy beads, enhance response rates to chemotherapy beads, improve tumor targeting with Y-90 products, and enhance cell therapy delivery to liver tumors.

PEDD Clinical Studies

In multiple clinical studies comparing PEDD devices to standard catheters, PEDD devices demonstrated improved therapy delivery in both TARE and TACE studies. For instance, such studies have shown that:

- PEDD has improved tumor targeting in liver radioembolization with resin 90Y microspheres and significantly increased both T/N ratio and dose delivery compared to a standard endhole microcatheter in head-to-head comparisons between PEDD devices and standard catheters in the two studies summarized below:
    - A prospective company sponsored study included 9 patients with a variety of tumor types who were referred for Y90 radioembolization treatment of their liver tumors. Prior to treatment via PEDD, each patient received two same-day sequential lobar infusions of macroaggregated albumin ("MAA") via endhole microcatheter and PEDD. Differences in MAA distribution within the tumors and non-target sites were evaluated and the results showed: a 33% to 90% (mean=68%; $p<0.05$) increase in tumor deposition; a 24% to 89% (mean=42%; $p<0.05$) decrease in nontarget embolization; and increased on-target deposition in 100% of the tumors.
    - A retrospective independent study of 61 patients with liver cancer (190 lesions) treated with resin Y90 radioembolization. All patients in the study underwent an MAA planning procedure delivered via a standard endhole ("EH") catheter. Resin Y90 was then delivered via either an EH catheter (control group) or via PEDD, followed by PET/CT imaging. Each patient's post-Y90 PET/CT was co-registered to their post- MAA SPECT/CT to compare the T/N ratio and tumor dose ("TD"). The results showed that across all tumor types, PEDD increased the T/N by a median of 24%, and the TD by a median of 23%, ($p<0.001$) with no significant difference seen in the standard EH catheter (control) group. The results showed that PEDD significantly improved both tumor targeting and dose delivery across multiple tumor types.

- PEDD achieved greater on-target distribution of chemotherapy eluting beads, delivering a significantly higher concentration of therapy in the tumor as compared to standard microcatheters and delivered higher radiographic and pathologic response rates in a head-to-head comparison between the PEDD device and standard catheters in the study summarized below;
- A retrospective, single-center study, included 88 treatment-naive patients with solitary HCC tumors <6.5cm who underwent treatment using either PEDD (n = 18) or a standard microcatheter (n = 70). PEDD patients exhibited lower aspartate aminotransferase (p = 0.003) and alanine aminotransferase (p = 0.044) at 6 months. Blinded radiological evaluation showed that PEDD achieved a significantly higher objective response rate, compared to the EH catheter (100% vs 76.5%; p=0.019). Following liver explant, a blinded review of the liver specimens found that PEDD achieved improved pathological response compared to the standard EH catheter (88.8% vs 33.8%; p=0.026) as well as a significantly higher concentration of therapy in tumor compared to the standard EH catheter (88.7 ± 10.6% vs 55.3 ± 32.7 %; p=0.002)

Real-world Support

TriSalus recently published a HEOR study looking at real-world data capturing both safety and clinical complications for TriNav as compared to conventional catheters over the 2020-2022 time period. This study utilized a large, 300 million patient datasets covering 98% of US payers. These data, which compared key characteristics and clinical complication rates of 258 PEDD patients with those of 8,940 non-PEDD patients, provide valuable insights into the benefits of PEDD technology that would otherwise have taken many years to accumulate through alternative approaches, e.g., randomized controlled clinical trials.

Key findings include that TriNav patients, despite a higher baseline disease burden and clinical complexity as compared to non-TriNav patients, showed overall clinical results comparable to the patients with lower disease burden. The study also revealed that:

- TriNav patients were more likely to have received prior systemic therapy and were much more likely to have received prior embolization.
- In TACE procedures, interventional radiologists could deliver significantly more chemotherapeutic to the tumor when using TriNav vs. the amount delivered using standard catheters, a critical treatment goal for TACE procedures.
- In a matched cohort comparison, TriNav patients had fewer 30-day inpatient visits post-procedure than non-TriNav patients.
- TriNav HCC patients were more likely to have a post-procedure liver transplant in a matched cohort comparison.
- TriNav TARE patients with liver metastases had fewer clinical complications post-procedure vs. non-TriNav patients in a matched cohort comparison.
- TriNav TARE patients with liver metastases had lower rates of post-procedure fatigue vs. non-TriNav patients.

These study data demonstrate that TriNav is preferentially selected to treat the complex patient with a higher burden of disease vs. patients treated with standard catheters, yet these patients show similar results post-treatment compared to patients with a lower disease burden. TriNav patients showed meaningful trends toward better outcomes in matched cohort comparisons, including an increased rate of liver transplants. TriSalus is committed to updating this data set continuously and affirming the benefit TriNav and the PEDD approach bring to patients, providers, and payers.

TriNav Market Opportunity

The incidence of primary and metastatic liver tumors has been increasing, presenting a large opportunity for developing technologies and therapeutics given the poor outcomes associated with liver cancers, whether primary or metastatic. According to the American Cancer Society, primary liver tumors, including intrahepatic cholangiocarcinoma ("ICC") and hepatocellular carcinoma ("HCC"), currently represent more than 41,000 cases annually in the U.S. The liver is also one of the most common sites for metastases, which is cancer that has spread from another site, and according to the National Cancer Institute and recent epidemiological data, there are at least 96,000 individuals diagnosed annually with liver metastases, primarily from colorectal cancer or non-small cell lung cancer, for a total of more than 137,000 new liver cancer diagnoses per year.

We estimate that 40% of these patients are eligible for TACE or TARE procedures and that between 25% and 30% are appropriate candidates for our current TriNav device, representing a potential market opportunity of approximately 37,000 units, or approximately $286 million, based on our current price of $7,750.

When TriNav Large, a larger version of TriNav capable of being used in larger vessel size (3.0-5.0 mm), is commercially launched, we expect that our addressable market will increase by approximately 25%, resulting in an aggregate opportunity of 47,500 units or approximately $368 million, based on current TriNav pricing. Currently, TriNav is used primarily for either TACE or TARE, both of which entail localized therapeutic delivery to HCC or metastatic liver tumors using standard interventional radiology techniques. We are also exploring additional indications for use, including uterine fibroid embolization, which fall within the present 510(k) clearance. Potential market impact of additional indications will be determined after clinical data become available.

TriNav Positioning

Multiple clinical studies, both in TACE and in TARE, have demonstrated that the PEDD approach can increase therapeutic delivery to the tumor while decreasing delivery of radioembolics or chemoembolics to healthy tissue. Our recently published HEOR study clearly demonstrates that TriNav is used in patients with a high burden of disease, and in patients who are more advanced in their disease progression as evidenced by higher comorbidities, greater levels of liver-related adverse events prior to their embolization procedures, higher rates of previous embolization, and higher rates of previous systemic therapy.

Given that TriNav patients have achieved outcomes similar to patients with lesser burden of disease overall, and trends towards better outcomes (successful liver transplant) and lower rates of clinical complications, we believe that TriNav is positioned to become the standard of care for the complex patient who may benefit from liver embolization. We believe that a significant majority of embolization patients are "complex patients" defined by one or more of the following:

- Previous embolization and/or systemic therapy;
- Multi-nodal or bilobar lesions – (Significant tumor burden);
- Large tumors (≥ 8 cm); and
- Multiple comorbidities.

Given this evidence base, we are positioning TriNav to become standard of care for complex patients and are instructing our sales organization to focus interventional radiologists' utilization of TriNav on these complex patients where TriNav has been shown to provide benefit when compared to standard catheters.

Reimbursement

In December 2023 TriNav received a unique and permanent HCPCS code from CMS, C9797, which has been assigned to APC 5194 (Level 4 Endovascular Procedures) for calendar year 2024 with a payment rate of $16,724.70. This code can be used without restriction for any embolization or occlusion procedure consistent with the TriNav Instructions for Use and is reimbursed in the hospital outpatient and ambulatory surgery center settings. With the provision of this new code, reimbursement for TriNav has continued uninterrupted from the launch year. The new C9797 code brings significant benefit vs. previous CMS coverage as the new code is not restricted to use in conjunction with specific CPT codes, which was the case under TPT status.

In November 2019, TriNav, with its innovative SmartValve technology, received transitional pass-through ("TPT") status for U.S. reimbursement. Receiving TPT requires meeting stringent clinical and effectiveness criteria, and TriNav is one of the few technologies to receive this in the Interventional Oncology arena. The launch of TriNav in February 2020 coincided with the onset of the COVID-19 pandemic, which temporarily limited access to hospitals and impeded the technology's adoption. Furthermore, it hindered our ability to gather essential data needed by the Centers for Medicare and Medicaid Services (CMS) for establishing a long-term reimbursement plan.

In late 2022, we collaborated with Congress to include a bi-partisan provision in the consolidated Omnibus Appropriations Act of 2023, P.L. 117-328, which extended the TPT reimbursement for an additional year. This extension provided us with the opportunity to collect the necessary data to work closely with CMS on developing a long-term reimbursement solution. Thanks to this additional year, we were able to conduct a HEOR study, a database of over 300 million patient lives, to gain insights into how TriNav with SmartValve is being used, the patient profiles, additional steps involved, and the procedures performed. This additional year of coverage provided the necessary data propelling CMS to provide the unique and permanent HCPCS code described above.

Our Customers & Stakeholders

We aim to interact closely with all our key stakeholders to ensure a patient's experience is beneficial. We view our customers as including the interventional radiologists, IR technicians, medical oncologists, nursing support, and the value

analysis committee staff, who either use our products or recommend the purchase of such products to hospitals and, most importantly, the patients they treat.

Our goal is to establish a high level of engagement and trust with the various clinicians and support individuals in the hospital as well as patients. Additionally, we believe that many hospitals are under cost pressure and need education on, and assistance to support and embrace, the use of modern technology. We have reimbursement, clinical and technical support to ensure each clinician and support individual feels confident in using our technology.

Another crucial stakeholder group comprises advocacy organizations that have been instrumental in supporting the use of TriNav and our company on a broader scale. TriSalus has partnered with several patient advocacy groups dedicated to assisting a diverse spectrum of liver cancer patients, encompassing both primary and secondary liver cancer. We aim to enhance awareness among patient communities regarding the array of available treatment options, including participation in our technology and nelitolimod clinical trials. Receiving a diagnosis such as liver or pancreatic cancer is devastating and overwhelming to patients. Our commitment is to provide patients, their clinicians and advocacy organizations with information regarding the benefits of our technology and platform approach with nelitolimod.

Sales and Marketing

We have established a commercial infrastructure designed to drive TriNav adoption among interventional radiologists and oncologists. Our commercial strategy for TriNav targets hospitals through direct sales engagements with clinicians and the broader medical, hospital and technical staff. TriSalus utilizes a direct sales model to hospitals and ambulatory surgery centers nationwide, eliminating the need to pay distributor fees and assuring that representatives are trained on TriNav's clinical benefit and use, and are not distracted by other sales priorities as would be the case if we utilized distributors. Our current sales focus is on targeting hospitals and major academic medical centers with the highest levels of TACE and TARE procedures.

Our sales representatives and sales managers have substantial medical device experience and market our products directly to interventional radiologists who perform TACE and TARE procedures. We are focused on developing strong relationships with our physicians and hospital customers in order to educate them on the use and benefits of our products. Similarly, our marketing team has a significant amount of domain expertise and a strong track record of success. Our sales and marketing team totals 41 professionals as of March 10, 2024.

The use of TriNav is consistent with the current steps an interventional radiologist utilizes to conduct TACE and TARE procedures. Following instructions from one of our sales representatives on how best to manage optimal functioning of the SmartValve, we believe the TriNav catheter is intuitive, and relatively easy to use. We believe this provides value to our customers and makes our sales model a source of competitive advantage. A lower service burden means we can develop a cost-efficient sales model by optimizing a mix of clinical specialists and salespeople. In the U.S., TriNav can be provided to hospitals on a consignment basis whereby title is transferred when the technology is used in clinical procedures. Other hospitals purchase TriNav directly, and TriNav is sold for a predetermined set fee for each catheter via a predetermined contract or purchase order.

TriNav Design & Specifications

TriNav is a flexible microcatheter that can be used to deliver diagnostic and therapeutic agents into peripheral vasculature beds, with its main clinical use being TACE or TARE procedures. It is equipped with a SmartValve, which is a one-way microvalve capable of generating infusion pressure greater than mean arterial pressure to help overcome intratumoral pressure and improve distribution of therapeutics. The SmartValve is designed to provide reflux protection and to maintain a centroluminal position during infusion.

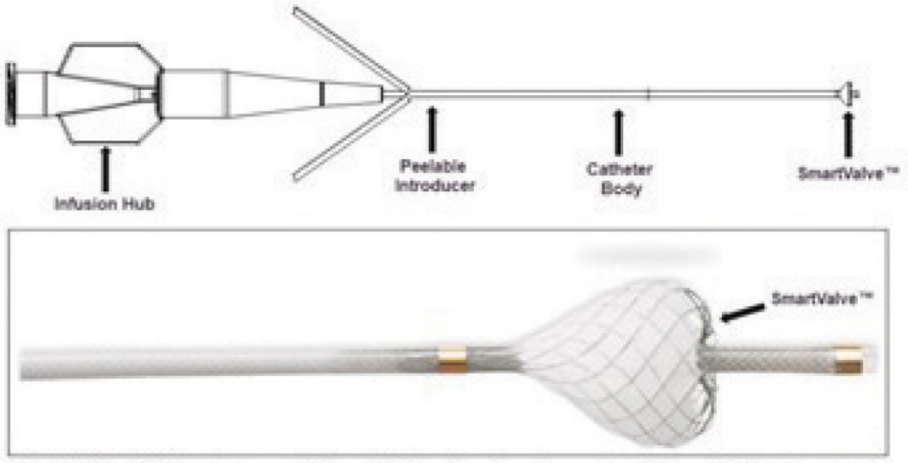
The unique ability of TriNav in generating infusion pressure to drive therapy deeper into solid tumors is driven by the SmartValve at the distal end of the catheter. It is made of ultra-thin nitinol fibers laid out in a precise braid geometry, which is then overlaid with nanofilaments made of composite polymers — creating a filter valve that allows particles >10µm (for example, red blood cells) to pass through. The exact geometry of the braid and composition of the polymers have been calibrated to create a soft, pliable valve that can react dynamically to varying pressure and flow conditions in vasculatures, yet that is strong enough to prevent reflux of material and generate sufficient pressure without imposing too much radial force on the vessel walls. TriNav’s dimensional specifications are as follows:

Dimensional Specifications

Parameter	Specification (nominal)

Usable Length	120 cm, 150 cm
Outer Diameter (max)	0.038 in (0.97 mm)
Inner Diameter (Infusion Lumen)	0.021 in (0.53 mm)
Expandable Tip Outer Diameter	3.7 mm

The catheter shaft is made of composite polymer (Pebax) segments of varying softness and reinforced with stainless-steel braid. The design and material of the shaft have been optimized to provide strength, kink resistance, ease of tracking and flexibility — all of which are important to enable navigation of the catheter over microwires in tortuous vasculature. At the distal end of the catheter, there are two radiopaque marker bands to help physicians locate the distal end of the catheter as it is being threaded through the vasculature. The inner lumen of the catheter shaft is lined with polytetrafluoroethylene, a highly inert and lubricious polymer, to minimize friction and maximize compatibility with microwires, chemotherapy, cell therapy products, and other agents used during the procedure. Finally, the device is coated with a hydrophilic formulation that is thin yet durable, making it even more trackable and capable of accessing the most tortuous vasculature.



The TriNav™ Device and SmartValve™. A schematic of the TriNav device is shown in the top image, with a high-power view of the SmartValve below.

Industry and Competition

Our industry is highly competitive and subject to rapid and significant technological change as research provides a deeper understanding of the pathology of diseases and new technologies and treatments are developed. We believe our scientific knowledge, technology, and development capabilities provide us with substantial competitive advantages, but we face potential competition from multiple sources, including large pharmaceutical, biotechnology, specialty pharmaceutical and, to a lesser degree, medical device companies.

TriNav Competition

The primary competition for TriNav is the standard microcatheter, which is frequently used in minimally invasive procedures for delivering therapeutics or devices. However, standard microcatheters do not have the ability to modulate pressure and flow nor do they have clinical evidence or data that they can improve therapeutic delivery to liver and pancreatic tumors.

Microcatheters are manufactured by a wide range of medical device manufacturers. Besides the standard microcatheter, there are two other competitive products: Embolix's Sniper and Guerbet's SeQure.

Some of our competitors are large, well-capitalized companies with significantly larger market shares and resources than we have. As a consequence, they are able to spend more money on product development, marketing, sales, and other products. We also compete with smaller, niche players that have less resources and more limited influence in the market.

Growth Opportunities - TriNav Portfolio Expansion

The next product that we plan to commercialize is a larger version of TriNav capable of being used in larger vessel sizes, 4.0-6.0 mm, which was 510(k) cleared by the FDA in May 2023. We intend to launch the product commercially once our ongoing market evaluation is completed, which is expected to occur in the second half of 2024. We believe that by offering additional devices to address a broader range of vessel sizes encountered in TACE and TARE procedures, there is a potential that TriNav and our next-generation of PEDD products could be positioned to be utilized

across the wide range of procedural approaches, disease stages, and patient vasculatures that interventional radiologists encounter. The SmartValve component, which is embedded into the catheter, is highly dynamic in that is opens and close in sync with the heartbeat to achieve the following:

- Enhances perfusion of the tumor by modulation of the vessel pressure gradient;
- Improves target delivery by redirecting blood flow to the tumor and away from the normal liver;
- Creates turbulence to mix therapeutic with the blood for reliable distribution; and
- Reduces reflux to protect normal tissue outside the liver.

TriSalus is committed to enhancing our technology to improve patient outcomes. A major area of product enhancement underway at the Company is to incorporate machine learning and sensing into our technology to improve patient outcomes through several mechanisms:

- **Precision Therapeutic Delivery** – By accurately measuring both pressure and flow within blood vessels feeding tumors, healthcare providers can overcome mechanical barriers in the tumor microenvironment with greater precision. This data can inform more precise and consistent treatment delivery, dosage of chemotherapy, radiation therapy or targeted therapies and ensure optimal tumor perfusion.
- **Real-time monitoring** – Continuous monitoring of pressure and flow allows for real-time assessment of optimal therapy delivery. This enables clinicians' ability to adjust treatment strategies promptly based on dynamic changes in the tumor's vascular characteristics, optimizing therapeutic efficacy while minimizing potential side effects.
- **Selection of optimal target vessel location** – Changes in pressure and flow patterns can negatively alter therapeutic delivery efficiency before clinically apparent. Early detection through sensing monitoring enables proactive intervention, allowing for improved therapeutic delivery.
- **Personalized Therapy Optimization** – Every tumor and vascular network is unique. By monitoring pressure and flow parameters over time, interventional radiologists can tailor treatment to the patient's specific vascular dynamics. This personalized approach enhances treatment efficacy while minimizing unnecessary interventions and risks.
- **Reduced treatment toxicity** – Fine-tuning treatment regimens based on real-time pressure and flow data can help minimize treatment toxicity by delivering therapeutic agents more precisely to the tumor while sparing healthy tissues. This has the potential to lead to improved patient tolerance of treatment and overall improved tumor response.
- **Enhanced research opportunities** – The data collected from pressure and flow sensors can contribute to better understanding of mechanical TME barriers and treatment response. This data can lead to "smart algorithms" to optimize treatment protocols and develop improved overall patient outcomes.

TriSalus is committed to enhancing our technology, incorporating machine learning and sensing technologies with a range of capabilities to provide valuable clinical insights, improving personalized treatment strategies, and most importantly, improve patient outcomes. R & D efforts are underway on a variety of different technologies with plans for future product launches within the next several years.

Pancreatic Retrograde Venous Infusion Device (PRVI)

Additionally, we are advancing our Pancreatic Infusion Technology ("PRVI"), which is currently 510(k) cleared by the FDA and in a Phase 1 clinical trial for locally advanced pancreatic cancer.

Our PRVI approach seeks to address many of the key challenges associated with delivering therapeutics to pancreas tumors. In contrast to the liver, pancreas arteries feeding tumors are small and tortuous, making targeted delivery challenging. venous access affords anatomic advantages due to the presence of larger diameter vessels. Additionally, pancreatic tumors exhibit a dense, desmoplastic stroma that limits the delivery of therapeutics. The PEDD method is design to address the mechanical barriers. Certain cell types within the stroma construct an immunologically suppressed microenvironment that prevents the local immune system from clearing the tumor. We believe our PRVI device may address these challenges by:

- Modulating pressure and flow to overcome mechanical barriers;
- Embedding real-time pressure sensing capability important to ensure a pressure flow that stays within safe and appropriate pressure levels and that avoids hypoxia; and

- Enabling a therapeutic index that is efficacious while limiting toxicity compared to systemic dosing.

The Pancreatic Retrograde Venous Infusion Device has not been commercialized and commercial sales are anticipated to coincide with approval, if any, of nelitolimod in locally advanced Pancreatic cancer.

Pre-clinical pancreatic cancer model experiments indicated that using the PRVI method of PEDD improved drug delivery 3.6-7.0-fold. We studied PRVI in an orthotopic murine model of PDAC and demonstrated that PRVI delivery of gemcitabine increased intra-tumoral drug concentrations and enhanced the subsequent tumor responses to treatment. PRVI infusion of gemcitabine resulted in more than 100-fold greater tumor concentrations compared with systemic delivery (127 vs 19 ng/mg; $P < .01$) and lesser tumor volume compared with both systemic gemcitabine and saline via PRVI (274 vs 857 vs 629 mm3; $P < .01$). The same mouse model was employed to assess the impact of PRVI on tumor uptake and response to oxaliplatin. It was found that PRVI administration of a 2mg dose of oxaliplatin resulted in a significant decrease in tumor size while preserving nerve conduction velocity and nerve tissue morphology as compared to standard delivery methods under histopathological analysis.

Near-Term Commercial Focus

Our near-term pipeline focus is to improve outcomes with TARE and TACE for patients, while concurrently investigating how nelitolimod may allow more patients with liver tumors to benefit from immunotherapy.

Current evidence for the efficacy of specific locoregional therapies is primarily based on retrospective reports and a large population-based study, as there are few prospective clinical trials. Given this landscape, along with our PERIO clinical program, we are supporting multiple investigator-initiated trials comparing PEDD with standard catheters for TACE and TARE procedures with respect to therapeutic delivery.

Other Commercialization Growth Opportunities

- ***Expand TriNav Sales Organization in the U.S.***: We sell TriNav through our direct sales organization in the U.S. Our sales team has in-depth knowledge of the markets in which we compete and in which we seek to compete. We have recently expanded our specialized sales organization across the U.S. to provide broader hospital coverage and increased time for the representative to expand utilization within hospital targets from which we expect to foster deep relationships with physicians and drive revenue growth. We intend to expand our commercial organization over the next several years to ensure full coverage of the Embolization market in a manner that will maximize shareholder value.
- ***Expand Internationally Through Distributors***: In addition to growing our direct sales organization in the U.S., we are considering the option of selling to distributors in Europe, where we believe that selling through third-party distributors is the best way to optimize our opportunities and resources. In addition, certain Asian markets have a very high incidence of both hepatocellular carcinoma ("HCC") and intrahepatic cholangiocarcinoma ("ICC"), and TACE procedures are the standard of care for many patient types. We currently have a distribution relationship with Hangzhou Ruizhen Therapeutics Co., Ltd. (“Hangzhou”) in China. In collaboration with Hangzhou, TriNav has been submitted for National Medical Products Administration (“NMPA”) approval and we expect a final determination regarding such approval sometime in the first half of 2024. If approved, Hangzhou is expected to have the responsibility to launch in the Chinese market with support from us.
- ***Develop Collaborations with Therapeutic Partners***. The PEDD approach has been shown to be able to improve uptake into tumor tissue of a range of therapeutics in both human studies and in animal models. Immunotherapeutics, chemo- and radioembolics, chemotherapeutics and cell therapies have all been shown to have improved uptake when delivered by a TriNav vs. standard approaches. We may explore opportunities to partner with therapeutics companies at all stages of development and commercialization by reading the delivery of therapies to patients in a manner that can improve outcomes in areas of high unmet medical need.
- ***Continue Partnering with Leading Academic Medical Centers.*** We will continue to progress our clinical evidence of the value of PEDD through TriSalus-sponsored and investigator-sponsored research. Currently we have multiple investigator-initiated trials at major medical centers exploring the benefit of TriNav and the PEDD method in TARE, TACE and uterine fibroid embolization. We intend to complete these trials while also planning and initiating additional trials that have the potential to further define the benefit that TriNav can bring to areas of unmet medical need.

Nelitolimod: Promising Therapeutic Opportunity

Strategic Acquisition of Nelitolimod

In July 2020, we acquired nelitolimod, a class C Toll-like Receptor 9 (TLR9) agonist, from Dynavax Technologies Corporation ("Dynavax"). Prior to acquiring nelitolimod, we embarked on a comprehensive landscape assessment evaluating assets currently or formerly in clinical development that would fit the criteria for optimal immunomodulation of the TME in the liver and pancreas. Our selection criteria included the identification of an immunotherapeutic with a potential mechanism of action to specifically address immunosuppressive mechanisms in the liver and/or pancreas; the potential to enable systemic checkpoint inhibition in patients with liver or pancreatic tumors to the extent observed in other indications, the ability to broadly reprogram the TME while addressing Myeloid Derived Suppressor Cells, (a key cell type that suppresses the immune system in the liver and pancreas) and a therapeutic where locoregional delivery would be expected to improve outcomes.

We chose to focus on TLR agonists since they are well known to have broad TME modulating effects with induction of immunity at distal sites and the potential to turn "cold tumors" such as those affecting the liver and pancreas, "hot", meaning responsive to immunotherapeutics such as ICIs. Many TLR agonists have been in clinical development with varying results, most often using needle injection strategies which limit the ability to treat multiple or large tumors. TLR agonists are generally not safe to be administered intravenously due to concerns related to excessive immune cell activation.

We acquired nelitolimod from Dynavax based on Phase 2 study data that demonstrated improved responsiveness to pembrolizumab with acceptable tolerability in stage IV cutaneous melanoma. In particular, Dynavax conducted the Synergy-001/KEYNOTE 184 Phase 1b/2 study (the "Synergy study") to assess the safety and preliminary efficacy of the combination of intratumoral nelitolimod and intravenous ("IV") pembrolizumab for cutaneous melanoma and head and neck cancer. In the Synergy study, nelitolimod + pembrolizumab was associated with a serious adverse event rate on par with that of pembrolizumab alone, and a response rate of 78% was achieved in treatment naïve patients. In the melanoma and head and neck carcinoma studies, nelitolimod in combination with anti-programmed cell death protein 1 ("PD-1") therapy produced response rates that are higher than those reported for anti-PD 1 therapy alone. See *(12) Dynavax Purchase* to our consolidated financial statements included elsewhere in this annual report for more information.

Since acquiring the worldwide rights to nelitolimod, we have initiated three Phase 1/1b Pressure Enabled Regional Immuno-oncology (PERIO™) ("PERIO") studies which are focused on four indications where we are testing the ability of the nelitolimod /PEDD therapeutic platform to enable systemic CPIs in the following Phase 1 clinical trials:

- Uveal melanoma with liver metastases (PERIO-01, NCT04935229);
- ICC and HCC (PERIO-02, NCT05220722); and
- Locally advanced pancreatic carcinoma (PERIO-03, NCT05607953).

We are collaborating with leading cancer centers across the country to help leverage our deep immuno-oncology expertise and our unique, proprietary platform to improve patient responses to CPI therapy and potentially allow a greater number of cancer patients to benefit from immunotherapy advances.

We believe our approach in combination with CPI therapy has the potential to extend and improve the lives of patients battling liver and pancreatic tumors.

Current Treatment and Limitations

Two critical barriers have historically hindered immunotherapy success in patients with intrahepatic and pancreatic malignancies: (1) delivery of immunotherapy agents into high-pressure liver tumors is inefficient with conventional approaches and (2) specific immunosuppression pathways hinder immunotherapy responsiveness. In the majority of liver and pancreatic cancers, the tumors are not infiltrated by T cells and the TME overall is suppressed. An accumulation of suppressive immune cells, such as MDSCs, further limit the ability of T cells to enter into tumors and remain in an activated state.

For immunostimulatory drugs like nelitolimod to enable CPIs and other forms of immunotherapy, successful delivery into tumors is necessary. Intratumoral pressure in the TME may result in subtherapeutic drug concentrations at the site of disease. With systemic intravenous (IV) infusion, it is difficult to achieve therapeutic levels within the tumor due to distribution of cardiac output and high intratumoral pressures, and off-target toxicity is common. Local needle injection, the traditional approach for TLR agonists since they typically cannot be administered systemically, is highly localized at the point of insertion, not uniformly distributed throughout the tissue (particularly in patients with large or multiple tumors), and physically impractical for most tumors, including liver and pancreas. Importantly, regional intravascular delivery with standard microcatheters does not address the intra-tumoral pressure barrier, while balloon catheters cause a cessation of forward blood flow, which may eliminate the ability to augment baseline intravascular pressure.

Nelitolimod mechanism of action.

As a class C TLR9 agonist, nelitolimod has the capacity to stimulate a broad array of immune cells and induce numerous cytokines. In addition, nelitolimod may be able to reduce myeloid suppressor cells in the liver and pancreas.

Nelitolimod: Cancer Types in Clinical Studies

Locally Advanced Pancreatic Adenocarcinoma ("LA-PDAC")

LA-PDAC is associated with rapid progression, resistance to conventional therapies, deterioration in quality of life, significant morbidity, and a high mortality rate. PDAC tumors are characterized by dense desmoplastic stroma with limited effector immune cells, rendering both drug delivery and stimulation of immune responses very challenging. Immuno-oncology approaches in general and CPI therapy have been highly successful in certain other malignancies, but PDAC is a particularly aggressive disease which has proven resistant to immuno-oncology regimens. Poor responses to CPI therapy in PDAC patients may be due to the presence of suppressive immune mediators such as MSDCs, scarcity of effector T cells, and drug delivery challenges due to a highly desmoplastic stroma creating high tumor pressures. Response rates to CPI in patients with PDAC are routinely below 10% and new therapeutic options capable of addressing the delivery and immunologic barriers are urgently needed. LA-PDAC immunotherapy success may be limited due to challenges with drug delivery and a deeply immunosuppressive TME driven by MDSC. The PERIO programs are designed to test delivery technology and class C TLR9 agonist with the potential to enhance immunotherapy performance in intrapancreatic indications.

Uveal Melanoma Liver Metastases

With fewer than 3,000 new diagnoses per year in the U.S., uveal melanoma is a rare solid organ malignancy in which metastatic spread to the liver results in rapidly progressive and often fatal disease. Uveal melanoma arises from melanocytes within the uveal tract, but it is a unique disease with distinct genetic, chromosomal, and biologic features not observed in cutaneous melanoma. Metastatic disease occurs in more than 50% of patients and involves the liver in up to 90% of metastatic patients.

The recent regulatory approval of Kimmtrak®, a bispecific T-cell receptor engager, which had a 1-year OS rate of 73% offers promise for patients with stage IV uveal melanoma and demonstrates that immunotherapy has potential application in addressing this disease. However, approximately 50% of patients are ineligible due to human leukocyte antigen ("HLA") type. While the OS data was positive, progression-free survival at one year was only approximately 19%, with a median progression-free survival of 3.3 months. Despite representing a crucial clinical advance, the unmet need in the stage IV uveal melanoma space persists.

For patients not eligible for Kimmtrak, CPIs that target CTLA-4, such as ipilimumab, and those that target PD-1, such as nivolumab and pembrolizumab are often used off-label. However, they have had limited efficacy in metastatic uveal melanoma. An important contributor to the failure of current therapies to effectively treat uveal melanoma is the profoundly immunosuppressive intrahepatic environment.

HCC and ICC

HCC and ICC are the most common primary liver tumors, with HCC representing approximately 90% of cases. While the underlying reasons for the biologic aggressiveness of HCC and ICC are not fully understood, the profoundly immunosuppressive intrahepatic environment is likely an important contributor to both disease progression and failure of current therapies. Given limited success of single agent CPI therapy for HCC and ICC, these drugs have been used in this patient population, but with less success than other diseases.

Current standard of care in first-line ICC is the combination of gemcitabine/cisplatin ("gem/cis") in combination with AstraZeneca's Imfinzi® (durvalumab or "durva"). Median overall survival in these patients is about 12.7 months. Some second line patients are eligible for targeted therapies which can provide hope for these patients, but the majority of 2nd line patients are not eligible for these targeted therapies. For these patients there are few options, generally receiving FOLFOX/ FOLFIRI chemotherapy with median overall survival of around 6 months. Addressing unmet need in either second line or in first line patients is an attractive market opportunity.

Our Platform Solution: Addressing the Limitations of Current Approaches in Cancer Immunotherapy

Our proprietary platform approach seeks to address immune dysfunction in liver and pancreatic tumors by combining our drug delivery technology with standard care therapies and immunotherapeutics. In a number of clinical studies, PEDD has shown the ability to overcome intra-tumoral pressure and enable delivery of therapeutics intravascularly into liver tumors relative to conventional regional delivery.

Platform Components

PEDD Devices: PEDD Delivery Technology is a technological solution to this intratumoral pressure barrier that can enable more effective delivery of therapeutic agents to liver and pancreatic tumors. PEDD devices are engineered to overcome high intratumoral pressure through creation of a favorable pressure gradient, causing increased blood flow to the tumor while constricting blood flow to normal tissue minimizing systemic exposure and decreasing toxicity.

TriNav is currently being used to deliver nelitolimod to tumors in the liver in our Phase 1 PERIO-01 and PERIO-02 trials. A second FDA-cleared device, our PRVI is designed for therapeutic delivery into pancreatic tumors and is currently being used to deliver nelitolimod to the pancreas in the Phase 1 PERIO-03 trial.

Nelitolimod: In July 2020, we acquired nelitolimod, a class C Toll-like Receptor 9 agonist (TLR9 agonist) from Dynavax and are investigating nelitolimod as a therapeutic candidate delivered by PEDD to reactivate the immune system within the liver and pancreas with the goal of enabling deeper, more durable responses to other immunotherapeutics (e.g., CPIs) in liver and pancreatic cancers for which limited therapeutic options currently exist. Broad immune suppression driven by MDSCs leads to failure of systemic immunotherapeutics in liver and pancreas tumors. Our phase 1 clinical and pre-clinical data support the concept that nelitolimod primes immune cells to promote anti-tumor T-cell function, induces interferon pathways, reduces MDSCs and broadly activates the local tumor immune system to reverse immunosuppression in the liver and pancreas.

Market Opportunity for TriNav Delivery Technology and Investigational Therapeutic Nelitolimod

Nelitolimod Market Opportunity

According to the American Cancer Society, the National Cancer Institute and our most up-to-date epidemiology, there are approximately 137,000 new cases of primary and secondary liver cancers diagnosed annually in the U.S. alone, and more than 60,000 cases of pancreatic cancer diagnosed each year. Of these, more than 80,000 may be addressable through our nelitolimod /PEDD platform for liver and pancreas. Additionally, there is a high global incidence in key targeted indications, such as HCC and ICC, providing an additional opportunity outside the U.S. The incidence of pancreatic cancer in the U.S. is more than 64,000 annually with more than 90% of these being pancreatic ductal adenocarcinoma (“PDAC”).

PDAC and liver cancers are areas of very high unmet medical need and represent large market opportunities. We are currently evaluating data from our Phase 1 clinical studies and determining which indication(s) we will progress into further clinical studies. A chosen indication would be one in which we believe there is evidence supportive of commercial success, and such progression would require us to raise additional capital.

Nelitolimod Potential Indications: Pancreatic Cancer

PDAC is a prevalent, highly lethal cancer, with a five-year survival rate of 13% across all stages. Systemic first-line therapies for advanced pancreatic carcinoma currently provide short-term disease control. Both locally advanced and metastatic PDAC face similar challenges with respect to drug delivery and deep immunosuppression.

The National Comprehensive Cancer Network recommends consideration of clinical trials as the preferred option in the first-line setting for metastatic PDAC, emphasizing the broad recognition that current therapies are failing. First-line therapy for advanced or recurrent disease patients is FOLFIRINOX, a chemotherapy regimen, often delivered in concert with radiotherapy. A hallmark of PDAC TME is the abundance of noncancer cell components, collectively designated as the stroma, including MDSCs. This stroma can account for up to 90% of the tumor mass. The stroma has been shown to inhibit both spontaneous and therapeutically inducted antitumor immunity making it difficult to treat.

Higher CPI response rates in mismatch repair (“MMR”) deficient PDAC patients suggest promise for CPI in combination with immune reprogramming agents, although fewer than 5% of PDAC patients are MMR deficient. The success of immunotherapy in PDAC may hinge on successful management of two critical barriers: (1) PDAC tumors are densely desmoplastic, with the stroma and high tumor pressures posing a major barrier to drug delivery and (2) PDAC tumors foster deep immunosuppression, which is driven in part by MDSCs.

We are initially focusing on locally advanced PDAC due to the potential of the PRVI device to deliver nelitolimod into pancreatic tumors with the PRVI approach. Drug delivery to pancreatic tumors is more challenging than to the liver, given the more complicated arterial anatomy for the pancreas. We believe that the potential to administer an immunomodulatory drug, such as nelitolimod, into pancreatic tumors with PEDD creates a highly differentiated clinical approach.

Nelitolimod Potential Indications: Liver Cancers

Nelitolimod is currently being studied in three liver cancer indications: ICC, HCC, and UMML. In liver cancer our focus is currently on ICC and UMML.

ICC

ICC is a relatively rare and aggressive form of primary bile duct cancer which carries a poor prognosis since it is typically diagnosed when the disease is already in advanced stages. Despite growing awareness and education of the disease, outcomes have not improved substantially in the last decade, with a 5-year survival rate of 3-23% depending on stage of diagnosis.

For patients with advanced or metastatic disease, systemic chemotherapy with gemcitabine + cisplatin ("gem/cis") has been the standard-of-care. Recently, the FDA approved the PD-L1 inhibitor, durvalumab, in combination with gem/cis, for the treatment of first-line patients with advanced or metastatic biliary tract cancers, including ICC. In this trial of first-line patients, median OS for durvalumab + gem/cis was 12.8 months, as compared to 11.5 months for gem/cis alone. The FDA has approved targeted fibroblast growth factor receptor 2 (FGFR2") and isocitrate dehydrogenase-1 ("IDH1") inhibitors for second line and third line treatment in CCA, but less than 15% of the patients are eligible. The results from CPI in microsatellite instability-high CCA (<10% of CCA patients) may suggest the potential for immunotherapy to work if the TME in microsatellite instability-stable patients can be reprogrammed effectively. Since ICC is typically a desmoplastic tumor with a "cold" TME, direct tumor administration of nelitolimod via PEDD has the potential to enhance patient outcomes. We currently expect to seek a second-line and beyond indication for ICC for which the current standard of care is systemic chemotherapy for those not eligible for targeted therapy. Although there is significant clinical development underway with targeted therapies, there is little clinical development ongoing focused on the majority of patients who are not targeted therapy eligible.

UMML

Uveal melanoma is a malignant tumor derived from melanocytes. Despite similarities between cutaneous and uveal melanoma with respect to cell of origin, the genetic, molecular, and clinical features are entirely distinct. In particular, uveal melanoma has a unique metastatic pattern, with the liver being the dominant site of spread. Uveal melanoma is more aggressive and resistant to current therapies than cutaneous melanoma. Up to 50% of patients develop metastatic disease, with 90% of stage IV patients developing liver metastases. The highly suppressive immune environment in the liver may prevent immunotherapies such as CPIs from achieving success in this patient population.

Currently, there are limited treatments for uveal melanoma. Immunocore's Kimmtrak® is indicated for the treatment of HLA-A*02:01 positive adults with unresectable or metastatic uveal melanoma. Although an improvement over previous therapeutic options, it is only available to approximately 50% of uveal melanoma patients due to its HLA restriction and with median overall survival of 21.7 months and 1-year overall survival of 73% in first line patients. Approximately 50% of the population who are HLA-A*02:01 negative still have not approved treatment option with limited late-stage clinical trials ongoing (Ideaya's, darovasertib, is being studied in combination with crizotinib, is currently in a trial that is potentially registrational). In these patients, dual agent CPI treatment is commonly used with median overall survival of approximately 19 months demonstrated in a small Phase 2 trial. Hepzato™ from Delcath was also recently approved and is available through a Risk Evaluation and Mitigation Strategy program. Use of Hepzato™ requires placement of three catheters (two in the groin and one in the neck) to deliver a chemotherapeutic.

We are seeking to create a TME more amenable to checkpoint inhibition, which we believe may potentially be achievable due to direct delivery of nelitolimod to the liver with PEDD, the dual mechanism effect of broad intratumoral immune stimulation coupled with elimination of MDSCs, and the absence of HLA restrictions.

Significant Potential Upside from Nelitolimod Program in Development:

We are investigating nelitolimod as a therapeutic candidate to re-activate the immune system within the liver and pancreas and to enable deeper and more durable responses to systematic immunotherapeutics (e.g., checkpoint inhibitors). We are initially evaluating nelitolimod for the treatment of uveal melanoma with liver metastases, hepatocellular carcinoma, intrahepatic cholangiocarcinoma, and locally advanced pancreatic ductal adenocarcinoma. We believe delivering nelitolimod through our proprietary FDA cleared device using our PEDD technology creates a potential opportunity to change the paradigm of how liver and pancreatic cancer are treated. Our current pipeline represents a major market opportunity, particularly for PDAC and ICC given the high unmet need in these indications.

Safety and feasibility data for 5 PDAC patients who received nelitolimod via PRVI was reported at the Society for Interventional Radiology 2024 Annual Meeting and indicated no serious treatment-related complications. Previous study data released in November 2023 for 3 patients demonstrated immune signals in these patients consistent with what we

reported for liver metastasis patients. We anticipate reporting the full phase 1 experience in the second half of 2024 and begin phase 1b enrollment in the second half of 2024 if the data remains supportive.

Phase 1 data for the PERIO-01 program was presented at a late-breaking oral session at the Society of Immunotherapy for Cancer meeting in November 2023. The data presented included safety data on 56 patients, of whom 65% had failed prior therapy. Grade 3 or greater adverse event rate was 11%. The disease control rate ("DCR") was 58% across all dose levels, and at the presumed optimal biologic dose (2mg, N=7), there was a DCR of 81%, median progression free survival of 11.7 months and 1-year overall survival rate of 86%. Amongst patients with available data ctDNA clearance was 59%, with 86% showing reduction in ctDNA.

We continue to follow ICC patients and expect to report initial data in mid-2024.

Growth Strategies

Our goal is to target the significant unmet medical needs of patients with pancreatic and liver cancers by improving how liver cancer is treated currently, utilizing the TriNav Infusion System to deliver chemoembolization and radioembolization more effectively while working to transforming immunotherapy treatment through using our PEDD method to administer our investigational class C TLR9 agonist, nelitolimod.

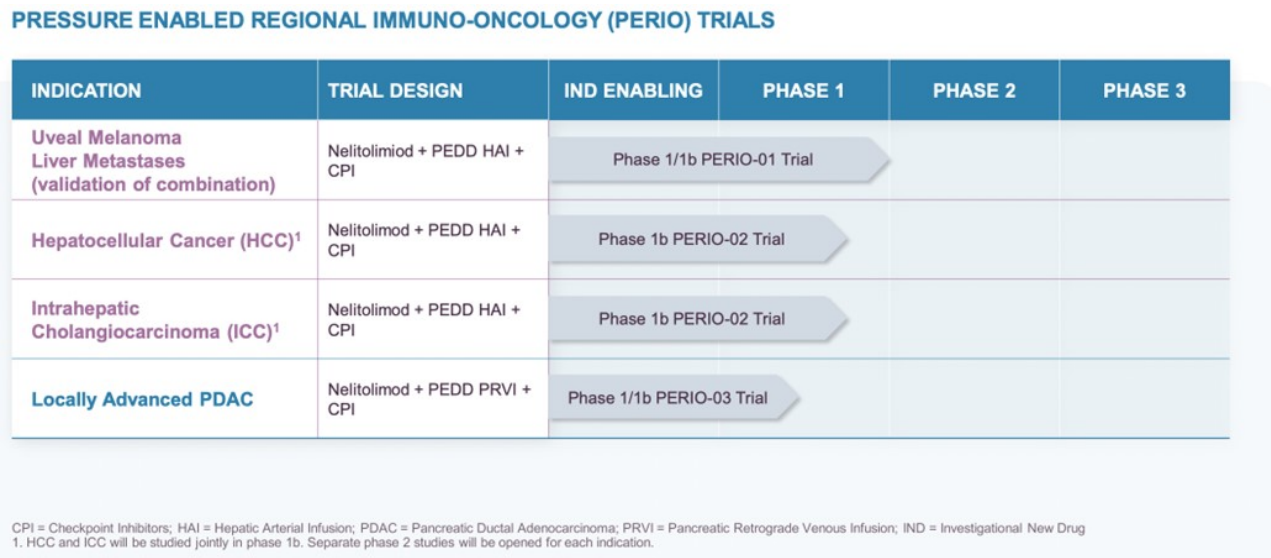
- ***Complete Development and Obtain Approval of Nelitolimod:*** Currently, our uveal melanoma, ICC, and pancreas cancer clinical programs are studying the delivery of nelitolimod deep into the vasculature of the liver or pancreatic tumors using our proprietary, FDA-cleared TriNav devices. Analysis of data expected in the second half of 2024 will be used to support decisions regarding the initiation and timing of next-phase trials. Related data milestones are dependent on multiple factors, including prioritization of available capital, interactions with regulatory authorities, enrollment rates, and external events which may impact operations at clinical sites.
- ***Seek Potential Expedited Development Pathway or Accelerated Approval Regulatory Pathway***: Our targeting of orphan indications and rare disease creates an opportunity to expedite development and the potential for an accelerated path to approval and commercialization. Nelitolimod is being studied for the treatment of ICC, uveal melanoma and HCC, diseases for which potential therapies have previously received orphan drug designations. However, nelitolimod does not currently have orphan designation, nor have we discussed possible use of the accelerated approval pathway for any indication with the FDA or other comparable regulatory agencies and it is possible that we may never be granted orphan designation or pursue accelerated approval.

  For approval of new medicines, the regulatory standard for proving "substantial evidence of efficacy" has often historically required the execution of two randomized, well-controlled clinical trials. In orphan and ultra-orphan indications with unmet medical need, including many cancer indications, there is significant precedent for FDA approval based on a single pivotal clinical trial. Further, in FDA's draft guidance on *Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics* issued in March 2023, FDA discusses the opportunities, and provides guidance for sponsors on using a single clinical trial to potentially support an accelerated approval and to verify clinical benefit. Certain drugs in development that have received orphan drug designation have been approved via the accelerated approval regulatory pathway. It is also possible, however, that in the context of either orphan or non-orphan drug development, the FDA may require more than one clinical study and/or may not accept certain clinical data.
- ***Conducting Clinical Trials with Checkpoint Inhibitors:*** The global current immunotherapy market represents the highest growth therapeutic sector in the pharmaceutical industry. This growth has been led, and we anticipate that this growth will continue to be led, by the continuing growth of CPIs, innovative new classes and an expanding patient pool. While immunotherapy targeting CTLA-4 and PD-1/PD-L1 in many cancer types has been introduced, response rates remain low in uveal melanoma, HCC, ICC and pancreatic cancer leaving significant unmet need in these patient groups. PD-(L)1 therapy has been transformational for a number of cancer types but outcomes with respect to the liver and pancreas have lagged in comparison. Despite this performance, PD-(L)1 companies have significant clinical programs studying various novel combinations of their PD-(L)1 inhibitors with both on-market and investigational drugs, including investigational immmunotherapeutics in hepatobiliary cancers. An increasing number of developmental programs are incorporating regional delivery approaches, where PEDD may add additional value.

We intend to use investigator's choice of anti-PD-1 in the development of nelitolimod in the described indications. If partnership with or rights of reference from a CPI manufacturer(s) becomes prudent or required, we believe that any such collaboration has the potential to provide any such partner companies with significant growth opportunities and differentiation from competitors.

Clinical Development Program for Nelitolimod

The following table sets forth information pertaining to the clinical trials for nelitolimod. We are currently advancing PERIO-03 while we evaluate data from the PERIO-01 and PERIO-02 trials. Initiation and timing of next-phase programs and data milestones are subject to change and dependent on multiple factors including interactions with regulatory authorities, enrollment rates, and external events which may impact operations at clinical sites.



Our anticipated upcoming milestones (which are subject to change based on enrollment, competitive environment, and regulatory feedback) include:

- Release of PERIO-01 Phase 1 overall survival and progression free survival data, with optimal biologic dose confirmation, in Q2 2024;
- PERIO-03 Phase 1 (monotherapy) enrollment completion and data release in Q4 2024 with initiation of Phase 1b (+ CPI); and
- PERIO-02 data release and initiation of next-phase enrollment in 2H 2024.

Clinical Progress to Date Using Our Therapeutic Platform

PEDD with nelitolimod: As of March 10, 2024, across three clinical trials, more than 400 infusions of nelitolimod have been delivered at multiple dose levels as monotherapy and in combination with CPIs in more than 100 patients.

Clinical Sites and Partnerships

MD Anderson Cancer Center

We have been engaged with top academic sites and leading clinicians in the liver and pancreas cancer spaces. All three PERIO programs are centered on a 5-year Alliance Program with the University of Texas MD Anderson Cancer Center ("MDACC") which we entered into in March 2021 (the "MDACC Agreement"). Pursuant to the MDACC Agreement, investigators at MDACC agreed to serve as the lead clinicians for the PERIO-01, PERIO-02, and PERIO-03 studies and we agreed to pay $10.0 million in collaboration funding to MDACC to conduct preclinical and clinical studies as mutually agreed by the parties. To date, we have paid an aggregate of $6.0 million towards these studies and will pay an additional $2.0 million following on each of the fourth and fifth anniversaries of the MDACC Agreement. The term of the agreement is for the later of (i) five years or (ii) until the applicable studies are completed. Prior to the expiration of the term of the MDACC Agreement, either party may terminate the MDACC Agreement if the other party commits a material breach of the agreement and fails to cure such breach within 30 days of receiving notice of such breach.

We have the right to terminate a study (and the corresponding study order) upon 30 days prior notice to MDACC, provided that the joint steering committee (which is composed of three representatives of each party and oversees the collaboration) has approved such termination and that all reasonable study costs and fees associated with wind-down activities and final monitoring visit shall be paid by us. Termination of one or more study orders will not automatically result in the termination of the MDACC Agreement or termination of any other study orders.

Under the terms of the MDACC Agreement, each party retains all right, title and interest in and to its own background intellectual property and no license to use such background intellectual property is granted to the other party except for MDACC's use of the study drug and study devices, as applicable, in a study as set forth in the MDACC Agreement. Within fifteen days after our receipt of an invention disclosure covering any invention, representatives from each party shall meet to assess whether, taking into consideration the intellectual property limits outlined in the MDACC Agreement, the applicable invention in which MDACC has an ownership interest can be assigned to us in full and exclusive ownership. If such assignment would not violate the intellectual property limits agreed to, MDACC assigns to us the sole and exclusive ownership in and to the applicable invention and we shall reimburse MDACC for reasonable patent costs, if any, incurred by MDACC prior to the date of assignment. No intellectual property has been developed or transferred to date.

Other Clinic Sites

Other active clinical sites for the PERIO programs include: University of Colorado Anschutz Medical School, Columbia University, Massachusetts General Hospital, Thomas Jefferson University Hospitals, University of Pittsburgh Medical Center, Stanford University, University of California — Los Angeles, University of Miami and University of Washington Medical Center. We also entered into an agreement with Lifespan to open the TriSalus Translational Immunotherapy Lab, which is part of a comprehensive, integrated, academic health system with The Warren Alpert Medical School of Brown University.

Nelitolimod Competition

We expect nelitolimod to compete primarily with a number of therapeutics that are now, or will soon be, approved for use in uveal melanoma with liver metastases, cholangiocarcinoma HCC, ICC, and locally advanced PDAC. These therapeutics include a range of immunotherapeutics (e.g., tebentafusp for HLA-A*02:01 positive metastatic uveal melanoma patients, atezolizumab in combination with bevacizumab for HCC patients), chemotherapeutics (e.g., gemcitabine combined with cisplatin for cholangiocarcinoma) and a limited number of targeted therapies (e.g., sorafenib or lenvatinib for HCC).

Pancreatic Ductal Adenocarcinoma (PDAC)

Current preferred therapy for PDAC is either a clinical trial or chemotherapy (commonly the FOLFIRINOX regimen, ± subsequent chemoradiation). Although there are a number of therapeutics and early stage clinical trials, there are currently no ongoing and active industry sponsored Phase 3 drug trials according to Clinicaltrials.gov.

Intrahepatic Cholangiocarcinoma (ICC)

Most patients at initial presentation of ICC are poor candidates for surgical resection and, in those that undergo surgical resection, recurrence rates are high. Chemotherapy is the primary treatment approach, although the recent approval of the PD-L1 inhibitor durvalumab in combination with gemcitabine + cisplatin for first-line ICC is likely to lead to this regimen becoming the standard of care. FGFs and IDH1 inhibitors have been approved by the FDA, but fewer than 15% of ICC patients are eligible to receive such treatment based on mutation presence. Initially, we will seek approval in previously treated patients.

Uveal Melanoma

Uveal melanoma has only one FDA-approved therapy, tebentafusp (KIMMTRAK). Tebentafusp is a bispecific fusion protein that recognizes two targets, with one target present on melanoma cells, and the second target present on T cells. As with all T-cell receptor products, only patients with specific HLA types are eligible for treatment. As a result, only approximately 50% of stage IV uveal melanoma patients are eligible to receive tebentafusp, and a significant unmet need still remains. Ideaya's darovasertib, in combination with crizotinib, is currently being studied in HLA:A*02:01 negative patients in a potentially registrational trial. We believe that nelitolimod delivered with PEDD to the site of disease with its believed dual mechanism effect of broad intratumoral immune stimulation coupled with elimination of MDSCs, combined with systemic checkpoint inhibition, has the potential to outperform current treatment options. Nelitolimod, if approved, would address the entire stage IV uveal melanoma patient population, with no limitations based on HLA typing.

Dynavax Asset Purchase Agreement

On July 31, 2020, we entered into an Asset Purchase Agreement with Dynavax pursuant to which we purchased from Dynavax (i) nelitolimod intellectual property and product know-how, together with any and all goodwill, rights to royalties, profits, compensation, license fees and all rights to obtain renewals, reissues and extensions of registrations, (ii) all permits related to nelitolimod, (iii) all regulatory documentation related to nelitolimod, (iv) the nelitolimod investigational new drug and (v) all clinical trial data associated with nelitolimod (the "Dynavax Agreement").

Pursuant to the Dynavax Agreement, we made an upfront payment to Dynavax of $5 million, and on December 30, 2020, made an additional payment of $4 million to reimburse Dynavax for clinical trial expenses incurred. Dynavax may also receive certain development milestone consideration dependent on the results of (a) certain clinical studies, (b) the dosing of patients in clinical trials, (c) what phase of clinical trial nelitolimod reaches, and (d) regulatory approval. The development milestones are valued up to $170 million. Dynavax may also receive certain commercial milestone payments based on (a) first commercial sale and (b) net sales in a fiscal year. Such commercial milestone payments are valued up to $80 million. As of December 31, 2023, we have made three milestone payments of $1 million each, totaling $3 million.

We also are obligated to pay Dynavax certain royalty payments equal to 10% of aggregate net sales of products containing the nelitolimod compound acquired during each fiscal year up to and including $1 billion and 12% for the portion of aggregate net sales during a fiscal year greater than $1 billion, subject to certain adjustments. Our royalty payment obligations shall expire on the latest to occur of: (i) expiration of the last-to-expire claim of an issued and unexpired patent relating to nelitolimod that claims such product (or compound contained therein) or the manufacture or use thereof in the applicable country of sale, or (ii) 10 years after the first commercial sale of such product in such country.

Manufacturing and Distribution

Manufacturing

We manufacture TriNav at our facility in Westminster, Colorado, and have adequate capacity to meet anticipated commercial and clinical demands throughout the next several years. We are continually strengthening our supply chain and are currently qualifying additional third-party suppliers for select components of TriNav. These alternate third-party suppliers of TriNav components are subject to qualification and approval from the FDA.

We contract with third parties for the manufacture, testing, and storage of nelitolimod. In our experience, contract manufacturers ("CMOs") are generally cost-efficient and reliable, and therefore, we currently have no plans to build our own manufacturing capabilities for nelitolimod. Because we rely on CMOs, we employ personnel with extensive technical, manufacturing, analytical, and quality experience to oversee contract manufacturing and testing activities and to compile manufacturing and quality information for our regulatory submissions. Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, and which govern record-keeping, manufacturing processes and controls, personnel, quality control, and quality assurance, among other activities. Our systems and our contractors are required to comply with these regulations, and we assess this compliance regularly through monitoring of performance and a formal audit program.

Distribution

Effective January 1, 2023, we became exclusive distributor in the U.S. for TriNav, which we now distribute directly to our customers.

In May 2019, we entered into a Distribution and Collaboration Agreement with Hangzhou (the "Hangzhou Agreement") pursuant to which Hangzhou was granted an exclusive, non-transferable and non-sublicensable right to distribute PEDD devices and to develop and commercialize PEDD combination products, if any, in China, Taiwan, Hong Kong and Macau (the "Territory").

We will collaborate with Hangzhou in the development, manufacture and commercialization of PEDD combination therapies. We must provide Hangzhou with sufficient quantities of PEDD devices to conduct clinical trials to obtain regulatory approval for each PEDD combination therapy in the Territory and use commercially reasonable best efforts to meet all supply needs to support the commercialization plan (if implemented). Hangzhou is responsible for (i) developing a commercialization plan, (ii) the cost of development activities to obtain regulatory approval for each PEDD combination therapy in the Territory, (iii) securing all rights to each of its drug candidates as necessary to execute the applicable plan and grant the corresponding U.S. option to TriSalus, and (iv) developing, commercializing and obtaining regulatory approvals for each PEDD combination therapy for the applicable indication in the Territory. To date, no clinical trials have commenced nor do we believe such commencement is imminent.

In connection with entering into the Hangzhou Agreement, we issued a convertible promissory note (which has been subsequently fully converted to TriSalus common stock) to an affiliate of Hangzhou for gross proceeds of $10 million. No other amounts have been paid or received under the Hangzhou Agreement to date. In collaboration with Hangzhou, we submitted TriNav for NMPA approval and we expect a final determination in the first half of 2024. The Hangzhou Agreement also requires Hangzhou to deliver to us a marketing plan no less than 12 months prior to the first distribution of any PEDD device. Such marketing plan has not been delivered to us as of the date of this Annual Report on Form 10-K and accordingly no PEDD devices have been sold pursuant to this Hangzhou Agreement or are expected to be sold in the immediate future.

The Hangzhou Agreement further includes an obligation for Hangzhou to pay us a milestone payment in the amount of $2.5 million for each PEDD combination therapy that receives regulatory approval in the covered jurisdictions and low-single digit royalties for any subsequent sales of such PEDD combination therapy on a country-by-country basis for the later of (i) ten years after the first commercial sale of such therapy in such country or (b) the first commercial sale of a generic version of such therapy by a third party. No submission for regulatory approval has been made as of the date of this Annual Report and none is expected to be made in the immediate future.

Importantly, under the terms of the Hangzhou Agreement, we will own all intellectual property that is discovered or generated in the course of performance of the collaboration that relates primarily and directly to any PEDD device, including any method of making or using any of the foregoing. Hangzhou shall own all intellectual property generated in the course of performance of the collaboration that relates primarily and directly to a Hangzhou drug candidate, including the composition, salt, polymorph, formulation of or any method of making or using the foregoing; except that TriSalus has the option to obtain an exclusive, non-transferable license under the Hangzhou intellectual property to develop, manufacture and commercialize Hangzhou drug candidates as PEDD combination therapies in the United States. The exercise of such option, or lack thereof, will result in further payment obligations of ours, if exercised, ranging from $0 to $10.0 million dependent on the timing of the exercise, and of Hangzhou in the amount of up to $10.0 million if unexercised. In the event of a material breach, the Hangzhou Agreement can be terminated by the non-breaching party effective upon (i) 90 days written notice of the breach if uncured, (ii) 30 days written notice if the alleged breach related to failure to make payments under the Hangzhou Agreement and is uncured, or (iii) immediately if such notice pertains to the willful and intentional breach related to compliance with anti-corruption laws, confidentiality obligations, distribution of competing PEDD devices, or violation of material intellectual property rights of the non-breaching party.

Intellectual Property

We strive to protect our proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our product candidates and technologies that are important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, as well as know-how, trademarks, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We internally developed our intellectual property related to TriNav and related technologies. We have sought and intend to continue to seek appropriate patent protection for our product candidates, as well as other proprietary technologies and their uses by filing patent applications in the U.S. and other select countries.

Patents

As of March 10, 2024, we owned at least 122 registered patents expiring between 2041 and 2043, with at least an additional 61 pending patent applications and four provisional applications.

For our TriNav device, we are the sole owner of five granted U.S. patents, seven pending U.S. patent applications, one granted patent in Japan and four pending foreign patent applications in Canada, China, Europe, and Hong Kong relating to a dynamic reconfigurable microvalve protection device and the PEDD method for infusing an immunotherapy agent to a solid tumor and method for selective pressure-controlled therapeutic delivery. The five granted U.S. patents expire between 2031 and 2038. The one granted patent in Japan expires in 2038. Any patents issuing from the pending patent applications (or in the case of priority applications, if issued from future non-provisional applications that we file) are expected to expire between 2030 and 2041, without accounting for potential terminal disclaimers or potentially available patent term adjustments or extensions.

For the TriSalus Infusion System, we are the sole owner of five granted U.S. patents, seven pending U.S. patent applications, 12 granted foreign patents (counting national validations in Europe) and four pending foreign patent applications in China, Europe, Hong Kong, and India relating to closed tip dynamic microvalve protection device, atraumatic occlusive system with compartment for measurement of vascular pressure change, method for selective pressure-controlled therapeutic delivery and the PRVI method for pressure-controlled retrograde venous therapeutic delivery. The five granted U.S. patents expire between 2035 to 2038. The 12 granted foreign patents expire between 2035 and 2040. Any patents issuing from the pending patent applications (or in the case of priority applications, if issued from future non-provisional applications that we file) are expected to expire between 2035 and 2041, without accounting for potential terminal disclaimers or potentially available patent term adjustments or extensions. Some patents and applications relating to the TriSalus Infusion System overlap with those identified for the TriNav device.

For nelitolimod, we are the sole owner of five granted U.S. patents, three pending U.S. patent application, three pending U.S. provisional patent applications, two pending PCT patent applications, 16 pending foreign patent applications, and 61 granted foreign patents in Australia, Canada, China, Europe (counting national validations), Hong Kong, Japan,

South Korea, New Zealand and Singapore relating to immunostimulatory sequence oligonucleotides and methods of using the oligonucleotides and specifically nelitolimod. All of the granted US and foreign patents that relate to composition of matter for nelitolimod expired in December 2023. Currently, we do not solely own any granted US or foreign patents relating to nelitolimod that expired past December 2023. However, we jointly own with Merck Sharp & Dohme LLC one granted US, seven granted foreign patents, and two pending foreign applications that relate to nelitolimod, which is a CPG-C type oligonucleotide, as discussed further below. We also jointly own a pending U.S. patent application with the Regents of the University of California and H. Lee Moffitt Cancer Center and Research Institute, Inc.

Any patents issuing from the pending patent applications (if issued from future national phase applications that we file) are expected to expire between 2041 and 2043, without accounting for potential terminal disclaimers or potentially available patent term adjustments or extensions.

We also jointly own with third parties one granted U.S. patent, two pending U.S. patent applications, and seven granted foreign patents in China, Europe (counting national validations), Hong Kong and Japan and tending foreign applications relating to combinations with CPG-C type oligonucleotides for treating cancer. The one granted U.S. patent and seven granted foreign patents in China, Europe (counting national validations), Hong Kong and Japan all expire in 2036. Any patents issuing from the two (2) pending U.S. patent applications and the two (2) pending foreign patent applications (or in the case of priority applications, if issued from future non-provisional applications that we file) are expected to expire between 2036 and 2039, without accounting for potential terminal disclaimers or potentially available patent term adjustments or extensions.

Upon regulatory approval of nelitolimod in the U.S., we expect to be granted five years of regulatory exclusivity in the U.S. We also intend to apply for orphan drug designation which, if granted, would extend the exclusivity period for an additional two years.

Nelitolimod is currently undergoing clinical trials using pressure enabled drug delivery of nelitolimod using TriNav and the TriSalus Infusion System in various cancers, and in combination with systemic checkpoint inhibitor therapy. Some of the patents and applications described with respect to TriNav and the TriSalus Infusion System are expected to be relevant to the manner nelitolimod is administered in clinical development, and post-marketing if nelitolimod is approved by regulatory authorities to be used in combination with TriNav and the TriSalus Infusion System.

Trade Secrets and Other Proprietary Information

We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants and other advisors to execute confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention provisions. Further, we generally require confidentiality agreements from business partners and other third parties that receive our confidential information.

Trademarks

We also rely on 16 registered trademarks and trade designs to develop and maintain our competitive position. TriNav, SmartValve, and TRISALUS LIFE SCIENCES are registered trademarks of ours in the U.S, and we have pending applications for U.S. trademarks for TRISALUS, SMARTSENSE, TRIGUIDE, TRISALUS CLINICAL ESSENTIALS.

Government Regulation

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act (the "FD&C Act") and the FDA's implementing regulations set forth, among other things, requirements for the testing, development, including clinical trials, manufacture, quality control, safety, effectiveness, approval/clearance, labeling, storage, record-keeping, reporting, distribution, import, export, sale, advertising and promotion of our products and product candidates. Although the discussion below focuses on regulation in the U.S. because that is currently our primary focus, we may seek approval/clearance for, and market, our products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences.

We expect the global regulatory environment will continue to evolve, which could impact the cost, the time needed to approve, and ultimately, our ability to maintain existing approvals or obtain future approvals for our products. Regulations

of the FDA and other regulatory agencies in and outside the U.S. impose extensive compliance and monitoring obligations on our business. These agencies review our design and manufacturing practices, labeling, record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed products. We are also subject to periodic inspections for compliance with applicable manufacturing and quality system regulations, which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, and servicing of finished drugs and medical devices intended for human use. In addition, the FDA and other regulatory bodies, both within and outside the U.S. (including the Federal Trade Commission, the Office of the Inspector General of the Department of Health and Human Services, the U.S. Department of Justice, and various state attorneys general), monitor the promotion and advertising of our products. Any adverse regulatory action, depending on its magnitude, may limit our ability to effectively market and sell our products, limit our ability to obtain future pre-market approvals or result in a substantial modification to our business practices and operations.

Medical Device Development and Approval

Unless an exemption applies, each medical device commercially distributed in the U.S. requires either FDA clearance of a 510(k) premarket notification submission, granting of a de novo request, or premarket application ("PMA") approval. Under the FD&C Act, medical devices are classified into one of three classes, Class I, Class II, or Class III, depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and includes those devices for which safety and effectiveness can be assured by adherence to the FDA's general controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices may require premarket notification to the FDA.

Class II devices are moderate risk devices and are subject to the FDA's general controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries, and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FD&C Act requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or another commercially available device that was cleared to through the 510(k) or de novo process.

Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. For a device that is Class III by default (because it is a novel device that was not previously classified and has no predicate), the device manufacturer may request that FDA reclassify the device into Class II or Class I via a de novo request.

510(k) Marketing Clearance. To obtain 510(k) clearance by the FDA, a premarket notification submission must be submitted to the FDA demonstrating that the proposed device is "substantially equivalent" to a predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976, and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I (e.g., via the de novo classification process), or a device that was previously cleared through the 510(k) process. The FDA's 510(k) review process usually takes from three to six months, but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant 510(k) clearance to market the device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, a de novo request or PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), de novo or a PMA in the first instance, but the FDA can review that decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until FDA has cleared or approved a 510(k), de novo or PMA for the change. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

De Novo Process. If a previously unclassified new medical device does not qualify for the 510(k) pre-market notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. If the FDA agrees with the down-classification, the de novo applicant will then receive authorization to market the device, and a classification regulation will be established for the device type. The device can then be used as a predicate device for future 510(k) submissions by the manufacturer or a competitor.

Premarket Approval Process. Class III devices require submission through the PMA process before they can be marketed. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain, among other things, a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA submission, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FD&C Act to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA application constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Clinical Trials. Clinical trials are almost always required to support de novo or a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's Investigational Device Exemption ("IDE") regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or

sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA notifies the manufacturer that the investigation may not begin or is subject to a clinical hold. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board ("IRB") for each clinical site. The IRB is responsible for the initial and continuing review of the IDE and may pose additional requirements for the conduct of the trial. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan.

During a clinical trial, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping, and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA, or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Drug Development and Approval

Under the FD&C Act, FDA approval of an NDA is required before any new drug can be marketed in the U.S. NDAs require extensive studies and submission of a large amount of data by the applicant.

Preclinical Testing. Before testing any compound in human patients in the U.S., a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the toxicity and dosing of the product. Certain animal studies must be performed in compliance with the FDA's Good Laboratory Practice ("GLP") regulations and the U.S. Department of Agriculture's Animal Welfare Act. Some nonclinical testing can happen during the clinical trials.

IND Application. Human clinical trials in the U.S. cannot commence until an investigational new drug ("IND") application is submitted and becomes effective. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA, and the clinical trial proposed in the IND may begin. Either before or after human clinical trials commence, the FDA may stop a clinical trial by placing it on "clinical hold" because of concerns about the safety of the product being tested or for other reasons.

Clinical Trials. Clinical trials involve the administration of a drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulations, including compliance with the FDA's Good Clinical Practice ("GCP") requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate and that the rights, safety, and well-being of study participants are protected. The conduct of clinical trials is subject to the FDA's Bioresearch Monitoring ("BIMO") program, a comprehensive program of on-site inspections, data audits, and remote regulatory assessments. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board ("IRB") for each clinical site. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events ("AEs"). Foreign studies conducted under an IND must meet the same or comparable requirements as those that apply to studies being conducted in the U.S. Data from a foreign study not

conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with GCP and U.S. regulations and the FDA is able to validate the data.

A study sponsor is required to publicly post specified details about certain clinical trials and clinical trial results on government or independent websites (e.g., http://clinicaltrials.gov). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap, be combined, or be subdivided. In some cases, particularly in the development of therapies to treat orphan or rare disease or diseases with unmet medical need, development is limited to one or two phases.

- Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to evaluate the safety, metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop initial data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential AEs.
- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, multi-site, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen. Phase 3 data often form the core basis on which the FDA evaluates a drug's safety and effectiveness when considering the product application.

The sponsoring company, the FDA or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

NDA Submission and Review. The FD&C Act provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505(b) of the FD&C Act is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505(b)(1) NDA contains results of the full set of preclinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate.

Section 505(b)(2) of the FD&C Act provides an alternate regulatory pathway to obtain FDA approval that permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

We plan to seek FDA approval of nelitolimod through a 505(b)(1) regulatory approval pathway, as part of a combination regimen with checkpoint inhibitor(s). A combination regimen requires data demonstrating the contribution of each drug in the regimen to the treatment of the disease under study. For nelitolimod to obtain approval, we will be required to produce data to confirm its contribution to the regimen improves the efficacy of the therapeutic regimen. There is FDA precedent for this data to be obtained from a number of sources, including, a comparator in a controlled trial, prior FDA approvals, historic data from other clinical trials or meta-analysis of clinical practice or "real world" data.

In addition to a combined therapy, the inclusion of a drug (nelitolimod) and a cleared device component (TriNav) in the platform is likely to be considered a "combination product" under FDA regulations. For nelitolimod, we expect that the FDA's Center for Drug Evaluation and Research ("CDER") will have primary jurisdiction for review of the NDA, and the drug and cleared device will be reviewed as a combination product under one marketing application. For a drug-device combination product, CDER typically consults with the FDA's Center for Devices and Radiological Health in the NDA review process. For TriNav to become part of a combination product, we may be required to produce data supporting TriNav or PEDD's contribution to the efficacy of nelitolimod in the targeted indications beyond the original data used in support of 510(k) clearance of the TriNav device. In addition, our PRVI device is currently being studied in combination with nelitolimod in the PERIO-03 trial. The PRVI device has received 510(k) clearance and may in the future also meet the definition of a "combination product" under FDA regulations. For the PRVI device to become part of a combination product, we may be required to produce data supporting PRVI or PEDD's contribution to the efficacy of nelitolimod in the targeted indications beyond the original data used in support of 510(k) clearance of the PRVI device.

The submission of an NDA generally requires payment of a substantial user fee to the FDA, however a drug that has received an Orphan Drug Designation is not subject to this user fee. Moreover, under section 736(d)(1)(D) of the FD&C Act, an applicant is eligible for a waiver of the application fee if the applicant is a small business submitting its first human drug application to the Agency for review and does not have another product approved under a human drug application and introduced or delivered for introduction into interstate commerce. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the FDA considers such recommendations carefully when making decisions.

Additional regulatory requirements may be implicated. The FDA may determine that a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to ensure that the benefits of a new product outweigh its risks prior to approving a new product. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, as amended by the FDA Reauthorization Act of 2017, certain molecularly targeted oncology drugs require early evaluation. Specifically, if an original NDA or Biologics License Application for a new active ingredient for adults is directed at a molecular target FDA determines to be substantially relevant to the growth or progression of a pediatric cancer, study of the molecularly targeted pediatric cancer must be submitted with the marketing application, unless FDA waives or defers the requirement. FDA also inspects the facility or facilities where the product is manufactured prior to approving an NDA. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with current Good Manufacturing Practice ("cGMP") requirements and an adequate quality system to assure consistent production of the product within required specifications.

Once the FDA accepts an NDA submission — which occurs, if at all, within 60 days after submission of the NDA — the FDA's goal for a non-priority review of an NDA is ten months. The review process can be and often is significantly extended, however, by FDA requests for additional information, studies, or clarification. After review of an NDA and the facilities where the product is manufactured, the FDA either issues an approval letter or a complete response letter ("CRL") outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional preclinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. FDA's goal for the review of an application granted priority review is six months after the 60-day acceptance period.

Developing a drug and obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as "Phase 4" or "post-marketing" studies.

Post-approval modifications to the drug or its use, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical studies or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval.

Post-Approval Regulation

Once approved, drug and medical device products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met, or if safety or manufacturing problems occur after the product reaches the market, the FDA may at any time withdraw product approval/clearance or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials, changes to a product's approved labeling, including the addition of new warnings and contraindications, or the implementation of other risk management measures, including distribution-related restrictions, if there are new safety information developments.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. If, after receiving approval, a company makes a material change in

manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product.

Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to take enforcement action or seek sanctions, including fines, issuance of warning letters, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party manufacturers, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements.

We also need to comply with some of the FDA's manufacturing and safety regulations for devices. In addition to cGMP, the FDA requires that devices or drug-device combination products comply with the QSR, which sets forth the FDA's manufacturing quality standards for medical devices. The FDA also requires that we comply with certain device safety reporting requirements for device or a drug-device combination product.

Advertising and Promotion. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs and medical devices through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and not described in the product's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. In addition to FDA restrictions on marketing of pharmaceutical products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug or medical device.

Other Requirements. Drug and medical device market authorization holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse experiences, and maintaining certain records.

RLD Patents. In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* which is referred to as the *Orange Book*. Following a drug's approval, a sponsor wishing to submit an Abbreviated New Drug Application ("ANDA" or "generic") NDA or 505(b)(2) application seeking to rely on the originally approved product as the reference-listed drug ("RLD") for its ANDA or 505(b)(2) must make one of several certifications regarding each listed patent. A "Paragraph I" certification is the sponsor's statement that patent information has not been filed for the RLD. A "Paragraph II" certification is the sponsor's statement that the RLD's patents have expired. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

Regulatory Exclusivities. The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a "new chemical entity", commonly referred to as an "NCE", which generally indicates that the active moiety has never before been approved in any drug, there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains new clinical data, other than bioavailability studies, derived from studies conducted by or for the sponsor, which were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the

FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD or listed drug NDA holder and patent owner that the application has been submitted and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit is filed during the fifth year of exclusivity, the regulatory stay extends until 7.5 years after the RLD approval. The FDA may approve the proposed product before the expiration of the regulatory stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Patent Term Restoration. A portion of the patent term lost during product development and FDA review of an NDA may be restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U.S. Patent and Trademark Office in consultation with the FDA reviews and approves the application for patent term restoration.

Other Exclusivities

Pediatric Exclusivity. Section 505A of the FD&C Act provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or *Orange Book* listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. When any product is approved, we will evaluate seeking pediatric exclusivity as appropriate.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the U.S. If a sponsor demonstrates that a drug product qualifies for orphan drug designation, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication generally is granted seven years of orphan drug exclusivity (to run concurrently with any other granted exclusivities). During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. The FDA can revoke a product's orphan drug exclusivity under certain circumstances, including when the product sponsor is unable to assure the availability of sufficient quantities of the product to meet patient needs. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Expedited Development and Review Programs. The FDA has various programs, including Fast Track Designation, Priority Review Designation, Accelerated Approval Program and Breakthrough Therapy Designation, which are intended to expedite or simplify the process for drug development and the review of product candidates. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will be lengthened. Generally, product candidates that are eligible for these programs are those for serious or life- threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track Designation is a process designed to facilitate the development and expedite the review of product candidates to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority Review Designation is designed to give a product candidate that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness, an initial review within eight months as compared to a standard review time of within ten months of the

date the FDA files the NDA. Although Fast Track Designation and Priority Review Designation do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track Designation product candidate and expedite review of the application for a Priority Review Designation product candidate.

U.S. Healthcare Reform

In the U.S., there have been and continue to be a number of healthcare-related legislative initiatives that have significantly affected the pharmaceutical industry. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act") was passed in March 2010, which substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly impact the pharmaceutical industry.

There have been judicial, congressional and executive branch challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the individual mandate was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act. 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 Affordable Care Act 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 through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to legal challenges and additional health reform measures in the future.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law which, among other things, led to aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

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. For example, 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. 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 will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. 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.

It is possible that other healthcare reform measures may be adopted in the future, which may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of our products and any product candidates for which we may obtain regulatory approval. Sales of any of our products and product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government healthcare programs such as Medicare and Medicaid, and private payors, such as commercial health insurers and managed care organizations. Third-party payors determine which drugs they will cover and the amount of reimbursement they will provide for a covered drug. In the U.S., there is no uniform system among payors for making coverage and reimbursement decisions. In addition, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

In order to secure coverage and reimbursement for our products we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costly studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct pharmacoeconomic studies, our products and product candidates may not be considered medically necessary or cost-effective by payors. Further, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved.

Furthermore, the healthcare industry in the U.S. 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. Nor can we 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. For example, CMS awarded TPT payments for TriNav for the two-year period through December 31, 2022. On December 29, 2022, the Consolidated Appropriations Act of 2023 (H.R. 2617) was signed into law and includes an extension of TPT status for certain devices, including TriNav, through December 31, 2023. In December 2023, CMS granted a New Technology HCPCS code for procedures involving TriNav. This new code, C9797, became effective on January 1, 2024, and may be reported by hospital outpatient departments and ambulatory surgical centers. There can be no assurance that continuing reimbursement will be available at similar reimbursement rates or at all.

Additional legislative changes, regulatory changes and judicial challenges related to the Affordable Care Act remain possible, as discussed above under the subheading "U.S. Healthcare Reform." In addition, there likely will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to contain healthcare costs. Thus, even if we obtain favorable coverage and reimbursement status for our products and any product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, our business is subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These laws include, but are not limited to, the following:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate in order to commit a violation.
- The federal civil and criminal false claims laws, including the False Claims Act, which can be enforced by private individuals on behalf of the government through civil whistleblower or qui tam actions, and civil monetary penalty laws prohibit individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or

knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the U.S. federal government.

- The Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, "HIPAA"), prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and its implementing regulations, imposes obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" and their subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also increased the civil and criminal penalties that may be imposed under HIPAA and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA.
- The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. Other states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co-pay assistance that pharmaceutical companies can offer to patients. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.
- The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members.

Compliance with such laws and regulations requires substantial resources. Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to legal challenge and enforcement actions. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity

Foreign Corrupt Practices Act

In addition, the U.S. Foreign Corrupt Practices Act of 1997 prohibits corporations and their intermediaries from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity.

Facilities

Our principal office is located in Westminster, Colorado, where we lease approximately 21,000 square feet of office, manufacturing, and warehouse space pursuant to a lease that expires on December 31, 2026. The lease includes two

extension options, each for five years. We have not yet determined if we will exercise the extension options. We also lease office facilities in Bannockburn, Illinois, and Cranston, Rhode Island. We also lease laboratory space at Rhode Island hospital in Providence, Rhode Island. We believe our facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space will be readily available on commercially reasonable terms.

Our Team

As of March 5, 2024, we had approximately 112 full-time employees, including 10 employees who held Ph.D. or M.D. degrees.

None of our employees is represented by a labor union or covered under collective bargaining agreement. We have not experienced any material work stoppages and we consider our relationship with our employees to be good, healthy and transparent. We actively engage with managers to collect feedback and ideas on how to improve our working environment.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining incentivizing and integrating our existing and new employees, advisors and consultants. The principal purpose of our equity and cash incentive plans is to attract, retain, and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of TriSalus by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

Our principal executive offices are located at 6272 W. 91st Ave., Westminster, Colorado 80031 and our telephone number is (888) 321-5212. Our corporate website address is www.trisaluslifesci.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this Annual Report is an inactive textual reference only. For additional information, see the "Introductory Statement" to this Annual Report, Item 7- Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report, and *(3) Business Combination* of our financial statements for the year ended December 31, 2023, included in Item 8 of this Annual Report for more information regarding the Merger.

We and our subsidiaries own or have rights to trademarks, trade names and service marks that they use in connection with the operation of their business. Other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, in some cases, the trademarks, trade names and service marks referred to in this prospectus are listed without the applicable ®, ™ and SM symbols.

Item 1A. Risk Factors

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 $59.0 million and $47.2 million for the years ended December 31, 2023, and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $248.4 million. We anticipate incurring 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 addition, 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.

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 be sufficient to fund operations into the second quarter of 2024. We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in the commercialization of TriNav, 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 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 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:

- 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;
- 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 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 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 incurrence of indebtedness would result in increased fixed or variable payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or 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 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.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders if we issue equity securities, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption or occurrence of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and 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 and related regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products 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-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, which could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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 for substantially all of revenue for the years ended December 31, 2023, and 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.

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 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. 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 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;
- 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.

We presently benefit from various reimbursement codes in the United States, including the following:

- Healthcare Common Procedure Coding System Code ("HCPCS"): C1982; and
- Current Procedural Terminology for physicians to support reimbursement for physician- rendered healthcare services Codes: 37242 Mapping and 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 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 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 and we have only one pharmaceutical product candidate, nelitolimod, 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 this product candidate, each of which are focused on a different target indication, specifically: uveal melanoma, intrahepatic cholangiocarcinoma and hepatocellular carcinoma. We will need to progress any early product candidates 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 candidates, 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. The success of these product candidates 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 and our proposed design of future clinical trials;
- demonstrating the safety and efficacy in the proposed indications for use of our product candidates 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, 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;
- 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.

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. 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 TLR agonists. 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 is composed, in part, of TLR9 agonist CpG oligonucleotides. 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. 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 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, 2024, we had approximately 112 full-time employees, ten 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 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 not, 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 require 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 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 are able to identify an appropriate business opportunity, we may not be successful in 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 transaction, combination, acquisition, disposition, joint venture or similar transaction will involve risks encountered in business relationships, 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 or businesses to achieve expected levels of revenue, 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, require us to license or waive intellectual property rights, or increase our liability;
- failure to successfully further develop any acquired product candidates or technology;
- liability for activities of the acquired or 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 specific transaction.

We may not make any strategic transactions, combinations, acquisitions, dispositions, joint ventures 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 securities, 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 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, 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 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, 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 approve pending applications or supplements to 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 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 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. 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 aggregate reductions of Medicare payments to providers of 2% per fiscal year that will remain in effect through 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 effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. 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. 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.

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 product candidates 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 sale of any products 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 product candidate, if 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 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 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 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 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 may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We may 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 these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, 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. 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, 2024, we owned at least 122 registered patents. Our issued U.S. patents expire between 2024 and 2040. All of our solely-owned granted U.S. and foreign patents that relate to composition of matter for nelitolimod will expire 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 in the U.S. and EU, respectively, which, if granted, would extend the exclusivity period beyond the initial five years of regulatory exclusivity 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 methods and compositions. As of April 3, 2024, we have at least 69 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 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, 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. 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 foreign patents relating to nelitolimod, but have recorded our ownership for at least the unexpired 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 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.

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.

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 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 and December 31, 2023, management identified material weaknesses in its internal control over financial reporting with respect (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; accounting for costs associated with the SEPA, patents and the Business Combination; and certain R&D accruals; (ii) to inadequate internal controls over the valuation of the warrant and tranche rights and obligations and liabilities resulting from the series B-2 preferred stock financing; and (iii) inadequate controls of the conversion of data from our legacy equity management system to our new system and assumptions used to calculate fair value of certain equity awards; 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, 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 effective. 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 Annual Report, we filed a Form 12b-25 (Notification of Late Filing) with the SEC to avail ourselves of a 15-day extension to file this Annual Report. 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, 2024, our common stock price has fluctuated from a low of $3.62 to a high of $12.00 per share, and the price of our Public Warrants has fluctuated from a low of $0.12 to a high of $1.19 per Public Warrant. The price of our Common Stock and Public 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;
- 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 involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of 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. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, 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 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 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 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 in 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, 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.

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 registration statement (the "Resale S-1") relating to the offer and sale from time to time by certain equityholders or 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 are issuable upon the conversion of the 4,015,002 PIPE Shares, issued at a price of $10.00 per share, (b) up to 4,062,500 Founder Shares originally issued in a private placement to the Sponsor prior to MTAC's initial public offering at a price of approximately $0.006 per share, including 3,125,000 Founder Shares subject to vesting and forfeiture, (c) up to 1,452,965 shares of Common Stock issuable upon exercise 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 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 Resale S-1 is in effect, subject to certain lock-up restrictions. Such restrictions began at the closing of the 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 8,281,779 Public Warrants to purchase an aggregate of 8,281,779 shares of Common Stock, 4,933,333 Private Placement Warrants to purchase an aggregate of 4,933,333 shares of Common Stock and 1,000,000 Conversion Warrants to purchase an aggregate of 1,000,000 shares of Common Stock became exercisable on September 10, 2023, 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 Warrants is $11.50 per share, or approximately $164.0 million in the aggregate, assuming none of the Warrants are exercised through "cashless" exercise. We have the unilateral right to reduce the exercise price of the Warrants, and may do so as a means of raising capital. There is no guaranty that the warrant holders will exercise their options 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 Warrants are "out of the money," we believe holders of our Warrants that were issued will be unlikely to exercise their warrants on a cash basis. On April 3, 2024, the reported sales price of our Common Stock was $9.78 per share and the last reported sales price of our Public Warrants was $1.04 per warrant, both of which are lower than the exercise price of the Warrants.

To the extent such Warrants are exercised, 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 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 million as of the end of that year's second fiscal quarter, or (2) our annual revenues exceeded $100 million during such completed fiscal year and the market value of Common Stock held by non-affiliates equals or exceeds $700 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, 2024, the last reported sales price of our Common Stock was $9.78 per share. So long as the trading price of our Common Stock is less than $11.50, meaning the 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 Warrants are unlikely to choose to exercise their Warrants. 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 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 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.

Item 1B. Unresolved Staff Comments

None

Item 1C. Cybersecurity

Risk Management and Strategy Overview

As cybersecurity threats rapidly evolve in sophistication and become more prevalent, especially with the increasing use of artificial intelligence technology, we have implemented a cybersecurity risk management program as part of our oversight, evaluation and mitigation of enterprise-level risks. We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to maintain the security, confidentiality, integrity, and availability of our business systems and confidential information, including personal information and intellectual property. Our cybersecurity risk management program leverages a combination of processes, technologies and personnel with expertise in cybersecurity to comply with applicable regulations and detect and respond to cyber-attacks, data breaches, security incidents, and compromises of personal information, as well as to regularly and promptly inform management and our Board of Directors of any significant cybersecurity risks and developments.

Our company currently does not have a Chief Information Security Officer ("CISO") due to our size; our Director of Operations ("DO"), with assistance from our third-party information technology ("IT") support firm, leads the Company's effort in establishing cybersecurity strategies and structures and helps identify, assess, and manage the Company's

cybersecurity threats and risk. Our DO regularly meets with our third-party IT support firm to discuss cybersecurity threats and risk. This team helps identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods and tools, for example, phishing and social engineering tests.

We have worked, and expect to continue to work, with third-party service providers, as appropriate, to assess, identify and manage cybersecurity risks. As such, our DO meets with the senior management from our IT support firm regularly to discuss work requests and issues raised that may need to be added to the network for security. We also conduct periodic and on-demand assessments of our cybersecurity risk management program with expert service providers to ensure it remains current, given the changing risk environment. The DO regularly updates cybersecurity matters to the executive management team.

We use third-party service providers to perform a variety of critical functions throughout our business, such as hosting providers, application providers, contract research organizations and contract manufacturing organizations. We have a vendor management program to manage cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our DO. Our DO is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, communicating key priorities to relevant employees and personnel, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances. Our DO, with the appropriate members of management, will work with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response plan includes reporting to the Audit Committee of the board of directors for certain cybersecurity incidents.

Governance

Cybersecurity risks are overseen by the Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our DO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings have included a range of topics, such as:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

As of the date of this report, there have been no cybersecurity threats that have materially affected or are reasonably likely to materially affect our business, operations, or financial condition.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report, including "***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.***"

Item 2. Properties

Our principal office is located in Westminster, Colorado, where we lease approximately 21,000 square feet of office, manufacturing, and warehouse space pursuant to a lease that expires on December 31, 2026. The lease includes two extension options, each for five years. We have not yet determined if we will exercise the extension options. We lease office facilities in Bannockburn, Illinois, and Cranston, Rhode Island. We also lease laboratory space at Rhode Island Hospital in Providence, Rhode Island. We believe our facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space will be readily available on commercially reasonable terms.

Item 3. Legal Proceedings

From time to time, we may be subject to legal proceedings. We are not currently a party to or aware of any pending or threatened legal proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not Applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common shares and public warrants are each traded on Nasdaq under the symbols "TLSI," and "TLSIW," respectively. Our common shares and public warrants commenced separate public trading on February 8, 2021.

Holders of Record

On April 3, 2024, there were 136 holders of record of our shares of Common Stock, 147 holders of record of our shares of Series A preferred stock, and 17 holders of record of our warrants.

Dividends

We have not declared or paid any cash dividends on our Common Stock to date. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of our board of directors at such time. In addition, our board of directors is not currently contemplating and does not anticipate declaring any stock dividends in the foreseeable future. Further, if we incur any indebtedness, our ability to declare dividends may be limited by restrictive covenants we may agree to in connection therewith.

Securities Authorized for Issuance Under Equity Compensation Plans.

Information about our equity compensation plans in Item 12 of Part III of this Annual Report is incorporated herein by reference.

Recent Sales of Unregistered Securities

As previously disclosed, in October 2023, we entered the SEPA with 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. As of the filing of this Annual Report, we have issued and sold 350,000 shares of Common Stock to Yorkville for gross proceeds of approximately $3.1 million. The shares issued to Yorkville were unregistered, but, pursuant to the Registration Statement on Form S-1 (File No. 333-276070) that we filed with the SEC on December 15, 2023, and which was declared effective on December 26, 2023, the shares issued to Yorkville have been registered for resale. The securities issued to Yorkville were issued and sold in reliance on the exemption from registration requirements thereof provided by Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of the financial condition and results of operations of TriSalus Life Sciences, Inc. (for purposes of this section, the "Company," "TriSalus" "we," "us" and "our") should be read together with TriSalus' audited consolidated financial statements as of and for the fiscal years ended December 31, 2023 and 2022, together with the related notes thereto, included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis includes forward-looking statements that involves risks and uncertainties. You should review the sections titled "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" for a discussion of forward-looking statements and important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are engaged in the research, development, and sales of innovative drug delivery technology and immune-oncology therapeutics to improve outcomes in difficult to treat liver and pancreatic cancer. Our technology is utilized in the delivery

of our therapeutics and administered by interventional radiologists. We are developing and marketing two product lines: Pressure Enabled Drug Delivery ("PEDD") infusion systems, in use today, and an investigational agent, called nelitolimod which shows potential to enhance immune system response in the treatment of hepatocellular cancer, pancreatic cancer and other solid tumors in the liver. The combination of our PEDD technology with nelitolimod, is focused on solving the two main barriers in the tumor micro environment that inhibits the success of immunotherapy. The first barrier (mechanical) is comprised of high intratumoral pressure within tumors that limits drug uptake and the second barrier (biological) is the reversal of intratumoral immunosuppression.

In 2020, we launched TriNav™, which is our newest liver therapy delivery device with SmartValve technology for our proprietary PEDD approach. Current sales consist of the TriNav Infusion System, introduced in 2020. In 2020, we gained transitional pass-through payments ("TPT") approval from the Centers for Medicare & Medicaid Services ("CMS"), which allows hospitals to cover the cost of using TriNav. The approval began in January 2020 and expired at the end of 2023. On December 14, 2023, CMS created a permanent New Technology Healthcare Common Procedure Coding System (HCPCS) code for procedures involving the TriNav® Infusion System. This new code became effective on January 1, 2024, and may be reported by hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) for the Company to obtain reimbursement for TriNav device.

We are currently in our early stage of development and have yet to generate revenues sufficient to drive positive cash flows from operations. Beginning in 2020, we began a strategic transformation from a company focused solely on the sale of our infusion systems to a therapeutic company whereby our medical devices are marketed alongside the pharmaceutical drugs and other treatments that the devices deliver to patients. This transformation led us to acquire our first immune-oncology drug, nelitolimod, in July 2020, and to begin clinical development of nelitolimod for the treatment of liver and pancreatic cancers. If our clinical trials are successful, we anticipate submitting a New Drug Approval ("NDA") request to the FDA no sooner than 2025, and assuming we receive FDA approval, commercial sales would begin thereafter, possibly in 2027.

The Business Combination

On November 11, 2022, Legacy TriSalus entered into an Agreement and Plan of Merger (the "Merger Agreement") with MedTech Acquisition Corporation ("MTAC") and MTAC Merger Sub, Inc., a wholly owned subsidiary of MTAC ("Merger Sub"), pursuant to which, Legacy TriSalus would merge with and into Merger Sub, with Legacy TriSalus surviving the merger and becoming a wholly owned subsidiary of MTAC (the "Business Combination"). The aggregate consideration payable to the stockholders of Legacy TriSalus was $220.0 million, payable in approximately 22,000,000 shares of MTAC common stock.

On August 8, 2023, the stockholders of MTAC approved the Business Combination, and the Business Combination closed on August 10, 2023. Pursuant to the Merger Agreement, 890,020,482 shares of Legacy TriSalus common stock (after conversion of all outstanding shares of Legacy TriSalus preferred stock and all in-the-money warrants) were exchanged for approximately 22,000,000 shares of MTAC common stock, reflecting an exchange ratio of approximately 0.02471853. All share and per share amounts of our common and preferred stock have been retrospectively adjusted for the exchange ratio in the following discussion.

Following the consummation of the Business Combination, we were deemed the accounting acquirer and are accounting for the Business Combination as a reverse recapitalization.

Factors Affecting Our Performance

We believe that our performance and future success depend on several factors that present significant opportunities for us but also pose risks and challenges, including those discussed below and in the section of this Annual Report titled "*Risk Factors*." In particular, our performance is affected by:

- *The continued acceptance and growth of TriNav in the marketplace*. While we believe TriNav to be a superior technology for the delivery of therapies to tumors, particularly high-density tumors, there are other technologies with which we compete. Our ability to grow TriNav sales depends on the skills of our sales force and the willingness of the marketplace to use TriNav.
- *Our ability to maintain our current TriNav pricing and gross margins to help fund the rest of our activities.* Our current pricing allows us to generate a substantial gross margin, which provides funds to support our growth and our research and development ("R&D") for both TriNav and nelitolimod. TriNav sells at a significant premium to competitive products. Our higher price was previously supported by the TPT payment program from CMS; however, the TPT authorization expired on December 31, 2023. 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 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 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 promptly obtain 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.

- *The success and cost of our clinical trials of nelitolimod*. Nelitolimod is in Phase 1 human trials to determine if, when delivered via TriNav, it is safe and effective in treating certain cancers. As with all drug candidates, the cost of operating clinical trials can be substantial, with no guarantee that the trials will result in favorable data.
- *Obtaining FDA approval of nelitolimod for sale*. Our clinical trials are still in early stages, and there is no certainty that we will generate favorable data or that, upon review, the FDA will approve nelitolimod for sale.

Recent Developments

Preferred Stock Financing

In October 2022, we sold 706,243 shares of Legacy TriSalus Series B-2 preferred stock in a private financing, primarily to existing stockholders, at a price of $14.16 per share (raising approximately $9.8 million, net of issuance costs) (the “Initial Preferred Stock Financing”). For each share sold, we also issued a warrant to purchase four shares of Series B-3 preferred stock for no additional consideration (warrants to purchase an aggregate of 2,824,974 shares of Series B-3 preferred stock were issued in the Initial Preferred Stock Financing). The strike price of the warrants issued was $2.03 per share. The Initial Preferred Stock Financing included, at the unilateral option of the Legacy TriSalus's Audit Committee, a second tranche for to the sale of up to 518,854 shares of Series B-2 preferred stock for approximately $7.3 million (which could be increased up to an aggregate of 706,243 shares of Series B-2 preferred stock for approximately $10.0 million), with each such share of Series B-2 preferred stock accompanied by a warrant to purchase four shares of Series B-3 preferred stock at a strike price of $2.03 per share (warrants to purchase up to an aggregate of 2,075,417 shares of Series B-3 preferred stock may be issued in closings of the second tranche of the Initial Preferred Stock Financing assuming the full $10.0 million is sold); and a third tranche, at the unilateral election of investors who participated in the second tranche, for the sale of up to 306,053 shares of Series B-2 preferred stock, for approximately $4.3 million (which could be increased up to an aggregate of 353,121 shares of Series B-2 preferred stock for approximately $5.0 million), with each such share of Series B-2 preferred stock accompanied by a warrant to purchase eight shares of Series B-3 preferred stock at a strike price of $2.03 per share (warrants to purchase up to an aggregate of 2,824,974 shares of Series B-3 preferred stock may be issued in the third tranche closing assuming the full $5.0 million is sold).

In March 2023, we effectuated closings (“Second Tranche Closings”) of a portion of the second tranche of the B-2 Preferred Stock Financing whereby (i) 207,541 shares of Series B-2 preferred stock and accompanying warrants to purchase 830,167 shares of Series B-3 preferred stock, representing 40.0% of the shares committed in the second tranche, were sold for an aggregate purchase price of approximately $2.9 million, net of execution costs, and (ii) 17,656 shares of Series B-2 preferred stock and accompanying warrants to purchase 70,624 shares of Series B-3 preferred stock, none of which were shares committed in the second tranche, were sold for an aggregate purchase price of $250 thousand. As a result of the closings of a portion of the second tranche of the B-2 Preferred Stock Financing described above, in accordance with the anti-dilution rights in the Legacy TriSalus’s certificate of incorporation, the conversion prices of the Legacy TriSalus's preferred stock were adjusted. The conversion prices were further adjusted as a result of the June 2023 exercise of a portion of the second tranche of the B-2 Preferred Stock Financing described below, which represent the conversion prices in effect on the Closing Date.

In June 2023, Legacy TriSalus effectuated closings of a portion of the second tranche of the B-2 Preferred Stock Financing whereby (i) 257,779 shares of Series B-2 preferred stock and accompanying warrants to purchase 1,031,116 shares of Series B-3 preferred stock, representing approximately 49.7% of the shares committed in the second tranche, were sold for an aggregate purchase price of approximately $3.7 million, and (ii) 165,967 shares of Series B-2 preferred stock and accompanying warrants to purchase 663,868 shares of Series B-3 preferred stock, none of which were shares committed in the second tranche, were sold for an aggregate purchase price of $2.4 million. As a result of the closings of a portion of the second tranche of the B-2 Preferred Stock Financing described above, in accordance with the anti-dilution

rights in the Legacy TriSalus's certificate of incorporation, the conversion prices of the Legacy TriSalus's preferred stock (i) were adjusted to $38.84 for Series A-1 preferred stock, $12.14 for Series A-2 preferred stock, $13.36 for Series A-3 preferred stock, $12.55 for Series A-4 preferred stock, $13.36 for Series A-5 preferred stock, $14.97 for Series A-6 preferred stock, $9.71 for Series B preferred stock, and $10.93 for Series B-1 preferred stock and (ii) remained the same for Series B-2 preferred stock $14.16 and Series B-3 preferred stock $2.03, which correlate to approximate (in each case rounded to three decimals) exchange ratios of 1.275 to 1 for Series A-1 preferred stock, 1.290 to 1 for Series A-2 preferred stock, 1.303 to 1 for Series A-3 preferred stock, 1.277 to 1 for Series A-4 preferred stock, 1.333 to 1 for Series A-5 preferred stock, 1.351 to 1 for Series A-6 preferred stock, 1.250 to 1 for Series B preferred stock, 1.296 to 1 for Series B-1 preferred stock, 1 to 1 for Series B-2 preferred stock and 1 to 1 for Series B-3 preferred stock. These conversion prices remained in effect at the Closing Date. Any portion of the Series B-3 Warrants that remained unexercised at the time the Business Combination is consummated were automatically net settled for shares of Legacy TriSalus Common Stock immediately prior to the closing of the Business Combination (see Note 3) and exchanged into shares of our Common Stock at the Closing Date.

In July 2023, holders of warrants to purchase 2,239,309 shares of Series B-3 preferred stock exercised their purchase rights for proceeds of approximately $4.5 million.

Components of Results of Operations

The following discussion sets forth certain components of our consolidated statements of operations as well as factors that impact those items.

Revenue

We currently operate in one reportable segment and revenue is generated primarily from sales of PEDD infusion systems to our customers, principally related to TriNav. Revenue is recognized when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration to which we expect to be entitled in exchange for those products or services.

The primary end-user customers for our products are hospitals, clinics and physicians. We had certain arrangements with our distributors under which they purchased our products and then resold them in geographic markets where we do not have a sales presence. These arrangements provided for a discount on the invoice when the distributor resold our units at our normal sales price. Such sales were recorded net of the discounts. All such arrangements were terminated on or before December 31, 2022.

We provide certain customers with rebates that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the conditions for the rebates are achieved. The rebates result from performance-based offers that are primarily based on attaining contractually specified sales volumes. We recognized $186 thousand of rebates in the 12 months ended December 31, 2023.

Cost of Goods Sold

Cost of goods sold primarily consists of raw materials, direct labor and manufacturing overhead costs related to production of TriNav.

Gross Profit and Gross Margin

Gross profit represents revenue less cost of goods sold. Gross margin is gross profit expressed as a percentage of revenue. Our gross margin and overall profitability may in the future fluctuate from period to period based on a number of factors, such as the innovation initiatives we undertake, and manufacturing costs and efficiencies.

Operating Expenses

Our operating expenses consist of R&D, sales and marketing and general and administrative expenses.

Research and Development

R&D expenses include engineering, regulatory, pre-clinical and clinical activities. We expense R&D costs as incurred. We recognize expenses for certain development activities, such as preclinical studies and manufacturing, based on an evaluation of the progress to completion of specific tasks using data or other information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of

expenses incurred. Non-refundable advance payments for goods or services to be received in the future for use in R&D activities are recorded as prepaid expenses. These amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered.

R&D activities account for a significant portion of our operating expenses. We expect our R&D expenses to increase significantly in future periods as we continue to implement our business strategy, which includes advancing our manufacturing technologies into and through clinical development of nelitolimod, expanding our R&D efforts, including hiring additional personnel to support our R&D efforts, and seeking regulatory approvals for our drug candidates that successfully complete clinical trials. In addition, drug candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Accordingly, although we expect our R&D expenses to increase as nelitolimod advances into later stages of clinical development, we do not believe that it is possible at this time to accurately project total program-specific expenses through to commercialization.

Sales and Marketing

Sales and marketing expense consists primarily of salaries, commissions, travel and related business expenses for our sales force, which is principally engaged in physician education regarding the features and benefits of TriNav. We also incur expenses for attendance at medical society meetings, product promotions and marketing activities.

General and Administrative

General and administrative expense includes executive management, finance, information technology, human resources, business development, legal, one-time costs associated with the Business Combination, and the administrative and professional costs associated with those activities. General and administrative costs also include corporate facility costs, including rent, utilities, depreciation and maintenance, not otherwise included in production or R&D expenses, as well as regulatory and professional fees for legal, patent, accounting and other consulting services. We also record public company costs in general and administrative, including board expenses, insurance, audit fees, NASDAQ fees, and costs associated with public company financial reporting.

Loss on Equity Issuance

Loss on equity issuance represents the excess of the fair value of the warrants to purchase Series B-3 preferred stock and the Series B-2 tranche liabilities over the proceeds received from the Initial Preferred Stock Financing and subsequent tranche closings.

Change in Fair Value of Contingent Earnout Liability

Change in fair value of contingent earnout liability represents the change recorded as a result of remeasurement of the fair value.

Change in Fair Value of Tranche and Warrant Liabilities

Change in fair value of warrant and tranche liabilities represents the change in fair value of the warrants to purchase Series B-3 preferred stock and the Series B-2 tranche liabilities at each reporting period that were issued as part of the Initial Preferred Stock Financing, and the change in fair value of the Public and Private warrants we assumed in the Business Combination.

Deemed dividend related to Series B-2 preferred stock down round provision

The deemed dividend represents the value attributed to the increase in shares of Legacy TriSalus common stock that preferred stockholders received as a result of the Series B-2 preferred stock financing rounds in October 2022, March 2023 and June 2023, which were deemed to be down rounds and triggered the anti-dilution provisions associated with our preferred stock. The resulting increase in value of the preferred stock was deemed to be a dividend to the preferred stockholders and was recognized as a non-cash adjustment to additional paid-in-capital.

Income Tax Benefit (Expense)

Our income tax provision consists primarily of U.S. federal and state income taxes. We maintain a full valuation allowance for our federal and state deferred tax assets, including net operating loss carryforwards, as we have concluded that it is not more likely than not that the deferred tax assets will be realized.

Results of Operations:

The following table sets forth our consolidated statements of operations data for each of the periods indicated (in thousands):

	Years Ended December 31,		2023 Compared to 2022	
	2023	2022	$ Change	% Change
Revenue	$ 18,511	$ 12,398	$ 6,113	49.3%
Cost of goods sold	2,605	2,258	347	15.4
Gross profit	15,906	10,140	5,766	56.9
Operating expenses:				
Research and development	29,510	21,358	8,152	38.2
Sales and marketing	17,034	12,738	4,296	33.7
General and administrative	23,512	12,483	11,029	88.4
Loss from operations	(54,150)	(36,439)	(17,711)	48.6
Interest income	431	180	251	139.7
Interest expense	(16)	(1)	(15)	1273.2
Loss on equity issuance	(4,353)	(8,312)	3,959	(47.6)
Change in fair value of tranche and warrant liabilities	(10,855)	(2,186)	(8,669)	396.6
Change in fair value of contingent earnout liability	10,293	—	10,293	NA
Other income and expense, net	(379)	(420)	41	(9.8)
Loss before income taxes	(59,029)	(47,178)	(11,851)	25.1
Income tax benefit (expense)	(9)	(9)	—	1.7
Net loss available to common stockholders	$ (59,038)	$ (47,187)	$ (11,851)	25.1%
Deemed dividend related to Series B-2 preferred stock down round provision	$ (2,981)	$ (2,829)	$ (152)	5.4%
Undeclared dividends on Series A preferred stock	$ (1,258)	$ —	$ (1,258)	NA
Net loss attributable to common stockholders	$ (63,277)	$ (50,016)	$ (13,261)	26.5%

Comparison of the Years Ended December 31, 2023, and 2022

Revenue

Revenue increased $6.1 million, or 49.3%, for the year ended December 31, 2023, as compared to the year ended December 31, 2022. The increase in revenue was due to higher sales volume of TriNav, amounting to $5.5 million, and the reduction in sales discounts of $0.6 million as a result of the termination of all distributor agreements in December 2022.

Cost of Goods Sold and Gross Profit

Cost of goods sold increased by $0.3 million, or 15.4%, for the year ended December 31, 2023, as compared to the year ended December 31, 2022. The increase in cost of goods sold was due to the higher volume of TriNav produced in the period to support the increase in revenue.

Gross profit increased by $5.8 million, or 56.9%, for the year ended December 31, 2023, as compared to the year ended December 31, 2022, and gross margin increased from 81.8% to 85.9%. The increase in gross profit was driven primarily by higher sales volume. The increase in gross margin was driven primarily by higher production and yield efficiencies.

Operating Expenses

Research and Development

R&D expenses increased by $8.2 million, or 38.2%, for the year ended December 31, 2023, as compared to the year ended December 31, 2022. The increase was primarily due to a $5.5 million increase in spending on nelitolimod research and development--driven by the increased size of the studies, an increase in headcount-related expenses of $0.7 million, an increase of $1.6 million in spend on development of the production resources for nelitolimod, and a $0.4 million increase in patent and facility expenses.

Sales and Marketing

Sales and marketing expenses increased by $4.3 million, or 33.7%, for the year ended December 31, 2023, as compared to the year ended December 31, 2022. The increase was primarily driven by $4.4 million increase for additional payroll and personnel expenses due to an increase in headcount of sales and marketing personnel to support the growth of TriNav, and $0.9 million of additional travel expense, partially offset by a $1.0 million decrease in marketing expense as we shift our marketing efforts to the expansion of the sales force.

General and Administrative Expenses

General and administrative expenses increased by $11.0 million, or 88.4%, for the year ended December 31, 2023, as compared to the year ended December 31, 2022. The increase was due to a $2.2 million increase for payroll and personnel expenses due to increased headcount of general and administrative personnel; $7.9 million in expenses (which will not recur) incurred in connection with the Business Combination, including legal, consulting and audit fees; and a $0.9 million increase in general legal and consulting expenses.

Interest Income

Interest income increased by $0.3 million, or 139.7%, for the year ended December 31, 2023, as compared to the year ended December 31, 2022. The increase was due higher return from the investment of our excess cash in short-term money market funds.

Interest Expense

Interest expense increased by $15 thousand, or 1273.2%, for the year ended December 31, 2023, as compared to the year ended December 31, 2022. Interest expense is incurred primarily in conjunction with our accounting for leases under Topic 742, *Leases*.

Loss on Equity Issuance

A loss on equity issuance of $4.4 million was recorded in the year ended December 31, 2023, compared to a loss of $8.3 million in the year ended December 31, 2022, attributable primarily to the issuance of Series B-2 preferred stock and the accompanying warrants to purchase Series B-3 preferred stock and related tranche obligations, which were valued in excess of the proceeds received as part of the transaction. The fair value exceeded proceeds primarily due to the issuance of warrants to purchase four shares of Series B-3 preferred stock for every one share of Series B-2 preferred stock purchased in the Initial Preferred Stock Financing.

Change in Fair Value of Tranche and Warrant Liabilities

The change in fair value of tranche and warrant liabilities resulted in a loss of $10.9 million in the year ended December 31, 2023, compared to a loss of $2.2 million in the year ended December 31, 2022, as a result of the tranche exercises in 2023 and the increase in the related warrant liabilities.

Change in Fair Value of Contingent Earnout Liability

The change in fair value of earnout liability resulted in a gain of $10.3 million for the year ended December 31, 2023, due to the decrease in the market price of the underlying common stock.

Other Income and Expense, Net

Other income and expense, net, decreased by $41 thousand, or 9.8%, for the year ended December 31, 2023, as compared to the year ended December 31, 2022, primarily due the costs associated with the conversion of the tranche and warrant liabilities from the merger.

Deemed dividend related to Series B-2 preferred stock down round provision

The deemed dividend is related to the Initial Preferred Stock Financing, which was deemed to be a down round and triggered the anti-dilution provisions associated with our Legacy TriSalus preferred stock. As a result, the conversion prices of all prior series of preferred stock were adjusted such that the holders would receive more shares of Legacy TriSalus common stock upon conversion than previously. The additional issuances of Series B-2 preferred stock in March and June 2023 were also deemed to be down rounds which triggered additional adjustments of the conversion prices. We recorded a $3.0 million non-cash adjustment to additional paid-in-capital due to the increased in value of the preferred stock was deemed to be a dividend to the preferred stockholders for the year ended December 31, 2023, compared to the $2.8 million, non-cash adjustment to additional paid-in-capital in the year end December 31, 2022.

Liquidity and Capital Resources

Overview

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future due to the investments we will continue to make in R&D and sales and marketing, and due to additional general and administrative costs we expect to incur as a public company. We incurred net losses of $59.0 million and $47.2 million for the year ended December 31, 2023, and the year ended December 31, 2022, respectively. We had cash and cash equivalents of approximately $11.8 million and $9.4 million as of December 31, 2023 and December 31, 2022, respectively. Since inception, we have financed operations primarily through the issuance of preferred stock, convertible notes, and term loans and proceeds from the exercise of warrants. We are still in our early stages of development and have yet to generate revenues sufficient to fund cash flows from operations. Our ability to fund future operations and execute our long-term business plan and strategy, including our transformation into a therapeutics company, will require that we raise additional capital through the issuance of additional equity and/or debt. There can be no assurance that we will be able to raise such additional financing on satisfactory terms. If additional capital is not secured when required, we may need to delay or curtail our operations until such funding is received. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected. As a result, we have concluded that there is substantial doubt of our ability to continue as a going concern for a reasonable period of time, which is considered to be one year from the issuance date of the financial statements.

Our ability to continue as a going concern is dependent upon obtaining additional capital and financing. Our financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should we be unable to continue as a going concern. We entered into the Merger Agreement with MTAC, and, upon consummation of the Business Combination on August 10, 2023, we raised $36.9 million of cash (net of expenses related to closing the Business Combination). In addition, as described below, we received $4.5 million in cash proceeds from the exercise of warrants to purchase Series B-3 preferred stock in July 2023.

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, existing holders of our securities 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 or other preferences that adversely affect your rights as a stockholder. Thus, existing holders of our securities 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 the SEPA with 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. As of this filing of this Annual Report, we have issued and sold 350,000 shares of our common stock for gross proceeds of approximately $3.1 million.

Unless we are able to raise additional capital, we do not currently expect that our existing cash and cash equivalents will be sufficient to fund our projected liquidity requirements for the next 12 months, creating substantial doubt about our ability to continue as a going concern. Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth in the section titled "*Risk Factors.*"

In October 2022, Legacy TriSalus raised an additional $9.8 million, net of issuance costs, through the issuance of Series B-2 preferred stock and warrants to purchase Series B-3 preferred stock. This issuance also included, at Legacy TriSalus's option, a second tranche of Series B-2 preferred stock and warrants to purchase Series B-3 preferred stock ("Series B-3 Warrants") for up to approximately $7.4 million (which could be increased to $10 million) and a third tranche, at the election of investors in the second tranche, of up to $4.3 million (which could be increased to $5 million) of Series B-2 preferred stock and warrants to purchase Series B-3 preferred stock, subject, in all respects, to the covenants in the Merger Agreement prohibiting us from issuing additional securities during the Interim Period without MTAC's prior consent. We offered the Series B-2 preferred stock to all of Legacy TriSalus's preferred stockholders at the time of the Initial Preferred Stock Financing (representing approximately 99.2% of Legacy TriSalus's then outstanding shares on an as-converted to common stock basis).

In January through March 2023, holders of warrants to purchase 94,294,112 shares of Series B-3 preferred stock exercised their purchase right, for proceeds of approximately $4.7 million.

In March through June 2023, Legacy TriSalus effectuated (i) a closing of a portion of the second tranche of the Initial Preferred Stock Financing whereby a total of 18,824,790 shares of Series B-2 preferred stock and accompanying warrants to purchase a total of 75,299,160 shares of Series B-3 preferred stock, representing 40-50% of the shares committed in the second tranche, were sold for an aggregate purchase price total of $6.6 million and (ii) an additional closing under the purchase agreement for the Initial Preferred Stock Financing whereby as total of 7,428,569 shares of Series B-2 preferred stock and accompanying warrants to purchase a total of 297,147,276 shares of Series B-3 preferred stock were sold for an aggregate purchase price total of $2.6 million.

Any Series B-3 Warrants that were not exercised for cash were automatically net settled for shares of TriSalus Common Stock immediately prior to the closing of the Business Combination and exchanged into shares of our Common Stock at the Effective Time.

Cash Flows

Comparison of the Year Ended December 31, 2023 and December 31, 2022

The following table presents net cash from operating activities, investing activities and financing activities (in thousands):

	Year Ended	
	2023	2022
Net cash used in operating activities	(50,045)	$ (32,313)
Net cash used in investing activities	(2,121)	(1,786)
Net cash provided by financing activities	54,629	13,462
Net increase / (decrease) in cash, cash equivalents and restricted cash	$ 2,463	$ (20,637)

Cash Used in Operating Activities

For the year ended December 31, 2023, net cash used in operating activities was $50.0 million. The net cash used in operating activities consisted of net loss of $59.0 million, adjusted for non-cash charges totaling $7.1 million, a $1.0 million adjustment related to a development milestone payment to Dynavax that is included as an investing cash outflow, and a net increase of $0.7 million in our net operating assets. The net operating assets net increase was primarily due to increases in accounts receivable of $2.0 million and inventory of $1.1 million, partially offset by an increase of $2.8 million in trade payables, accrued expenses and other liabilities, and a decrease of $1.0 million in prepaid expenses.

For the year ended December 31, 2022, net cash used in operating activities was $32.3 million. The net cash used in operating activities consisted of net loss of $47.2 million adjusted for non-cash charges totaling $11.6 million, a $1.0 million adjustment related to a development milestone payment to Dynavax that is included as an investing cash outflow, and a net decrease of $2.3 million in our net operating assets. The decrease in our net operating assets was driven by an increase of $5.2 million in trade payable, accrued expenses and other current liabilities, partially offset by increases in

prepaid expenses of $2.6 million and inventory of $0.2 million. The increase in our prepaid expenses was due principally to the deferral of costs associated with the Business Combination.

Cash Used in Investing Activities

Net cash used in investing activities of $2.1 million for the year ended December 31, 2023, was primarily due to purchases of property and equipment of $0.6 million, cash paid to Dynavax for a milestone payment in connection with the purchase of nelitolimod of $1.0 million, and cash paid for purchase of other intellectual property and licenses of $0.5 million.

Net cash used in investing activities of $1.8 million for the year ended December 31, 2022, was primarily due to purchases of property and equipment of $0.7 million, cash paid to Dynavax for a milestone payment in connection with the purchase of nelitolimod of $1.0 million, and cash paid for purchase of intellectual property and licenses of $0.1 million.

Cash Provided by Financing Activities

Net cash provided by financing activities of $54.6 million for the year ended December 31, 2023, consisted of consisted principally of proceeds received upon consummation of the Business Combination of $36.9 million, proceeds from the issuance of Series B-2 preferred stock of $9.2 million, and proceeds from the exercise of warrants to purchase Series B-3 preferred stock of $9.6 million, partially offset by expenses incurred related to the Business Combination of $1.1 million

Net cash provided by financing activities of $13.5 million for the year ended December 31, 2022, consisted of proceeds from the issuance of preferred stock, net of issuance costs, of $13.5 million, proceeds from the exercise of stock options and warrants for common stock of $0.1 million, partially offset by payments on finance lease liabilities of $0.1 million.

Funding Requirements

Our primary use of cash is to fund operating expenses, which consist of research, development and clinical expenses related to our lead product candidate nelitolimod, and preclinical programs, sales and marketing expenses related to the growth of TriNav, as well as general and administrative expenses. We plan to advance the development of nelitolimod, initiate new research and pre-clinical development efforts and seek marketing approval for product candidates that we successfully develop. If we obtain approval for our product candidates, we expect to incur commercialization expenses, which may be significant, related to establishing sales, marketing, manufacturing capabilities, distribution and other commercial infrastructure to commercialize such products. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. However, global economic conditions may worsen, including disruptions to, and volatility in, the credit and financial markets in the U.S. as well as disruptions to the U.S. banking system. 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. Regardless of whether these conditions exist, we may be unable to access additional capital or our liquidity could otherwise be impacted. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs and/or future commercialization efforts.

We also expect to continue to incur significant expenses in connection with our ongoing activities related to TriNav, including sales and marketing expenses and expenditures to support expansion of our production capacity to support our expected sales growth. Our future capital requirements, both near and long-term, will depend on many factors, including but not limited to: the success of our commercialization of TriNav including, among other things, continued patient and physician adoption of TriNav and our ability to maintain adequate reimbursement for TriNav; the cost of commercialization activities for TriNav, including manufacturing, distribution, marketing and sales; net product revenues received from sales of TriNav; the outcome, timing and cost of the regulatory approval process for nelitolimod by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect; the costs involved in preparing, filing and prosecuting patent applications and annuity fees relating to issued patents; the cost of maintaining and enforcing our intellectual property rights, as well as the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us; the initiation, progress, timing, costs and results of clinical trials and other research and development related to our product candidates; and the extent to which we in-license, acquire or otherwise partner in development or commercialization of other products, product candidates or technologies; the achievement of milestones or occurrence of other developments that trigger payments under the Dynavax Agreement or any other collaboration or other agreements; the number of future product candidates that we may pursue and their development requirements; the costs of commercialization activities for any of our product candidates

that may receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities; the amount and timing of future revenue, if any, received from commercial sales of our current and future product candidates upon any marketing approvals; and the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of securities offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing ownership interest in our company may be materially diluted, and the terms of these securities may include liquidation or other preferences that adversely affect common stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

As of December 31, 2023, we had $11.8 million in cash and cash equivalents. As of December 31, 2023, we have the right but not the obligation to sell up to $30.0 million of our Common Stock at our request under the SEPA, subject to terms and conditions specified in the agreement. We will likely require additional capital in the near term in order to continue to fund our operations through equity or debt financings, partnerships, collaborations, or other sources which may not be available on a timely basis, on favorable terms, or at all, and such capital, if obtained, may not be sufficient to enable us to continue to implement our long-term business strategy. In March 2024, we sold 350,000 shares of our Common Stock under the SEPA, raising approximately $3.1 million.

Additionally, we may never become profitable, or if we do, may not be able to sustain profitability on a recurring basis. If we cannot capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected and we may need to delay or curtail our operations until such funding is received.

Our continuation as a going concern is dependent on our ability to generate sufficient cash flows from operations and/or obtain additional capital through equity or debt financings, partnerships, collaborations, or other sources to carry out our long-term business strategy. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than fair value for such assets and less than the value at which such assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. As discussed in *Note (1) Nature of Business* to our consolidated financial statements included elsewhere in this Annual Report, there is doubt regarding our ability to continue as a going concern as of December 31, 2023 and the date of this Annual Report.

Contractual Obligations and Commitments

Our contractual obligations as of December 31, 2023, include lease obligations of $1.9 million, reflecting the minimum commitments for our principal administrative and production facility and other office spaces. See Note *(17) Leases* to our audited consolidated financial statements included elsewhere in this Annual Report for more information on our lease obligations, including the scheduled maturities and timing of cash payments related to these obligations.

Pursuant to the Asset Purchase Agreement, dated July 31, 2020, between TriSalus and Dynavax, we have paid Dynavax $12.0 million as of December 31, 2023, and may be required to pay Dynavax up to an additional $157.0 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 low double-digit royalties based on potential future net sales of product 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.

We do not have any outstanding debt as of December 31, 2023.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet financing arrangements or any relationships with unconsolidated entities or financial partnerships, including entities sometimes

referred to as structured finance or special purpose entities, which were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Estimates:

Our significant accounting policies are summarized in Note *(2) Summary of Significant Accounting Policies* in the audited consolidated financial statements included elsewhere in this Annual Report. While all of these significant accounting policies affect the reporting of our financial condition and results of operations, we view certain of these policies as critical. Policies determined to be critical are those policies that have the most significant impact on our financial statements and require us to use a greater degree of judgment and/or estimates. Actual results may differ from those estimates. Additionally, changes in accounting estimates could occur in the future from period to period.

Revenue Recognition

Our revenue is derived from shipments of our TriNav infusion devices to our customers which are generally comprised of hospitals, clinics and physicians, and is recognized in accordance with the provisions of the Financial Accounting Standards Board ("FASB") ASC 606, *Revenue from Contracts with Customers*, and all related applicable guidance.

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we perform the following five steps: (i) identify the contract; (ii) identify the performance obligation; (iii) determine the transaction price; (iv) allocate the transaction price; and (v) recognize revenue.

We contract with our customers based on customer purchase orders. For each contract, we consider the promise to transfer products, each of which is distinct, to be the identified performance obligation. As part of our performance obligation, products are delivered in accordance with the terms of the purchase order and we do not have any on-going service obligation after delivery.

We maintain a single, discrete transaction price for each of the products, with no adjustments since the price is approved by CMS. We do not have multiple performance obligations to complete when a purchase order is fulfilled, hence the transaction price is always allocated fully to the units being sold.

Revenue is recognized when the units for a purchase order have been shipped and control of the units has transferred to the customer. Ex-works shipment is followed, wherein we recognize revenue when the shipment leaves our premises. In certain cases where purchase orders specify alternate shipping terms, usually delivery at place, revenue recognition is deferred until we are assured the units are delivered.

Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue. Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established for discounts, returns, rebates and allowances. We do not have a history of any refunds, allowances or other concessions provided to our customers from the agreed-upon sales price after delivery of the product. We do not offer discounts, except to distributors as discussed below. We had certain arrangements with distributors under which the distributors purchased and then resold our products in geographic markets where we did not have sales presence. These arrangements provided for a discount on the invoice. When the distributor resold our units at our normal sales price, the discount served to compensate the distributor for their efforts. We recorded these sales net of the discounts. One of our distributors, ACD, accounted for approximately 20% of our sales for the year ended December 31, 2022. All of the distributor agreements were discontinued on or before December 31, 2022.

We provide certain customers with rebates that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the conditions for the rebates are achieved. The rebates result from performance-based offers that are primarily based on attaining contractually specified sales volumes.

Contingent Earnout Liability

In connection with the Business Combination, the Sponsor received shares that will vest upon the achievement of certain share price targets and change in control events. In accordance with ASC 815-40, *Derivatives and Hedging*, the earnout shares were classified as a liability as they do not qualify as being indexed to the Company's own stock and therefore are measured at fair value at each reporting date with changes in fair value recorded in the Consolidated Statements of Operations.

The estimated fair value of the earnout liability was determined using a Monte Carlo simulation valuation model using a distribution of potential outcomes. The inputs and assumptions utilized in the calculation require management to apply judgment and make estimates including:

- expected volatility, which is based on the historical equity volatility of publicly traded peer companies for a term equal to the expected term of the earnout period;
- expected term, which we based on the earnout period per the agreement;
- risk-free interest rate, which was determined by reference to the U.S. Treasury yield curve for time periods commensurate with the expected term of the earnout period; and
- expected dividend yield, which we estimate to be zero based on the fact that we have never paid or declared dividends.

These estimates may be subjective in nature and involve uncertainties and matters of judgment and therefore cannot be determined with exact precision.

Research and Development

R&D costs include our engineering, regulatory, pre-clinical and clinical activities. R&D costs are expensed as incurred. Approximately 9% of our R&D costs are headcount-related; the balance is external services we purchase, such as pre-clinical supplies and materials, clinical study management and supplies, and consulting related to our R&D.

We are required to estimate our expenses resulting from our obligations under agreements with vendors, consultants, and contract research organizations, in connection with conducting R&D activities. The financial terms of these contracts are subject to negotiations, which vary from agreement to agreement and may result in payment flows that do not match the periods over which goods or services are provided. We reflect R&D expenses in our consolidated financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the agreements, along with preparation of financial models, taking into account discussions with research and other key personnel as to the progress of studies or other services being performed. To date, we have had no material differences between our estimates of such expenses and the amounts actually incurred. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Tranche Rights and Obligation Liabilities

We classified the Series B-2 tranche rights and obligations and Series B-3 Warrants as liabilities on the Condensed Consolidated Balance Sheets. We measured the Series B-2 Tranche Rights and Series B-3 Warrants at fair value upon issuance in October 2022, March 2023, and June 2023, and remeasured the liabilities to fair value at December 31, 2022, March 31, 2023, June 30, 2023, and August 10, 2023, with changes in the fair value at each measurement date recognized in Change in fair value of tranche and warrant liabilities in the consolidated statements of operations. The Series B-2 Tranche Rights and series B-3 Warrants were extinguished in the Business Combination.

The fair value of the Series B-2 tranche liabilities was determined using a Binomial Tranche Model. The fair value of the Series B-3 Warrants was determined using a probability-weighted expected outcome model whereby the following two scenarios were probability-weighted based on the Company's expectation of each occurring: (1) a status quo scenario whereby the Company would continue as a private company and (2) a scenario where the Business Combination would close. Under the status quo scenario, the Series B-3 Warrants, including warrants to be issued under the second and third tranches, were valued using the Black-Scholes model.

The fair value of the Series B-2 tranche liabilities and Series B-3 Warrants used various inputs and assumptions that required management to apply judgment and make estimates, including:

- the equity value under the status quo scenario, which was determined using the Guideline Public Company method within the market approach to estimate the fair value of equity on a minority, marketable basis using selected publicly traded peer companies and valuation multiples based on size, growth, profitability, and other relevant factors;
- the fair value of underlying Series B-2 preferred stock, which was determined using the Option Pricing Model to allocate the Company's equity value among its various classes of equity securities under the status quo scenario;
- issuance and exercise price, which was based on the terms of the purchase agreement;

- expected term, which we based on the expiry periods as defined in the purchase agreement;
- expected volatility, which was based on the historical equity volatility of publicly traded peer companies for a term equal to the expected term of the warrants and tranche liabilities;
- risk-free interest rate, which was determined by reference to the U.S. Treasury yield curve for time periods commensurate with the expected terms of the warrants and tranche liabilities; and
- expected dividend yield, which we estimate to be zero based on the fact that we have never paid or declared dividends.

These estimates may be subjective in nature and involve uncertainties and matters of judgment and therefore cannot be determined with exact precision. The scenario probability is the most sensitive estimated input into the calculation of the fair value of the Series B-3 Warrants. The risk of exposure is estimated using a sensitivity analysis of potential changes in the significant unobservable inputs, primarily the scenario probability input that is the most susceptible to valuation risk.

Emerging Growth Company Status

Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards. The JOBS Act provides that a company can choose not to take advantage of the extended transition period and comply with the requirements that apply to non-emerging growth companies, and any such election to not take advantage of the extended transition period is irrevocable. We are an emerging growth company and are availing ourselves of the extended transition period that the emerging growth company status permits. During the extended transition period, it may be difficult or impossible to compare our financial results with the financial results of another public company that complies with public company effective dates for accounting standard updates because of the potential differences in accounting standards used.

We will remain an emerging growth company under the JOBS Act 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 have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Recent Accounting Pronouncements

Note *(2) Summary of Significant Accounting Policies* to our audited consolidated financial statements included elsewhere in this Annual Report includes more information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one, of their potential impact on our financial condition and our results of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not Applicable for a "smaller reporting company" as defined under Item 10(f)(1) of Regulation S-K of the Securities Act

Item 8. Financial Statements and Supplementary Data

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of TriSalus Life Sciences, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of TriSalus Life Sciences, Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and needs to raise additional equity or debt to fund its operations. These matters raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2022.

Denver, Colorado
April 11, 2024

TRISALUS LIFE SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS
December 31, 2023 and 2022
(in thousands, except share and per share data)

	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 11,777	$ 9,414
Accounts receivable	3,554	1,557
Inventory, net	2,545	1,471
Prepaid expenses	2,986	4,772
Total current assets	20,862	17,214
Property and equipment, net	2,091	2,231
Right-of-use assets	1,179	1,381
Intangible assets, net	1,127	802
Other assets	466	367
Total assets	$ 25,725	$ 21,995
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Trade payables	$ 3,391	$ 4,947
Accrued liabilities	10,556	6,377
Series B-2 tranche liabilities	—	4,702
Series B-3 warrant liabilities	—	15,819
Short-term lease liabilities	351	370
Other current liabilities	389	142
Total current liabilities	14,687	32,357
Long-term lease liabilities	1,244	1,593
Contingent earnout liability	18,632	—
Warrant liabilities and other long-term liabilities	17,100	369
Total liabilities	51,663	34,319
Convertible Preferred Stock	—	164,006
Stockholders' deficit:		
Preferred Stock, Convertible preferred stock, Series A, $0.0001 par value per share, $10.00 liquidation value per share. Authorized 10,000,000 and 0 shares at December 31, 2023 and 2022, respectively; issued and outstanding, 4,015,002 and 0 shares at December 31, 2023 and 2022, respectively	—	—
Common stock, $0.0001 par value per share. Authorized 400,000,000 and 30,898,162 shares at December 31, 2023 and 2022, respectively; issued and outstanding 26,413,213 shares and 347,926 shares at December 31, 2023 and 2022, respectively	2	—
Additional paid-in capital	222,437	10,028
Accumulated deficit	(248,377)	(186,358)
Total stockholders' deficit	(25,938)	(176,330)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 25,725	$ 21,995

See accompanying notes to consolidated financial statements.

TRISALUS LIFE SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended December 31, 2023 and 2022
(in thousands, except share and per share data)

	2023	2022
Revenue	$ 18,511	$ 12,398
Cost of goods sold	2,605	2,258
Gross profit	15,906	10,140
Operating expenses:		
Research and development	29,510	21,358
Sales and marketing	17,034	12,738
General and administrative	23,512	12,483
Loss from operations	(54,150)	(36,439)
Interest income	431	180
Interest expense	(16)	(1)
Loss on equity issuance	(4,353)	(8,312)
Change in fair value of tranche and warrant liabilities	(10,855)	(2,186)
Change in fair value of contingent liabilities	10,293	—
Other income and expense, net	(379)	(420)
Loss before income taxes	(59,029)	(47,178)
Income tax expense	(9)	(9)
Net loss available to common stockholders	$ (59,038)	$ (47,187)
Deemed dividend related to Series B-2 preferred stock down round provision	$ (2,981)	$ (2,829)
Undeclared dividends on Series A preferred stock	$ (1,258)	$ —
Net loss attributable to common stockholders	$ (63,277)	$ (50,016)
Net loss per share, basic and diluted	$ (6.73)	$ (161.55)
Weighted average common shares outstanding, basic and diluted	9,395,748	309,609

See accompanying notes to consolidated financial statements.

TRISALUS LIFE SCIENCES, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
Years ended December 31, 2023 and 2022
(in thousands, except share data)

	Preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
At December 31, 2021	—	$ —	264,978	$ —	$ 6,737	$ (136,342)	$ (129,605)
Exercise of options	—	—	82,879	—	94	—	94
Exercise of common stock warrants	—	—	69	—	—	—	—
Share-based compensation	—	—	—	—	368	—	368
Deemed dividend	—	—	—	—	2,829	(2,829)	—
Net loss	—	—	—	—	—	(47,187)	(47,187)
At December 31, 2022	—	$ —	347,926	$ —	$ 10,028	$ (186,358)	$ (176,330)
Exercise of options	—	—	247,612	—	180	—	180
Share-based compensation	—	—	—	—	1,402	—	1,402
Deemed dividend	—	—	—	—	2,981	(2,981)	—
Impact of Business Combination							
Conversion of redeemable convertible preferred stock into common stock in connection with the Business Combination	—	—	21,500,867	2	204,234	—	204,236
Assumption of warrants to purchase common stock in connection with the Business Combination	—	—	—	—	(2,568)	—	(2,568)
Issuance of common stock upon closing the Business Combination, net of expenses	—	—	4,316,808	—	957	—	957
Contingent earnout liability recognized upon closing of the Business Combination	—	—	—	—	(28,927)	—	(28,927)
Assumption of preferred stock in connection with the Business Combination	4,015,002	—	—	—	34,150	—	34,150
Net loss			—	—	—	(59,038)	(59,038)
At December 31, 2023	4,015,002	$ —	26,413,213	$ 2	$ 222,437	$ (248,377)	$ (25,938)

See accompanying notes to consolidated financial statements.

TRISALUS LIFE SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2023 and 2022
(in thousands)

	2023	2022
Cash flows from operating activities:		
Net loss	$ (59,038)	$ (47,187)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	702	398
Loss on equity issuance	4,353	8,312
Change in fair value of tranche and warrant liabilities	10,855	2,186
Change in fair value of contingent earnout liabilities	(10,293)	—
Share-based compensation expense	1,402	368
Loss on disposal of fixed assets	44	310
Loss on impairment of intangible assets	190	—
Milestone payment to Dynavax	1,000	1,000
Changes in operating assets and liabilities:		
Accounts receivable	(1,979)	(200)
Inventory	(1,073)	(179)
Prepaid expenses	1,032	(2,592)
Operating lease right-of-use assets	202	112
Operating lease liabilities	(281)	(87)
Trade payables, accrued expenses and other liabilities	2,839	5,246
Net cash used in operating activities	(50,045)	(32,313)
Cash flows from investing activities:		
Purchases of property and equipment	(588)	(655)
Milestone payment to Dynavax	(1,000)	(1,000)
Cash paid for intellectual property and licenses	(533)	(131)
Net cash used in investing activities	(2,121)	(1,786)
Cash flows from financing activities:		
Proceeds from the issuance of preferred stock, net of costs of $0 and $242, in the years ended December 31, 2023 and 2022, respectively	9,189	13,499
Proceeds from exercise of preferred stock warrants	9,630	—
Purchase of common stock warrants	(20)	—
Proceeds from Business Combination	36,854	—
Offering costs related to Business Combination	(1,116)	—
Payments on finance lease liabilities	(87)	(131)
Cash proceeds from the exercise of stock options for common stock	179	94
Net cash provided by financing activities	54,629	13,462
Increase (decrease) in cash, cash equivalents and restricted cash	2,463	(20,637)
Cash, cash equivalents and restricted cash, beginning of period	9,664	30,301
Cash, cash equivalents and restricted cash, end of period	$ 12,127	$ 9,664
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Income taxes	14	9
Supplemental disclosure of noncash items:		
Fixed asset purchases included in trade payables and accrued expenses	19	12
Transfer of warrant liability to preferred stock upon exercise of warrants	25,409	—

See accompanying notes to consolidated financial statements.

TRISALUS LIFE SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(amounts in thousands, except percentages, share and per share data)

(1) Nature Of Business

On August 10, 2023 (the "Closing Date"), TriSalus Life Sciences, Inc., a Delaware corporation (the "Company," "TriSalus," "we," "us"), formerly known as MedTech Acquisition Corporation ("MTAC"), consummated the previously announced merger pursuant to the Agreement and Plan of Merger, dated as of November 11, 2022, as amended by that certain First Amendment to Agreement and Plan of Merger, dated as of April 4, 2023, the Second Amendment to Agreement and Plan of Merger, dated as of May 13, 2023, and the Third Amendment to Agreement and Plan of Merger, dated as of July 5, 2023 (as amended, the "Merger Agreement"), by and between MTAC Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of MTAC ("Merger Sub") and TriSalus Operating Life Sciences, Inc. (formerly known as TriSalus Life Sciences, Inc.), a Delaware corporation ("Legacy TriSalus"), whereby Merger Sub merged with and into Legacy TriSalus with the separate corporate existence of Merger Sub ceasing (the "Merger" and, together with the other transactions contemplated by the Merger Agreement, the "Business Combination") and TriSalus Life Sciences, Inc. becoming the surviving company. The closing of the Business Combination is herein referred to as "the Closing." In connection with the consummation of the Merger, on August 10, 2023, Legacy TriSalus changed its name from TriSalus Life Sciences, Inc. to TriSalus Operating Life Sciences, Inc., and MTAC changed its name from MedTech Acquisition Corporation to TriSalus Life Sciences, Inc., the surviving company ("New TriSalus"). As further described in Note *(3) Business Combination*, Legacy TriSalus was deemed to be the accounting acquirer and predecessor company in the Business Combination. Thus, the prior periods presented in these consolidated financial statements are of Legacy TriSalus.

We are engaged in the research, development, and sales of innovative drug delivery technology and immune-oncology therapeutics to improve outcomes in difficult to treat liver and pancreatic cancer. Our technology is utilized in the delivery of our therapeutics and administered by interventional radiologists. We are developing and marketing two product lines — Pressure Enabled Drug Delivery ("PEDD™) infusion systems, in use today, and an investigational agent, nelitolimod (SD-101), which shows potential to enhance immune system response in the treatment of hepatocellular cancer, pancreatic cancer and other liver solid tumors. The combination of our PEDD technology with nelitolimod is focused on solving the two main barriers in the tumor micro environment that inhibits the success of immunotherapy. The first barrier (mechanical) is comprised of high intratumoral pressure within tumors that limits drug uptake and the second barrier (biological) is the reversal of intratumoral immunosuppression. Our PEDD with SmartValve™ is the only technology designed to work in synchrony with the cardiac cycle to open collapsed vessels in the tumor to enable deeper perfusion and improve therapeutic drug delivery in tumors with high intratumoral pressure. PEDD with SmartValve has been shown in prospective and retrospective clinical studies and in multiple pre-clinical models to improve therapy uptake and tumor response. nelitolimod has a dual mechanism of action in solid tumors which includes the alteration of the tumor microenvironment by reducing immunosuppressive myeloid derived suppressor cells while simultaneously activating immune response and recruiting T cells to the tumor, allowing checkpoint inhibitors to work more effectively.

TriNav™ is the newest therapy delivery device with SmartValve technology for the proprietary PEDD approach. Current sales consist of the TriNav Infusion System, introduced in 2020, and a family of related guiding catheters. In 2020, we gained transitional pass-through payments ("TPT") approval from the Centers for Medicare & Medicaid Services ("CMS"), which allows hospitals to cover the cost of using TriNav. The approval expired at the end of 2023. On June 1, 2023, we applied for a new technology APC code with CMS. In December 2023, CMS granted a New Technology Healthcare Common Procedure Coding System ("HCPCS") code for procedures involving TriNav. This new code, HCPCS C9797, has been assigned to the Ambulatory Payment Classification ("APC") code 5194 - Level 4 Endovascular procedures. The new code became effective on January 1, 2024, and may be reported by hospital outpatient departments and ambulatory surgical centers.

We believe the full potential of our technology can be realized through the combination of our drug delivery technology with immune-oncology drugs, so, in July 2020, we acquired our first immune-oncology drug, nelitolimod, and began clinical development of nelitolimod for treatment of liver and pancreatic cancers.

We have funded operations to date principally with proceeds from the sale of preferred stock, from the issuance of debt and convertible debt, the exercise of warrants, and from proceeds received upon the closing of the Business Combination. Since inception of the Company in 2009 through December 31, 2023, we have issued for cash $164,364 of preferred stock, (of which $36,854 was raised at the closing of the Business Combination, including issuance of Series A convertible preferred stock), which, along with $560 of common stock and $57,466 of convertible notes and warrants, has funded the cumulative net losses of $248,377. During the year ended December 31, 2023, we raised a total of $9,189 in

cash through issuance of Series B-2 and B-3 preferred stock, $9,630 from the exercise of warrants, and $179 from the exercise of stock options. See note *(14) Convertible Preferred Stock* for further discussion of the convertible debt, warrants and the 2023 financing rounds.

As of December 31, 2023, we had cash, cash equivalents and restricted cash of $12,127. The Company is still in its early stage, has a history of recurring operating losses, has yet to generate revenues sufficient to create positive cash flow and has accumulated deficit of $248,377 as of December 31, 2023. We are currently undergoing a strategic transformation from a company focused solely on the sale of our infusion systems to a therapeutic company whereby our medical devices will be marketed alongside the pharmaceutical drugs and other treatments that the devices deliver to patients. This transformation requires that we restructure our operating infrastructure, resulting in an increase in operating expenses — including the development of a candidate pharmaceutical — that, in the short term, will not be fully offset by increased revenues. Without additional financing and based on our sales, operations and research and development plans, our management estimates that our existing cash and cash equivalents will be insufficient to fund our projected liquidity requirements for the next 12 months.

In accordance with ASC Topic 205-40, *Presentation of Financial Statements, Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, we are required to evaluate whether there is substantial doubt about our ability to continue as a going concern each reporting period. In evaluating our ability to continue as a going concern, management projected our cash flow sources and needs and evaluated the conditions and events have raised substantial doubt about our ability to continue as a going concern within one year after the date that these consolidated financial statements were issued. Management's plans to address the conditions and events have considered our current projections of future cash flows, current financial condition, sources of liquidity and debt obligations for at least one year from the date of issuance of these consolidated financial statements in considering whether we have the ability to fund future operations and meet our obligations as they become due in the normal course of business.

Our ability to fund future operations and to continue the execution of our long-term business plan and strategy, including our transformation into a therapeutics company, will require that we raise additional capital through a combination of collaborations, strategic alliances and licensing arrangements, and issuance of additional equity and/or long-term debt. As described in note *(13) Standby Equity Purchase Agreement, w*e have the right but not the obligation to sell up to $30,000 of our Common Stock at our request under Standby Equity Purchase Agreement, subject to terms and conditions specified in the agreement. Outside of this agreement, there can be no assurance that we will be able to raise such additional financing or, if available, that such financing can be obtained on satisfactory terms. If adequate capital resources are not available on a timely basis, we intend to consider limiting our operations substantially. This limitation of operations could include a hiring freeze, reductions in our workforce, reduction in cash compensation, deferring clinical trials and capital expenditures, and reducing other operating costs.

Our current operating plan, which is in part determined based on our most recent results and trends, along with the items noted above, causes substantial doubt to exist about our ability to continue as a going concern and management's plans do not alleviate the existence of substantial doubt. Our financial statements have been prepared assuming we will continue as a going concern, which contemplates the continuity of normal business activities and realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments that might be necessary should we be unable to continue as a going concern.

We are subject to various risks and uncertainties frequently encountered by companies in the early stages of growth, particularly companies in the rapidly evolving market for medical technology-based and pharmaceutical products and services. Such risks and uncertainties include, but are not limited to, a limited operating history, need for additional capital, a volatile business and technological environment, the process to test and obtain approval to market the candidate pharmaceutical, an evolving business model, and demand for our products. To address these risks, we must, among other things, gain access to capital in sufficient amounts and on acceptable terms, maintain and increase our customer base, implement and successfully execute our business strategy, develop the candidate pharmaceutical, continue to enhance our technology, provide superior customer service, and attract, retain, and motivate qualified personnel. There can be no guarantee that we will succeed in addressing such risks.

(2) Summary Of Significant Accounting Policies

(a) Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries as of December 31, 2023 and 2022, respectively: TriSalus Operating Life Sciences, Inc., TriSalus Medical LLC and TriSalus Therapeutics LLC. Unless otherwise specified, references to the

Company are references to TriSalus Life Sciences Inc. and its consolidated subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation.

(b) Cash, Cash Equivalents, and Restricted Cash

We consider all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. We invest excess cash primarily in money market funds. Restricted cash is held in a separate account at our bank to support our corporate credit card program. It is recorded in other assets on our consolidated balance sheet.

(c) Concentrations of Credit Risk and Other Risks and Uncertainties

Our cash is deposited primarily with two financial institutions. At times, the deposits in these institutions may exceed the amount of insurance provided on such deposits. We have not experienced any losses in such accounts and believe that we are not exposed to any significant risk on these balances.

(d) Accounts Receivable and Customer Concentrations

Accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review our allowance for doubtful accounts periodically and establish reserves based on management's expectations of realization based on historical write-off experience, as well as current general economic conditions and expectations regarding collection. Account balances are charged against the allowance after all reasonable means of collection have been exhausted and the potential for recovery is considered remote.

We did not sell to any distributors during the year ended December 31, 2023. As of December 31, 2022, one distributor customer constituted 19% of our accounts receivable balance.

We had one distributor customer which constituted 0% and 20% of our revenue for the years ended December 31, 2023 and 2022, respectively. The arrangement with this distributor terminated on December 31, 2022.

(e) Inventory

Inventory is carried at the lower of cost or net realizable value. The balance includes the cost of raw materials, and finished goods — including direct labor and manufacturing overhead — and is recorded on the first-in first-out method. Write-downs for excess and obsolete inventory are charged to cost of goods sold in the period when conditions giving rise to the write-downs are first recognized. Valuation reserves are recorded when, in our best judgment, we determine the carrying value of the affected inventory may be impaired or its net realizable value exceeds its cost.

(f) Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ significantly from those estimates. The most significant estimates relate to the valuation of warrant liabilities and tranche liabilities, the contingent earnout liability, certain of our clinical expense accruals, and the valuation allowance on deferred tax assets.

(g) Property and Equipment

Property and equipment are recorded at cost. Repairs and maintenance costs are expensed as incurred. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which range from two to seven years. Leasehold improvements are amortized on a straight-line basis over the lesser of estimated useful lives or the lease term.

(h) Leases

We account for leases in accordance with Accounting Standards Codification ("ASC") Topic 842, *Leases*. We determine if an arrangement is or contains a lease at contract inception, and, if it does, the lease is recorded on the Consolidated Balance Sheets with right-of-use assets ("ROU") representing the Company's right to use an underlying asset for the lease term and lease liabilities representing our obligation to make lease payments. Lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. Lease ROU assets also include the effect of any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. As the implicit rate in our leases is typically unknown, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. When calculating our incremental borrowing rates, we consider our credit risk, the term of

the lease, and total lease payments and adjusts for the impacts of collateral as necessary. The lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense is recognized on a straight-line basis over the lease term.

We have elected to not separate lease and non-lease components for any leases within our existing classes of assets and, as a result, account for any lease and non-lease components as a single lease component. We have also elected not to apply the recognition requirement for leases with a term of 12 months or less. We recognize an ROU asset and a lease liability at the lease commencement date.

For operating and finance leases, the lease liability is initially measured at the present value of the unpaid lease payments at the lease commencement date. The lease liability is subsequently measured at amortized cost using the effective-interest method.

The ROU asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received.

For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

For finance leases, the ROU asset is subsequently amortized using the straight-line method from the lease commencement date to the earlier of the end of its useful life or the end of the lease term unless the lease transfers ownership of the underlying asset to the Company or the Company is reasonably certain to exercise an option to purchase the underlying asset. In those cases, the ROU asset is amortized over the useful life of the underlying asset. Amortization of the ROU asset is recognized and presented separately from interest expense on the lease liability. Finance lease ROU assets are presented with property and equipment, net in the Consolidated Balance Sheets.

(i) Contingent Earnout Liability

In connection with the execution of the Merger Agreement, MTAC entered into a sponsor support agreement (the "Sponsor Support Agreement") with MedTech Acquisition Sponsor LLC (the "Sponsor"), Legacy TriSalus and MTAC's directors and officers (the Sponsor and MTAC's directors and officers, collectively, the "Sponsor Holders"). Pursuant to the Sponsor Support Agreement, 3,125,000 shares of common stock in the Company ("Common Stock") held by the Sponsor Holders immediately after the Closing Date (such shares, the "Sponsor Earnout Shares") became unvested and subject to potential forfeiture if certain triggering events are not achieved prior to the 5th anniversary of the Closing Date (the "Earnout Period"). The Sponsor Earnout Shares are classified as a liability in the Company's Consolidated Balance Sheets because they do not qualify as being indexed to the Company's own stock. The earnout liability was initially measured at fair value at the Closing Date and is subsequently remeasured at the end of each reporting period. The change in fair value of the earnout liability is recorded in the Consolidated Statements of Operations. See Notes *(4) Financial Instruments* and *(9) Contingent Earnout Liability* for further detail.

(j) Standby Equity Purchase Agreement

In October 2023, the Company entered into a SEPA with Yorkville. Pursuant to the Purchase Agreement, the Company has the right, but not the obligation, to sell to Yorkville up to $30,000 of shares of Common Stock at the Company's request any time during the 24 months following the execution of such purchase agreement, subject to certain conditions. The SEPA, in its entirety, is not classified as a liability pursuant to ASC 480, is accounted for as a derivative pursuant to ASC 815-10, *Derivatives and Hedging* ("ASC 815-10"). Changes in the fair value are recognized in earnings.

(k) Impairment and Disposal of Long-Lived Assets

We review long-lived assets and intangible assets (principally patents) for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is generally measured by a comparison of the carrying amount of the asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amounts of the assets exceed the estimated fair values of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less cost to sell.

(l) Share-Based Compensation

We account for all employee share-based compensation awards by recording expense based on the estimated fair value of the awards at the time of grant using the Black-Scholes-Merton option valuation model ("Black-Scholes") for stock

options and price of our common stock on the grant date for restricted stock units ("RSUs"). The determination of fair value using an option-pricing model is affected by the estimated fair value of the Company's stock, as well as assumptions regarding a number of variables including, but not limited to, the fair value of underlying stock at the grant date, expected volatility of the underlying stock over the term of the awards, projected employee stock option exercise behaviors, and risk-free interest rates. We have elected to not include an estimated forfeiture rate in our share-based compensation expense recognition, in accordance with ASC Topic 718, *Compensation — Stock Compensation*, and we account for forfeitures in the period in which they occur. The estimated fair value of options and RSUs granted is recognized as compensation expense on a straight-line basis over the expected life for each separately vesting portion of the awards.

(m) Segment Reporting

We have determined, in accordance with ASC Topic 280, *Segment Reporting*, that we operate under one operating segment, and therefore one reportable segment, TriSalus. Our Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of assessing performance and allocation resources. All of our long-lived assets, and all of our customers, are located in the United States.

(n) Revenue Recognition

Our revenue is derived from the shipments of our PEDD infusion systems to our customers. Our customers are generally comprised of hospitals, clinics and physicians. Under ASC Topic 606, *Revenue Recognition*, we evaluate five steps to determine the appropriate timing and amount to recognize revenue. The five steps are:

1. Identify the contract — We do not maintain long-term contracts with our customers. Typically, customers will submit a purchase order to us for delivery of a quantity of our products, which incorporate enforceable rights and obligations constituting the contract with the customer.
2. Identify the performance obligation — Our performance obligation is to deliver the ordered products in accordance with the terms of the purchase order, which constitutes a single performance obligation. We do not have any on-going service obligation after delivery.
3. Determine the transaction price — We maintain a single sales price for each of our products, which is generally fixed. We do not have a history of any significant refunds, allowances or other concessions provided to our customers from the agreed-upon sales price after delivery of the product.
4. Allocate the transaction price — We do not have multiple performance obligations to complete when we fulfill a purchase order, as such, the transaction price is allocated fully to the units being sold.
5. Recognize revenue — We recognize revenue at the point-in-time when the units for a purchase order have been shipped and control of the units has transferred to the customer, as evidenced by the delivery terms on the shipping documents. Typically, we ship Ex Works, so we recognize revenue when the shipment leaves our premises. In certain cases, the purchase order specifies alternate shipping terms, usually DAP (delivery at place). In those cases, we defer revenue recognition until we are assured the units have been delivered and control has transferred to the customer.

(o) Research and Development

Research and development ("R&D") costs include our engineering, regulatory, pre-clinical and clinical activities. R&D costs are expensed as incurred and included development milestone payments of $1,000 to Dynavax for nelitolimod in each of the years ended December 31, 2023 and 2022, respectively. See Note *(12) Dynavax Purchase* for further discussion of Dynavax.

We are required to estimate our expenses resulting from our obligations under agreements with vendors, consultants, and contract research organizations, in connection with conducting R&D activities. The financial terms of these contracts are subject to negotiations, which vary from agreement to agreement and may result in payment flows that do not match the periods over which goods or services are provided. We reflect R&D expenses in our consolidated financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the agreements, along with preparation of financial models, taking into account discussions with research and other key personnel as to the progress of studies or other services being performed. To date, we have had no material differences between our estimates of such expenses and the amounts actually incurred. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

(p) Advertising

Advertising expense, which is included in sales and marketing costs, is expensed as incurred, and expense for the years ended December 31, 2023 and 2022, was $1,346 and $2,201, respectively.

(q) Income Taxes

We account for income taxes pursuant to ASC Topic 740, *Income Taxes*, which requires the use of the asset-and-liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is recorded to the extent it is more likely than not that a deferred tax asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

The Company recognizes the effect of income tax positions when it is more likely than not, based on technical merits, that the position will be sustained upon examination. Through 2023, management determined that no uncertain tax positions have been taken or are expected to be taken that could have a material effect on the Company's income tax liabilities.

(r) Warrants and Tranche Rights and Obligation Liabilities

Freestanding financial instruments that permit the holder to acquire shares that are either puttable by the holder, redeemable or contingently redeemable are required to be reported as liabilities in the financial statements. We present such liabilities on the balance sheets at their estimated fair values. Changes in fair value of the liability are calculated each reporting period, and any change in value are recognized in the consolidated statements of operations. We have determined that the warrants issued to investors and lenders, which are exercisable for shares of our convertible preferred stock, should be classified as liabilities due to contingent redemption features of the underlying convertible preferred stock.

In connection with the Business Combination, we assumed warrants to purchase common stock. The warrants include both publicly traded and privately held warrants. We value the liability for both sets of warrants based on the trading price of the publicly-held warrants. See Note *(10) Warrants* and *(4) Financial Instruments* for further discussion.

The B-2 Preferred Stock Financing (as described in Note *(14) Convertible Preferred Stock* included second and third tranche rights and obligations to investors who participated in the initial B-2 Preferred Stock Financing round. We offered the Series B-2 preferred stock to all of our preferred stockholders at the time of the initial B-2 Preferred Stock Financing round (representing approximately 99.2% of our then outstanding shares on an as-converted to common stock basis). The second and third tranche rights and obligations are exercisable into shares of our convertible preferred stock at a specified future date. The second and third tranche rights and obligations are considered freestanding financial instruments, and are classified as liabilities under ASC 480. See Note *(14) Convertible Preferred Stock* for further discussion.

(s) Net Loss per Share

Net loss per share is calculated using the weighted average number of shares and dilutive common stock equivalents outstanding during the period. Warrants, convertible preferred stock, stock options, and restricted stock units, as described in Notes *(10) Warrants*, *(14) Convertible Preferred Stock*, and *(15) Stockholders' Equity*, are considered to be common stock equivalents. Potentially dilutive shares are excluded from the computation of earnings per share if their effect is anti-dilutive. As we reported a net loss for the years ended December 31, 2023 and 2022, all potentially dilutive shares were excluded from net loss per share in both years.

(t) Recent Accounting Pronouncements

Recently issued and Adopted Accounting pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*. Current GAAP requires an "incurred loss" methodology for recognizing credit losses that delays recognition until it is probable a loss has been incurred. ASU 2016-13 replaces the current incurred loss methodology for credit losses and removes the thresholds that companies apply to measure credit losses on financial statements measured at amortized cost, such as loans, receivables, and held-to-maturity debt securities with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to form credit loss estimates. The determination of the allowance for credit losses under the new standard would typically be based on evaluation of a number of factors, including, but not

limited to, general economic conditions, payment status, historical collection patterns and loss experience, financial strength of the borrower, and nature, extent and value of the underlying collateral. For smaller reporting companies, ASU 2016-13 is effective for fiscal years and for interim periods within those fiscal years beginning after December 15, 2022. It requires a cumulative effect adjustment to the balance sheet as of the beginning of the first reporting period in which the guidance is effective. We adopted ASU 2016-13 on January 1, 2023. The effect of the adoption had an immaterial impact on our consolidated financial statements.

In August 2020, the FASB issues ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40)*, which simplifies the accounting for convertible instruments and equity-linked financial instruments in addition to amending the EPS guidance in ASC 260 to improve the consistency of the diluted EPS calculation. The guidance modified the if-converted method of calculating diluted EPS and requires entities to use this method for all convertible instruments. For instruments that may be settled in cash or shares and aren't liability-classified share-based payment awards, it requires entities to include the effect of potential share settlements in the diluted EPS calculation (if the effect is more dilutive). In addition, the ASU expanded the scope of the recognition and measurement guidance in ASC 260 to include equity-classified convertible preferred stock that includes a down round feature. We adopted ASU 2020-06 on January 1, 2022. The effect of the adoption had an immaterial impact on our consolidated financial statements.

Recently issued Accounting Pronouncements Not Yet Adopted

In June 2022, the FASB issued ASU 2022-03, *Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*, which clarifies the guidance on ASC Topic 820 on the fair value measurement of equity security that is subject to a contractual sale restriction and requires specific disclosures related to such an equity security. Specifically, the ASU clarifies that a "contractual sale restriction prohibiting the sale of an equity security is a characteristic of the reporting entity holding the equity security and is not included in the equity security's unit of account." As such, the entity should not apply a discount related to the contractual sale restriction when measuring the equity security's fair value. In addition, the ASU prohibits an entity from recognizing a contractual sale restriction as a separate unit of account. For public companies, the amendments for this update are effective for fiscal years beginning after December 15, 2023. For all other entities, the amendments are effective for fiscal year beginning after December 15, 2024, and interim periods within those fiscal years. We will adopt ASU 2022-03 on January 1, 2024. We do not anticipate that the adoption of ASU 2022-03 will have a material impact on our consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, *Improvements to Disclosures About Reportable Segments*. The ASU improves reportable segment disclosure requirements through enhanced disclosures about significant segment expenses in annual and interim reports, clarifies circumstances in which an entity can disclose multiple segment measures of profit or loss, add disclosure requirements for entities with a single reportable segment, and other enhancements. The ASU is effective for all public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 31, 2024. We will adopt ASU 2023-07 on January 1, 2024. We do not anticipate that the adoption of ASU 2022-07 will have a material impact on our consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*. Under the ASU, Public Business Entity ("PBE") must annually "(1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5% of the amount computed by multiplying pretax income or loss by the applicable statutory income tax rate)." This guidance is effective for public companies for annual periods beginning after December 15, 2024. For other companies, the amendments are effective for annual periods beginning after December 15, 2025. We are currently evaluating the impact the adoption of this ASU will have on our consolidated financial statements.

(3) Business Combination

On August 10, 2023, we consummated the previously announced merger pursuant to the Merger Agreement by and among MTAC, Merger Sub, Inc., and TriSalus Life Sciences, Inc. Upon the closing of the transactions contemplated by the Merger Agreement, Merger Sub merged with and into Legacy TriSalus (the "Business Combination") with Legacy TriSalus surviving the merger as a wholly-owned subsidiary of MTAC, renamed "TriSalus Operating Life Sciences, Inc." In addition, in connection with the consummation of the Business Combination, MTAC was renamed "TriSalus Life Sciences, Inc."

Immediately prior to the effective time of the Business Combination, each in-the-money warrant of Legacy TriSalus that was unexercised and unexpired was automatically net exercised into the respective series of preferred stock of Legacy TriSalus. Each share of preferred stock of Legacy TriSalus ("Legacy TriSalus Preferred Stock") that was issued and outstanding was then automatically converted into shares of common stock of Legacy TriSalus ("Legacy TriSalus

Common Stock") in accordance with the Amended and Restated Certificate of Incorporation of Legacy TriSalus at the then current conversion price, such that each converted share of Legacy TriSalus Preferred Stock was no longer outstanding and ceased to exist, and each holder of Legacy TriSalus Preferred Stock thereafter ceased to have any rights with respect to such securities.

At the Closing Date, by virtue of the Business Combination and without any action on the part of MTAC, Merger Sub, Legacy TriSalus or the holders of any of the following securities:

(a) each share of Legacy TriSalus Common Stock (including shares of Legacy TriSalus Common Stock resulting from the conversion of shares of TriSalus Preferred Stock described above) that was issued and outstanding immediately prior to the Effective Time were exchanged at an exchange ratio of 0.02471853 (the "Exchange Ratio") for an aggregate of 21,999,886 shares of our Common Stock;

(b) each option to purchase shares of Legacy TriSalus Common Stock, whether vested or unvested, converted into an option to purchase shares of our Common Stock ("TriSalus Assumed Option"), with each TriSalus Assumed Option subject to the same terms and conditions as were applicable to the original Legacy TriSalus option and with the resulting exercise price and number of shares of TriSalus Common Stock purchasable based on the Exchange Ratio and other terms contained in the Merger Agreement; and

(c) each Legacy TriSalus restricted stock unit ("RSU") award converted into a restricted stock unit award to receive shares of our Common Stock ("TriSalus Assumed RSU Award"), with each TriSalus Assumed RSU Award subject to the same terms and conditions as were applicable to the original Legacy TriSalus restricted stock unit award, and with the number of shares of TriSalus Common Stock to which the TriSalus Assumed RSU Award relates being based on the Exchange Ratio and other terms contained in the Merger Agreement.

The Business Combination was accounted for as a reverse recapitalization in conformity with accounting principles generally accepted in the United States. Under this method of accounting, MTAC was treated as the "acquired" company for financial reporting purposes. This determination was primarily based on the fact that subsequent to the Business Combination, the Legacy TriSalus stockholders have a majority of the voting power of TriSalus, Legacy TriSalus comprises all of our ongoing operations, Legacy TriSalus has appointed a majority of our governing body, and Legacy TriSalus' senior management comprises all of our senior management. Accordingly, for accounting purposes, the financial statements of the combined entity represented a continuation of the financial statements of Legacy TriSalus with the business combination being treated as the equivalent of Legacy TriSalus issuing stock for the net assets of MTAC, accompanied by a recapitalization. Operations prior to the Business Combination are those of Legacy TriSalus. Reported shares and earnings per share available to holders of the Company's common stock, prior to the Business Combination, have been retroactively restated as shares reflecting the exchange ratio established in the Business Combination (1.0 share of Legacy TriSalus for approximately 0.02471853 shares of TriSalus).

Proceeds from this transaction totaled $42,854. These proceeds were comprised of $2,704 from the MTAC trust account, and $40,150 received from the assumption of a concurrent private investment in public equity financing ("PIPE Financing"). Pursuant to the terms of the Merger Agreement, $6,000 of the proceeds were used to pay expenses incurred by MTAC related to the merger, resulting in net cash proceeds of $36,854. The Company incurred $6,069 in transaction costs relating to the merger with MTAC, of which $1,742 was recorded as a reduction of equity and the balance of $4,327 was recorded in general and administrative expense.

Pursuant to the terms of the Merger Agreement, the existing stockholders of Legacy TriSalus exchanged their interests for shares of common stock of TriSalus. In addition, MTAC had previously issued public warrants and private placement warrants (collectively, the "MTAC Warrants") as part of its initial public offering in November 2020. None of the terms of the MTAC Warrants were modified as a result of the Business Combination. On the Closing Date, the Company recorded a liability related to the MTAC Warrants of $2,568. During the period from August 10, 2023, to December 31, 2023, the fair value of the MTAC Warrants increased to $16,916, resulting in a loss on the change in fair value of $14,348 and a gain of $10,855 in the Condensed Consolidated Statements of Operations for the year ended December 31, 2023.

Immediately following the Business Combination, there were 26,316,681 shares of our Common Stock outstanding, options and RSUs to purchase an aggregate of 2,816,224 shares of common stock, and warrants outstanding to purchase 14,266,605 shares of common stock.

PIPE Financing

On the Closing Date, certain investors agreed to purchase an aggregate of 4,015,002 newly-issued shares of Series A Convertible Preferred Stock at a purchase price of $10.00 per share for an aggregate purchase price of $40,150, pursuant to

separate subscription agreements dated June 7, 2023, and July 4, 2023 (collectively, the "Subscription Agreements"). See Note *(14) Convertible Preferred Stock* for further discussion.

Sponsor Earnout

In connection with the execution of the Merger Agreement, MTAC entered into the Sponsor Support Agreement. Pursuant to the Sponsor Support Agreement, the 3,125,000 Sponsor Earnout Shares became unvested and subject to potential forfeiture if certain triggering events are not achieved prior to the 5th anniversary of the Closing Date. Pursuant to the Sponsor Support Agreement, (i) 25% of the shares of our Common Stock held by the Sponsor Holders will only vest if, during the five years period following the Closing, the volume weighted average price of our Common Stock equals or exceeds $15.00 for any 20 trading days within a period of 30 consecutive trading days, (ii) 25% of the shares of our Common Stock held by the Sponsor Holders will only vest if, during the five years period following the Closing, the volume weighted average price of our Common Stock equals or exceeds $20.00 for any 20 trading days within a period of 30 consecutive trading days, (iii) 25% of the shares of our Common Stock held by the Sponsor Holders will only vest if, during the five years period following the Closing, the volume weighted average price of our Common Stock equals or exceeds $25.00 for any 20 trading days within a period of 30 consecutive trading days; and (iv) 25% of the shares of our Common Stock held by the Sponsor Holders will only vest if, during the five years period following the Closing, the volume weighted average price of our Common Stock equals or exceeds $30.00 for any 20 trading days within a period of 30 consecutive trading days. Additionally, the Sponsor Earnout Shares will vest if there is a change in control of our company on or before the 5th anniversary of the Closing Date that results in the holders of our Common Stock receiving a price per share equal to or in excess of the applicable earnout targets. Any such shares held by the Sponsor Holders that remain unvested after the 5th anniversary of the Closing will be forfeited. See Note *(9) Contingent Earnout Liability* for additional discussion of the Sponsor Earnout Shares and the liability we have recorded for them.

(4) Financial Instruments

Our financial instruments consist of cash, accounts receivable, trade accounts payable, tranche and warrant liabilities to purchase preferred stock and the contingent earnout liability. The carrying values of these financial instruments (other than the contingent earnout liability, tranche liabilities, and warrant liabilities, which are held at fair value) approximate fair value for the years ended December 31, 2023 and 2022. In general, asset and liability fair values are determined using the following categories:

Level 1 — Inputs utilize quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs include quoted prices for similar assets or liabilities in active markets, and inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly.

Level 3 — Inputs are unobservable inputs and include situations where there is little, if any, market activity for the balance sheet items at period end. Pricing inputs are unobservable for the terms and are based on the Company's own assumptions about the assumptions that a market participant would use.

Our warrant, tranche and earnout liabilities are measured at fair value on a recurring basis.

Financial Instruments Prior to the Business Combination

Our financial instruments, including tranche liabilities and warrant liabilities, are measured at fair value on a recurring basis, including immediately prior to exercise. The carrying amount of liabilities related to purchase Legacy TriSalus preferred stock was zero and $16,188 at December 31, 2023 and 2022, respectively, and the carrying amount of outstanding tranche liabilities was zero and $4,702 at December 31, 2023 and 2022, respectively. These carrying values represent the remeasurement to fair value at each reporting period based on unobservable inputs, or Level 3 inputs, using assumptions made by us, including the probabilities assigned to a status quo scenario and the potential closing of the Business Combination (see Note *(3) Business Combination*) scenario, the value of the Series B-3 Warrants (as defined below) upon closing of the Business Combination, the fair value of the Company, the fair value of the underlying preferred stock, the Company's volatility, discount rate, and expected term of the related instrument. See Note *(14) Convertible Preferred Stock* for further discussion.

In October 2022, we sold shares of Series B-2 preferred stock with accompanying warrants to purchase Series B-3 preferred stock (see Note *(14) Convertible Preferred Stock*). This also included rights and obligations exercisable for additional Series B-2 preferred stock and Series B-3 warrants through a second and third tranche. We offered the Series B-2 preferred stock to all of our preferred stockholders at the time of the initial B-2 Preferred Stock Financing round (representing approximately 99.2% of our then outstanding shares on an as-converted to common stock basis). At issuance, the warrants issued to purchase Series B-3 preferred stock had a fair value of $11,966 and were classified as a liability

(remeasured to $15,819 at December 31, 2022), the tranche rights and obligations associated with the second tranche had a fair value of $3,109 (remeasured to $2,250 at December 31, 2022), and the tranche rights and obligations associated with the third tranche had a fair value of $3,238 (remeasured to $2,452 at December 31, 2022), all of which have been classified as liabilities. The fair value is determined based on unobservable inputs, or Level 3 inputs, using assumptions made by us, including the probabilities assigned to both a status quo scenario and the potential closing of the Business Combination (see Note *(3) Business Combination*), the value of the Series B-3 warrants upon closing of the Business Combination, the fair value of the Company and resulting fair value of the underlying preferred stock, volatility, and expected term; see note *(10) Warrants* for further discussion.

In the first half of 2023, we sold shares of Series B-2 preferred stock with accompanying warrants to purchase Series B-3 preferred stock as part of the Second Tranche Closings (see Note *(10) Warrants*). At issuance, the warrants issued to purchase Series B-3 preferred stock had a fair value of $4,654 and $10,047 were classified as a liability in March and June 2023, respectively. The issuance of the Series B-2 preferred stock and accompanying warrants to purchase Series B-3 preferred stock as part of the Second Tranche Closings resulted in a $584 and $3,425 loss on equity issuance in March and June 2023.

Immediately prior to the exercise of the warrants to purchase Series B-3 preferred stock in February, March, June and July 2023, the associated liabilities were remeasured to fair value.

In July 2023, warrants to purchase 2,239,309 shares of Series B-3 preferred stock were exercised for $4,530.

At the Closing Date of the Business Combination, all in-the-money outstanding warrants and Series B-3 Warrants were remeasured to fair value, net-exercised, converted to shares of common stock of Legacy TriSalus, and then exchanged for shares of TriSalus common stock at the Exchange Ratio. Out-of-the-money warrants expired, resulting in a gain on expiration of $18. The Series B-2 tranche liabilities also expired at the Closing Date of the Business Combination.

The following tables summarize the changes in fair value of our outstanding warrant and tranche liabilities for the years ended December 31, 2023 and 2022:

Level 3 Liabilities	Fair Value at December 31, 2021	Change in Unrealized (Gains) Losses	Issuances (Settlements)	Net Transfer In (Out) of Level 3	Fair Value at December 31, 2022
Warrant liability	$ 391	$ (22)	$ —	$ —	$ 369
Series B-2 tranche liabilities	$ —	$ (1,645)	$ 6,347	$ —	$ 4,702
Series B-3 warrant liabilities	$ —	$ 3,853	$ 11,966	$ —	$ 15,819

Level 3 Liabilities	Fair Value at December 31, 2022	Change in Unrealized (Gains) Losses	Issuances (Settlements)	Net Transfer In (Out) of Level 3	Fair Value at December 31, 2023
Warrant liability	$ 369	$ (107)	$ (262)	$ —	$ —
Series B-2 tranche liabilities	$ 4,702	$ (3,200)	$ (1,502)	$ —	$ —
Series B-3 warrant liabilities	$ 15,819	$ (311)	$ (15,508) [1]	$ —	$ —

(1) *This amount includes settlements of $25,409, and final net exercise of $4,800, transferred to convertible preferred stock, offset by issuances of $14,701*

Financial Instruments After Business Combination

At the Closing Date, we assumed warrants to purchase 14,266,605 shares of common stock for $11.50 (see Note *(10) Warrants*). Of these, 8,333,272 are traded publicly and 5,933,333 are privately held. At the Closing Date, we determined the fair value of all the warrants to be $2,568 based on the closing price of $0.18 for the publicly traded warrants (Level 1).

At the Closing Date, we determined the fair value of the earnout liability to be $28,927 based on a Monte Carlo simulation of future trading prices for our common stock. See Note *(9) Contingent Earnout Liability* for further discussion.

In August 2023, the Board approved a warrant repurchase program (the "Warrant Repurchase Program"), authorizing an aggregate expenditure of up to $4,000 of the Public Warrant. Through December 31, 2023, we had repurchased 51,493 Public Warrants for $20. The purchase plan was discontinued in December 2023.

On October 2, 2023, we entered into a SEPA with Yorkville. Upon execution of the SEPA, we determined the fair value of the SEPA derivative liability to be $183 based on a scenario-based model. See *Note (13) Standby Equity Purchase*

Agreement for further discussion. We determined the fair value of the SEPA derivative liability to be $185 at December 31, 2023; we recorded the change in fair value in other income and expense, net.

The carrying amount of our outstanding Public and Private Placement Warrants liabilities was $16,916 at December 31, 2023. The carrying amount of outstanding earnout liability was $18,632 at December 31, 2023. The carrying amount of the outstanding SEPA derivative liability was $185 at December 31, 2023. The carrying values of the warrant liabilities represent the remeasurement to fair value each reporting period based on Level 1 inputs for the publicly traded Public Warrants and Level 2 inputs for the private placement Private Placement Warrants. The carrying amounts of the contingent earnout liability and SEPA derivative liability represent the remeasurement to fair value each reporting period based on unobservable, or Level 3, inputs, using assumptions made by us, including the market price of our common stock and the observed volatility of a peer group of companies.

The following tables summarize the changes in fair value of our outstanding warrant liabilities, contingent earnout liability and SEPA derivative liability for the year ended December 31, 2023. The warrant, earnout liability, and SEPA derivative liabilities were not present for the year ended December 31, 2022.

Level 3 Liabilities	Fair Value at December 31, 2022	Change in Unrealized (Gains) Losses	Issuances (Settlements)	Net Transfer In (Out) of Level 3	Fair Value at December 31, 2023
Warrant liabilities	$ —	$ 14,368	$ 2,548	$ —	$ 16,916
Contingent earnout liability	$ —	$ (10,295)	$ 28,927	$ —	$ 18,632
SEPA derivative liability	$ —	$ 2	$ 183	$ —	$ 185

(5) Cash, cash equivalents and restricted cash

Cash, cash equivalents and restricted cash, as presented in the Consolidated Statements of Cash Flows, consisted of the following:

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 11,777	$ 9,414
Restricted cash (included in Other assets)	350	250
Total cash, cash equivalents and restricted cash shown in the Consolidated Statements of Cash Flows	$ 12,127	$ 9,664

Restricted cash is $350 held by our bank to support our corporate credit card program.

(6) Inventory

The components of inventory at December 31 are summarized as follows:

	2023	2022
Raw materials	$ 607	$ 753
Finished goods	1,938	718
Inventory, net	$ 2,545	$ 1,471

The finished goods amounts in the table above include a reserve for excess inventory of $117 and $43 as of December 31, 2023 and 2022, respectively.

(7) Long-Lived Assets

Property and Equipment

Property and equipment as of December 31, 2023 consists of the following:

	Useful Life (Years)	2023	2022
Machinery and equipment	5 – 7	$ 2,955	$ 2,795
Computers and software	2	970	602
Furniture	5	474	475
Leasehold improvements	5	772	772
Other property	7	13	12
Gross property and equipment		5,184	4,656
Less accumulated depreciation		(3,093)	(2,425)
Net property and equipment		$ 2,091	$ 2,231

Depreciation expense for property and equipment for the years ended December 31, 2023 and 2022, was $684 and $276, respectively. The Company did not recognize any impairment losses for the years ended December 31, 2023 and 2022, other than losses on disposal of $44 and $310 in 2023 and 2022, respectively.

Intangible Assets

Intangible assets consist entirely of patent costs that provide the Company with rights, titles, and interests in the development of certain processes, discoveries, and inventions with the right to commercialize that are probable of future economic benefits. Patent costs associated with pharmaceutical intellectual property are expensed as incurred as future economic benefits are not deemed to be probable. Intangible assets are recorded at cost and are amortized over the estimated life of the patents, based on the approval and expiration dates applicable to each patent — typically 20 years — on a straight-line basis. Amortization expense related to intellectual property for 2023 and 2022 was $18 and $122, respectively. We recorded an impairment loss of $190 in 2023; no loss was recorded in 2022. The estimated aggregate amortization expense for intangible assets subject to amortization for each of the five succeeding fiscal years is as follows:

2024	$ 88
2025	88
2026	88
2027	88
2028	88
Thereafter	687
	$ 1,127

(8) Accrued Liabilities

Accrued liabilities consists of the following:

	December 31,	
	2023	2022
Accrued liabilities - clinical trials	$ 3,115	$ 410
Accrued liabilities - other	$ 2,790	$ 2,495
Accrued incentives	3,736	2,896
Accrued vacation	327	329
Accrued payroll	557	247
Accrued taxes	$ 31	$ —
	$ 10,556	$ 6,377

(9) Contingent Earnout Liability

As described in Note *(2) Summary Of Significant Accounting Policies* and Note *(3) Business Combination*, in connection with the execution of the Merger Agreement, MTAC entered into the Sponsor Support Agreement with the Sponsor Holders and Legacy TriSalus, pursuant to which, 3,125,000 of the shares of our Common Stock held by the Sponsor immediately after the Closing Date became unvested and subject to potential forfeiture if certain triggering events are not achieved during the Earnout Period. The earnout shares are classified as a liability and were initially measured at fair value at the Closing Date and will subsequently be remeasured at the end of each reporting period with the change in fair value of the earnout liability recorded in the Consolidated Statements of Operations.

The estimated fair value of the total contingent earnout liability at the closing on August 10, 2023, was $28,927 based on a Monte Carlo simulation valuation model. The liability was remeasured to its fair value of $18,632 as of December 31, 2023. This remeasurement resulted in the recording gain of $10,295 for the year ended December 31, 2023, classified as change in fair value of contingent earnout liability in the Consolidated Statements of Operations. Assumptions used in the valuation are described below:

	December 31, 2023	September 30, 2023
Current stock price	$ 8.45	$ 5.12
Expected share price volatility	65.0 %	65.0 %
Risk-free interest rate	3.9 %	4.6 %
Expected term (years)	4.6	4.9
Estimated dividend yield	— %	— %

The estimated fair value of the liability was determined using a Monte Carlo simulation valuation model using a distribution of potential outcomes. The inputs and assumptions utilized in the calculation require management to apply judgment and make estimates including:

(a) expected volatility, which is based on the historical equity volatility of publicly traded peer companies for a term equal to the expected term of the earnout period;

(b) expected term, which we based on the earnout period per the agreement;

(c) risk-free interest rate, which was determined by reference to the U.S. Treasury yield curve for time periods commensurate with the expected term of the earnout period; and

(d) expected dividend yield, which we estimate to be zero based on the fact that we have never paid or declared dividends.

These estimates may be subjective in nature and involve uncertainties and matters of judgment and therefore cannot be determined with exact precision.

(10) Warrants

Warrants outstanding at December 31, 2023, and December 31, 2022, are as follows:

	December 31, 2023	December 31, 2022
Public Warrants	8,281,779	—
Private Placement Warrants	5,933,333	—
Series B-3 Warrants	—	15,819,000
Total warrants	14,215,112	15,819,000

Public and Private Placement Warrant Liabilities

In connection with consummation of the Business Combination, the Company assumed the warrant liabilities associated with 8,333,272 Public Warrants. Each Public Warrant is exercisable to purchase one share of common stock at a price of $11.50 per share, subject to adjustment in September 2023. As of December 31, 2023, there were 8,281,779 Public Warrants outstanding. The Public Warrants expire on August 10, 2028 or earlier upon redemption or liquidation.

In addition to the Public Warrants, the Company assumed the warrant liabilities associated with 5,933,333 MTAC Private Placement Warrants. The Private Placement Warrants are identical to the Public Warrants, except that the Private Placement Warrants and the common stock issuable upon the exercise of the Private Placement Warrants would not be

transferable, assignable or saleable until 30 days after the completion of the Business Combination, subject to certain limited exceptions. As of September 10, 2023, the Private Placement Warrants became transferable, except for those warrants held by persons who signed a lockup agreement in association with the Business Combination. Additionally, the Private Placement Warrants are exercisable on a cashless basis and will be non-redeemable so long as they are held by the initial purchasers or their permitted transferees. If the Private Placement Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Placement Warrants will be redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants. As of December 31, 2023, there were 5,933,333 Private Placement Warrants outstanding.

On December 26, 2023, the SEC declared effective an amended registration statement on Form S-1 registering the issuance of the shares of common stock issuable upon exercise of the warrants and will use its best efforts to maintain a current prospectus relating to those shares of common stock until the warrants expire or are redeemed, as specified in the warrant agreement.

The Company may redeem for cash the outstanding Warrants:

a. in whole and not in part;

b. at a price of $0.01 per Warrant;

c. upon not less than 30 days' prior written notice of redemption to each warrant holder; and

d. if, and only if, the reported closing price of the Common Stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading day period ending three business days before the Company sends the notice of redemption to the warrant holders.

If and when the warrants become redeemable by the Company, the Company may exercise its redemption right even if it is unable to register or qualify the underlying securities for sale under all applicable state securities laws.

If the Company calls the Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a "cashless basis." The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, or recapitalization, reorganization, merger or consolidation. However, except as described below, the warrants will not be adjusted for issuances of common stock at a price below its exercise price. Additionally, in no event will the Company be required to net cash settle the warrants. Accordingly, the warrants may expire worthless.

We determined that both the Public and Private placement Warrants do not meet the criteria to be equity classified and should be recorded as liabilities. Our analysis concluded liability classification under ASC 815, *Derivatives and Hedging*, as these warrants include a provision that could allow cash settlement upon an event outside the control of the Company, and such event may not result in a change in control of the Company. As a result, the Private and Public Warrants do not meet the criteria for equity classification.

At the close of the Business Combination, the fair values of the Public Warrants and Private Placement Warrants were $1,500 and $1,068, respectively. As of December 31, 2023, the fair values of the Public Warrants and Private Placement Warrants were $9,855 and $7,061, respectively. The fair value of the Public Warrants has been measured based on the quoted price of such warrants on the Nasdaq Global Market. The transfer of Private Placement Warrants to anyone outside of a small group of individuals who are permitted transferees would result in the Private Placement Warrants having substantially the same terms as the Public Warrants. Therefore, we determined that the fair value of each Private Warrant is equivalent to that of each Public Warrant.

Series B-3 Warrants

The Series B-3 Warrants were issued in conjunction with shares of Series B-2 preferred stock in October 2022, March 2023 and May 2023. Each warrant allowed the holder to purchase one share of Series B-3 preferred stock for $0.05. The Series B-3 Warrants expired at the earlier of October 5, 2028, or the closing date of a change of control transaction. All in-the-money warrants that were outstanding at a change of control transaction would automatically net exercise.

In July 2023, Series B-3 Warrants to purchase 2,239,309 shares of Series B-3 preferred stock were exercised for $4,530. At the Closing Date of the Business Combination, all in-the-money outstanding warrants and Series B-3 Warrants were net-exercised and converted to shares of common stock of Legacy TriSalus, then exchanged for shares of TriSalus common stock. Out-of-the-money warrants for other classes of preferred stock expired. The Series B-2 tranche liabilities also expired at the Closing Date of the Business Combination.

Warrant Repurchase Program

In August 2023, our Board approved a warrant repurchase program, authorizing the repurchase of some or all of the Public Warrants (the "Warrant Repurchase Program"). The Board authorized an aggregate expenditure of up to $4,000 for such repurchases. The repurchases were to be made from time to time in open market or privately negotiated transactions. The Warrant Repurchase Program did not obligate us to purchase any Public Warrants and could be terminated, increased or decreased by the Board in its discretion at any time. We adopted a purchase plan pursuant to Rule 10b5-1 under the Exchange Act in October 2023. Through December 31, 2023, we repurchased 51,493 Public Warrants for $20. The purchase plan was discontinued in December 2023.

(11) Income Taxes

We utilize the balance sheet method of accounting for income taxes and deferred taxes which are determined based on the differences between the financial statements and tax basis of assets and liabilities given the provisions of the enacted tax laws.

The income tax expenses (benefits) from continuing operations for the years ended December 31, 2023 and 2022, are summarized as follows:

	2023	2022
Federal:		
Current	$ —	$ —
Deferred	—	—
	—	—
State:		
Current	9	9
Deferred	—	—
	9	9
Total	$ 9	$ 9

The provision for income taxes differs from income taxes computed at the federal statutory tax rates for the years ended December 31, 2023 and 2022, due to the following items:

	2023	2022
Statutory rate	21.0%	21.0%
State and local taxes	3.4	2.0
Change in valuation allowance	(22.0)	(19.0)
Disallowed interest expense on convertible debt	—	—
Prior year true-up	1.0	1.0
Permanent differences	(3.4)	(5.0)
	—%	—%

The income tax effects of temporary differences that give rise to significant portions of the deferred income tax assets and liabilities at December 31, 2023 and 2022, are presented below:

	2023	2022
Deferred tax assets:		
NOL carryforwards	$ 37,322	$ 30,421
Fixed assets and intangibles	2,565	2,371
Accruals	1,115	815
Inventory	222	76
Charitable contributions	37	35
Right-of-use assets	46	52
Capitalized R&D expenses	10,176	4,613
Stock-based compensation expense	305	76
Total deferred income tax assets	51,788	38,459
Deferred tax liabilities:		
Prepaid expenses	(470)	(101)
Total deferred income tax assets and liabilities	51,318	38,358
Less: valuation allowance	(51,318)	(38,358)
Net deferred income tax assets and liabilities	$ —	$ —

In assessing the realizability of our deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. As we do not have any historical taxable income, projections of future taxable income over the periods in which the deferred tax assets are deductible, and after consideration of the history of operating losses, we do not believe it is more likely than not that we will realize the benefits of the net deferred tax assets and, accordingly, have established a valuation allowance equal to 100% of net deferred tax assets. The change in the valuation allowance for the years ended December 31, 2023 and 2022 was $13,192 and $8,728, respectively.

As of December 31, 2023, we had net operating losses ("NOLs") as follows (the NOLs which do not expire are subject to an annual utilization limitation of 80% of taxable income):

	December 31, 2023	
	Federal	State
NOLs expiring between 2029 and 2037	$ 43,912	$ 81,902
NOLs which do not expire	109,966	26,351
Total NOLs	$ 153,878	$ 108,253

The Internal Revenue Code contains provisions that may further limit the net operating loss carryovers available to be used in any one year if certain events occur, including significant changes in ownership interests. Utilization of net operating loss and tax credit carryforwards are subject to a substantial annual limitation due to the ownership change limitations set forth in Section 382 of the Code and similar state provisions. We prepared an Internal Revenue Code 382 analysis to determine the annual limitations on our consolidated net operating loss carryforwards. All of our tax attributes are subject to an annual limitation. Such annual limitations could result in the expiration of the net operating loss and tax credit carryforwards before utilization.

As of December 31, 2023 and 2022, we did not have any unrecognized tax benefits and do not expect that the amount of unrecognized tax benefits will change significantly within the next 12 months. Our accounting policy is to accrue interest and penalties related to unrecognized tax benefits as a component of income tax expense.

We are subject to taxation in the United States, various state jurisdictions, and various foreign jurisdictions. We are subject to income tax examination by U.S. and state tax authorities for the calendar year ended December 31, 2023 and forward. However, to the extent allowed by law, the taxing authorities may have the right to examine prior periods where net operating losses and credits were generated and carried forward, and make adjustments up to the amount of the net operating losses and credits utilized in open tax years.

(12) Dynavax Purchase

We purchased all of the intellectual property and trial drug substance for nelitolimod from Dynavax Technologies ("Dynavax") in 2020. This was a purchase of in-process research and development ("IPR&D"). nelitolimod, an investigational agent in development, is a toll-like receptor 9 ("TLR9") agonist which is believed to bind to the TLR9 receptors found on suppressive immune cells including myeloid-derived suppressor cells ("MDSCs") and antigen-presenting immune cells. We believe that nelitolimod, when delivered using our PEDD devices, can improve therapeutic distribution to solid tumors and improve outcomes for liver metastases and pancreatic cancer.

Payments under the Dynavax purchase agreement consist of: (a) one upfront payment of $9,000 that was split into two payments ($5,000 and $4,000, paid in July and December 2021, respectively), (b) milestone payments upon the achievement of certain development and commercial milestones, and (c) royalty payments based on aggregate annual net sales after nelitolimod receives FDA approval to be sold.

The milestone payments range from $1,000 to $10,000, triggered by development achievements for each of up to four indications. The development milestone payments cannot exceed $170,000. We made a milestone payment of $1,000 in each of September 2021, after initiating our clinical study of uveal melanoma liver metastases; June 2022, after initiating our clinical study for primary liver tumors; and August 2023, after initiating our clinical study for pancreatic cancer. In aggregate, the commercial milestones shall not exceed $80,000. We will also pay annual royalties at the rate of 10% for aggregate annual net sales less than or equal to $1,000,000 and 12% for aggregate annual net sales above that amount.

We recorded the development milestone payments in R&D in 2023 and 2022. We have reflected these milestone payments in the Consolidated Statements of Cash Flows as investing activities to reflect the contractual investment in the IPR&D. The milestone payments and royalty payments are contingent upon future events and therefore will also be recorded as expense when it is probable that a milestone has been achieved or when royalties are due.

(13) Standby Equity Purchase Agreement

On October 2, 2023, we entered into a Standby Equity Purchase Agreement ("SEPA") with Yorkville. Yorkville is a fund managed by Yorkville Advisors Global, LP.

Pursuant to the SEPA, the Company shall have the right, but not the obligation, to sell to Yorkville up to $30.0 million of Common Stock, par value $0.0001 per share, at the Company's request any time during the commitment period commencing on October 2, 2023 (the "Effective Date") and terminating on the first day of the month following the 24-month anniversary of the Effective Date. Each issuance and sale by the Company to Yorkville under the SEPA (an "Advance") is subject to a maximum limit equal to the greater of: (i) an amount equal to 100% of the average of the daily volume of the Common Stock on the Nasdaq Stock Market ("Nasdaq") for the 10 trading days immediately preceding an Advance notice, or (ii) 1,000,000 shares of Common Stock. At the election of the Company, the shares will be issued and sold to Yorkville at a per-share price equal to: (i) 96% of the Market Price (as defined below) for any period commencing on the receipt of the Advance notice by Yorkville and ending on 4:00 p.m. New York City time on the applicable Advance notice date (the "Option 1 Pricing Period"), or (ii) 97% of the Market Price for any three consecutive trading days commencing on the Advance notice date (the "Option 2 Pricing Period," and each of the Option 1 Pricing Period and the Option 2 Pricing Period, a "Pricing Period"). "Market Price" is defined as, for any Option 1 Pricing Period, the daily volume-weighted average price ("VWAP") of the Common Stock on Nasdaq, and for any Option 2 Pricing Period, the lowest VWAP of the Common Stock on the Nasdaq during the Option 2 Pricing Period. The Advances are subject to certain limitations, including that Yorkville cannot purchase any shares that would result in it beneficially owning more than 4.99% of the outstanding voting power or Common Stock. Further, Yorkville cannot purchase shares that would result in it acquiring more than 5,260,704 shares of Common Stock, which represents 19.99% of the outstanding Common Stock, as of the Effective Date of SEPA.

As described in *Note (2) Summary of Significant Accounting Policies*, the SEPA is accounted for as a derivative pursuant to ASC 815-10 and will be recognized at fair value in accordance with ASC 820. The Company intends to utilize the SEPA to access capital to fund its operations. The Company did not issue any Advances during the year ended December 31, 2023.

The estimated fair value of the SEPA derivative liability on October 2, 2023 was $183, which was determined using a scenario-based valuation model. The liability was remeasured to its fair value of $185 as of December 31, 2023, and is classified within other long-term liabilities in the Consolidated Balance Sheets. This remeasurement resulted in the recognition of a loss of $2 for the year ended December 31, 2023, classified as change in fair value of contingent liabilities in the Consolidated Statement of Operations. Assumptions used in the valuation are described below:

Valuation assumptions:	December 31, 2023	October 2, 2023
Expected draws	$ 5,000	$ 5,000
Expected probability of draws	90.0%	90.0%
Risk-free interest rate	5.4%	4.9%

The estimated fair value of the liability was determined using a scenario-based valuation model which assigned a probability to a number of different outcomes. The inputs and assumptions utilized in the calculation require management to apply judgment and make estimates including:

(a) total expected draws of $5,000 through the issuance of five separate advances under the Option 1 Pricing Period;

(b) the expected probability of the draws on the SEPA, which we estimate based on our expectation of the draws being completed; and

(c) risk-free interest rate, which was determined by reference to the U.S. Treasury yield curve for time periods commensurate with the expected term of the agreement in relation to the date of the expected draw.

These estimates may be subjective in nature and involve uncertainties and matters of judgment and therefore cannot be determined with exact precision.

As of December 31, 2023, we did not sell any common stock under the SEPA. In March 2024, we sold 350,000 shares of common stock under the SEPA, raising approximately $3,141.

(14) Convertible Preferred Stock

Series A Convertible Preferred Stock

The Company is authorized to issue up to 10,000,000 shares of preferred stock. At the Closing Date, we issued 4,015,002 shares of Series A Convertible Preferred Stock for $40,150.The original issue price of the Series A Convertible Preferred Stock was $10.00. The Series A Convertible Preferred Stock accrues cumulative dividends at the rate of 8.00% per annum on the original issue price. As of December 31, 2023, total undeclared cumulative dividends were $1,258. We have not recorded the undeclared dividends in our consolidated financial statements.

All shares of Series A Convertible Preferred Stock had the following rights:

i. Conversion

(a) Optional Conversion

The Series A Convertible Preferred Stock are convertible at any time at the option of the holder thereof into the number of shares of our Common Stock determined by the quotient of (i) the sum of $10.00 (as adjusted for any stock dividend, stock split, reverse stock split, combination or similar event affecting the Series A Convertible Preferred Stock) (the “Liquidation Preference”) and, if we have not elected to otherwise pay the accrued Annual Dividends (as defined below) in cash to the holder, the accrued Annual Dividends on such shares as of the date of conversion, divided by (ii) the Conversion Price (as defined in our Certificate of Designations, Preferences, and Rights of Series A Convertible Preferred Stock (the "Certificate of Designations")) of such shares in effect at the time of conversion.

(b) Automatic Conversion

On the four-year anniversary of the Closing, all then outstanding shares of Series A Convertible Preferred Stock shall automatically convert into the number of shares of our Common Stock equal to the quotient of (i) the sum of the Liquidation Preference and if we had not elected to otherwise pay the accrued Annual Dividends in cash to the holder, the accrued Annual Dividends on such shares as of the date of conversion, divided by (ii) the Conversion Price of such shares in effect at the time of conversion.

ii. Voting Rights

Holders of the Series A Convertible Preferred Stock are entitled to vote with the holders of our Common Stock on all matters submitted to a vote of our stockholders, except as otherwise provided in the Certificate of Designations or as required by applicable law, voting together with the holders of our Common Stock as a single class. Each holder is entitled to a number of votes in respect of the shares of Series A Convertible Preferred Stock owned as of the record date by it, or if

no such record date is established, as of the date such vote is taken or any written consent of stockholders is solicited, equal to the quotient of (i) $10.00 divided by (ii) the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of our Common Stock as determined at Closing.

As long as any shares of Series A Convertible Preferred Stock are outstanding, we shall not, without the affirmative vote of the Holders of a majority of the then-outstanding shares of the Series A Convertible Preferred Stock, (i) amend, alter, repeal or otherwise modify any provision of our certificate of incorporation or the Certificate of Designations in a manner that would alter or change the terms or the powers, preferences, rights or privileges of the Series A Convertible Preferred Stock as to affect them adversely; (ii) authorize, create, increase the authorized amount of, or issue any class or series of capital stock senior to the Series A Convertible Preferred Stock; (iii) increase the authorized number of shares of Series A Convertible Preferred Stock or enter into any agreement with respect to the foregoing.

iii. Dividends

Holders of the Series A Convertible Preferred Stock are entitled to participate equally in any dividends declared to holders of Common Stock. In addition, each holder of the Series A Convertible Preferred Stock is entitled to receive cumulative annual dividends that accrue and accumulate on a daily basis at a rate per annum (calculated on the basis of an actual 365- or 366-day year, as applicable) equal to 8.00% of the original issue price of $10.00 per share (the "Annual Dividends"). The Annual Dividends will be either paid in cash, paid by issuing fully paid and nonassessable shares of Common Stock, or a combination thereof when, as and if authorized and declared by our Board. Upon conversion or a change of control, any unpaid Annual Dividends will be paid to the holders, either in the form of common stock upon a conversion, or in cash upon a change of control. So long as any shares of Series A Convertible Preferred Stock remain outstanding, unless all Annual Dividends on all outstanding shares of Series A Convertible Preferred Stock have been declared and paid in cash, we will be prohibited from declaring any dividends on, or making any distributions relating to, other classes of our capital stock ranking junior to the Series A Convertible Preferred Stock, subject to certain exceptions.

iv. Anti-dilution Provisions

The initial Conversion Price of $10.00 is subject to customary adjustments in the case of certain distributions to holders of our Common Stock payable in shares of our Common Stock, subdivisions, splits or combinations of the shares of our Common Stock and distributions to all holders of shares of our Common Stock of any convertible securities or options or any other assets for which there is no corresponding distribution in respect of the Series A Convertible Preferred Stock.

The Conversion Price will automatically reset upon each of February 10, 2025, and July 10, 2027, the eighteen-month and forty-seven-month anniversaries of the Closing Date, to be equal to the lowest of:

(i) Initial Conversion Price, subject to adjustments for stock dividends and distributions or other distributions made to common stockholders for which there is no corresponding distribution for Preferred Stock,

(ii) the then-current Conversion Price, and

(iii) the higher of 1) the Floor Price ($2.10 per share) or 2) the trailing ten-Trading Day VWAP of the Common Stock determined as of the date of such reset.

v. Liquidation Preferences

The terms of the Series A Convertible Preferred Stock provide for liquidation preferences in the event of a change in control, liquidation, dissolution, or certain other fundamental transactions of the Company (a "Liquidation Event"), none of which were deemed probable as of December 31, 2023. The Liquidation Preferences of $10.00 per share, plus all unpaid dividends, are payable prior to payment to any class of capital stock that is junior to the Series A Convertible Preferred Stock.

If the assets of the Company or the consideration received in such Liquidation Event are insufficient to make payment of the full Liquidation Preferences to all holders of Series A Convertible Preferred Stock, then such assets will be distributed ratably to the holders of Series A Convertible Preferred Stock in proportion to the full amounts to which they would otherwise have been entitled. After payment of the aforementioned Liquidation Preferences, any remaining proceeds from a Liquidation Event will be distributed to all classes of capital stock that are junior to the Series A Convertible Preferred Stock pro rata on an as-if converted basis.

Legacy TriSalus Preferred Stock

Since inception, we have issued various series of preferred stock as more fully described below. As described in Note *(3) Business Combination*, all of the Legacy TriSalus Preferred Stock was converted to Legacy TriSalus Common Stock

immediately prior to the Business Combination and, upon consummation of the Business Combination, were exchanged for shares of our Common Stock. In accordance with the terms of the Legacy TriSalus Preferred Stock, upon an acquisition of the Company, the proceeds would be used to first pay the liquidation preferences on the preferred stock prior to payment to common stockholders. We have determined this is an in-substance redemption feature since holders of preferred stock represent a majority of our Board and control a majority of the stockholder vote on an as-if-converted basis. Thus, a decision to pursue an acquisition or accept the terms of an acquisition — and thereby redeem the convertible preferred stock — was deemed to be outside of our control. As a result, the Legacy TriSalus Preferred Stock has been classified as temporary equity in the accompanying Consolidated Balance Sheets. We have not adjusted the carrying values of the convertible preferred stock to the respective liquidation preferences of such shares as the instruments were not currently redeemable and we believed it was not probable that the instruments would become redeemable.

Convertible preferred stock, net of issuance costs, at December 31, 2023 and 2022, is as follows:

	December 31,	
Series	**2023**	**2022**
Series A-1 preferred stock, $0.001 par value per share. Authorized, issued, and outstanding 0 and 131,797 shares at December 31, 2023 and 2022	$ —	$ 6,065
Series A-2 preferred stock, $0.001 par value per share. Authorized, issued, and outstanding 0 and 576,126 shares at December 31, 2023 and 2022	—	8,976
Series A-3 preferred stock, $0.001 par value per share. Authorized, issued, and outstanding 0 and 612,822 shares at December 31, 2023 and 2022	—	10,611
Series A-4 preferred stock, $0.001 par value per share. Authorized, issued, and outstanding 0 and 127,787 shares at December 31, 2023 and 2022	—	1,993
Series A-5 preferred stock, $0.001 par value per share. Authorized 734,533 shares; issued and outstanding 0 and 730,320 shares at December 31, 2023 and 2022	—	12,858
Series A-6 preferred stock, $0.001 par value per share. Authorized 805,848 shares; issued and outstanding 0 and 800,657 shares at December 31, 2023 and 2022	—	15,476
Series B preferred stock, $0.001 par value per share. Authorized 7,021,678 shares; issued and outstanding 0 and 6,984,971 shares at December 31, 2023 and 2022, respectively	—	84,528
Series B-1 preferred stock, $0.001 par value per share. Authorized 1,659,672 shares; issued and outstanding 0 and 1,659,672 shares at December 31, 2023 and 2022, respectively	—	23,499
Series B-2 preferred stock, $0.001 par value per share. Authorized 1,765,609 shares; issued and outstanding 0 and 706,243 shares at December 31, 2023 and 2022, respectively	—	—
Series B-3 preferred stock, $0.001 par value per share. Authorized 8,474,924 shares; issued and outstanding 0 at shares at December 31, 2023 and 2022	—	—
Total convertible preferred stock	$ —	$ 164,006

The following table summarizes activity in convertible preferred stock for the years ended December 31, 2023 and 2022.

Series	**Balance at January 01, 2022**	**Issuances**	**Balance at December 31, 2022**
Series A-1	$ 6,065	$ —	$ 6,065
Series A-2	8,976	—	8,976
Series A-3	10,611	—	10,611
Series A-4	1,993	—	1,993
Series A-5	12,858	—	12,858
Series A-6	15,476	—	15,476
Series B	84,528	—	84,528
Series B-1	20,000	3,499	23,499
Total convertible preferred stock	$ 160,507	$ 3,499	$ 164,006

Series	Balance at December 31, 2022	Issuances	Retirements / Conversions	Balance at December 31, 2023
Series A-1	$ 6,065	$ —	$ (6,065)	$ —
Series A-2	8,976	—	(8,976)	—
Series A-3	10,611	—	(10,611)	—
Series A-4	1,993	—	(1,993)	—
Series A-5	12,858	—	(12,858)	—
Series A-6	15,476	—	(15,476)	—
Series B	84,528	109	(84,637)	—
Series B-1	23,499	1	(23,500)	—
Series B-2	$ —	$ —	$ —	—
Series B-3	$ —	$ 39,858	$ (39,858)	$ —
Total convertible preferred stock	$ 164,006	$ 39,968	$ (203,974)	$ —

2023 Financing

In January through June 2023, holders of warrants to purchase 4,771,642 shares of Series B-3 preferred stock exercised their purchase rights, for proceeds of approximately $9,630. In addition, $25,409 of warrant liabilities was transferred to Series B-3 preferred stock. Also, holders of warrants to purchase 11,123 shares of Series B preferred stock exercised their purchase rights, for proceeds of $4, plus the transfer of warrant liabilities of $106 to Series B preferred stock.

In March 2023, we effectuated two closings of a portion of the second tranche of the B-2 Preferred Stock Financing whereby (i) 207,541 shares of Series B-2 preferred stock and accompanying warrants to purchase 830,167 shares of Series B-3 preferred stock, representing approximately 40% of the shares committed in the second tranche, were sold for an aggregate purchase price of $2,939, and (ii) 17,656 shares of Series B-2 preferred stock and accompanying warrants to purchase 70,624 shares of Series B-3 preferred stock, representing approximately 3% of the shares committed in the second tranche, were sold for an aggregate purchase price of $250. As a result of the closings of a portion of the second tranche of the B-2 Preferred Stock Financing described above, in accordance with the anti-dilution rights in the Company's certificate of incorporation, the conversion prices of the Company's preferred stock were adjusted. The conversion prices were further adjusted as a result of the June 2023 exercise of a portion of the second tranche of the B-2 Preferred Stock Financing described below, which represent the conversion prices in effect on the Closing Date.

In May 2023, we amended the Series B-2 preferred stock agreement and warrant agreement to purchase Series B-3 preferred stock to extend the expiration date for the second tranche from February 28, 2023, to May 31, 2023.

In June 2023, we effectuated closings of a portion of the second tranche of the B-2 Preferred Stock Financing whereby (i) 257,779 shares of Series B-2 preferred stock and accompanying warrants to purchase 1,031,116 shares of Series B-3 preferred stock, representing approximately 49.7% of the shares committed in the second tranche, were sold for an aggregate purchase price of approximately $3,650, and (ii) 165,967 shares of Series B-2 preferred stock and accompanying warrants to purchase 663,868 shares of Series B-3 preferred stock, none of which were shares committed in the second tranche, were sold for an aggregate purchase price of $2,350. As a result of the closings of a portion of the second tranche of the B-2 Preferred Stock Financing described above, in accordance with the anti-dilution rights in the Company's certificate of incorporation, the conversion prices of the Company's preferred stock (i) were adjusted to $38.84 for Series A-1 preferred stock, $12.14 for Series A-2 preferred stock, $13.36 for Series A-3 preferred stock, $12.55 for Series A-4 preferred stock, $13.36 for Series A-5 preferred stock, $14.97 for Series A-6 preferred stock, $9.71 for Series B preferred stock, and $10.93 for Series B-1 preferred stock and (ii) remained the same for Series B-2 preferred stock $14.16 and Series B-3 preferred stock $2.03, which correlate to approximate (in each case rounded to three decimals) exchange ratios of 1.275 to 1 for Series A-1 preferred stock, 1.290 to 1 for Series A-2 preferred stock, 1.303 to 1 for Series A-3 preferred stock, 1.277 to 1 for Series A-4 preferred stock, 1.333 to 1 for Series A-5 preferred stock, 1.351 to 1 for Series A-6 preferred stock, 1.250 to 1 for Series B preferred stock, 1.296 to 1 for Series B-1 preferred stock, 1 to 1 for Series B-2 preferred stock and 1 to 1 for Series B-3 preferred stock. These conversion prices remained in effect at the Closing Date. Any portion of the Series B-3 Warrants that remained unexercised at the time the Business Combination is consummated were automatically net settled for shares of Legacy TriSalus Common Stock immediately prior to the closing of the

Business Combination (see Note *(3) Business Combination*) and exchanged into shares of our Common Stock at the Closing Date.

The fair value of the Series B-3 Warrants as of December 31, 2022, was determined using a probability-weighted expected outcome model whereby the following two scenarios were probability-weighted based on the Company's expectation of each occurring: (1) a status quo scenario whereby the Company would continue as a private company and (2) a scenario where the Business Combination would close. The fair value of the Series B-3 Warrants as of August 10, 2023, was determined solely using the scenario where the Business Combination would close. Under the status quo scenario, the Series B-3 Warrants, including warrants to be issued under the second and third tranches, were valued using the Black-Scholes model. The fair value of the Series B-2 Tranche Liability was determined using a Binomial Tranche Model. Both models incorporated the following significant assumptions for the respective valuation dates:

	December 31, 2022
Series B-2 preferred stock fair value per share	$14.97
Series B-2 preferred stock exercise price per share	$14.16
Series B-3 preferred stock fair value per share	$3.24
Series B-3 Warrants exercise price per share	$2.03
Volatility	50.0% – 65.0%
Risk free rate	4.0% – 4.7%
Series B-2 Tranche Liability expected term	0.2 – 0.4 years
Series B-3 Warrants expected term	5.8 – 6.0 years
Expected dividends	$ —

The fair value of the underlying shares of Series B-2 preferred stock and the Series B-3 Warrants used in these models were derived from estimates of the Company's equity fair value using the Guideline Public Company Method, specifically revenue multiples of comparable public companies were multiplied by the Company's forecasted 2023 and 2024 revenue. The valuation of Series B-3 Warrants under the Business Combination scenario incorporates an estimate of the fair value of the underlying Series B-3 preferred stock upon the close of the Business Combination of $9.31 and $10.93 per share, as of August 10, 2023, and December 31, 2022, respectively, which is based upon the enterprise value stated in the Merger Agreement of $220,000 allocated to all outstanding shares of preferred stock, warrants to purchase preferred stock, and common stock on an as-if converted basis, and for the December 31, 2022 valuation, discounted at 30% from the expected Business Combination Closing Date. The Business Combination scenario as of August 10, 2023, and December 31, 2022, assumed there would be no additional exercises of the second and third tranches, and thus no value was assigned to the outstanding tranche rights and obligations, as the Company would not exercise its right to call the remaining second tranche.

The fair value of the Series B-3 Warrant Liabilities at issuance resulting from the completion of the Second Tranche Closings was estimated at $14,701. The excess of the warrant liability's fair value compared to the proceeds received in the Second Tranche Closings resulted in a charge to loss on equity issuance in the Consolidated statements of operations of $1,402 for the year ended December 31, 2023.

(15) Stockholders' Equity

(a) Common Stock

As of December 31, 2023 and 2022, the Company's authorized shares of common stock were 400,000,000 and 30,898,162, respectively. As of December 31, 2023, the Company had reserved the following shares of common stock for

future issuance in connection with the conversion of shares of Preferred Stock, at the applicable conversion rates (see Note *(14) Convertible Preferred Stock*) and upon the exercise of certain options and warrants:

Preferred stock:	2023	2022
Series A convertible preferred stock (assuming maximum conversion)	25,237,155	—
Series A-1	—	152,188
Series A-2	—	675,638
Series A-3	—	712,198
Series A-4	—	148,834
Series A-5	—	868,487
Series A-6	—	953,163
Series B	—	8,059,581
Series B-1	—	1,936,284
Series B-2	—	706,243
Total preferred stock	25,237,155	14,212,616
Warrants:		
Public Warrants	8,333,333	—
Private Placement Warrants	5,933,333	—
Warrants to purchase Series A-5 preferred stock	—	5,010
Warrants to purchase Series A-6 preferred stock	—	6,179
Warrants to purchase Series B preferred stock	—	42,354
Warrants to purchase Series B-3 preferred stock	—	2,824,974
Total Warrants	14,266,666	2,878,517
Employee Stock Purchase Plan	1,396,252	—
Equity Awards:		
Stock options and restricted stock units outstanding	3,666,234	1,671,076
Shares available for future grant	3,515,303	432,413
Total Equity Awards	7,181,537	2,103,489
Grand Total	48,081,610	19,194,622

(b) Equity Awards

We currently maintain the 2023 Equity Incentive Plan (the "2023 Plan"), which our Board of Directors and stockholders approved in connection with the Business Combination, for purposes of granting equity-based incentive awards to our employees and consultants, including our executive officers and directors. Prior to the Business Combination, TriSalus granted equity incentive awards under the 2009 Amended and Restated Equity Incentive Plan (the "2009 Plan"). The 2009 Plan will not be used following the Business Combination. However, any awards granted under the 2009 Plan remain subject to the terms of the 2009 Plan and the applicable award agreement. Historically, we have used options as an incentive for long-term compensation to our executive officers because options allow our executive officers to realize value from this form of equity compensation only if the value of the underlying equity securities increase relative to the option's exercise price, which exercise price is set at the fair market value of the underlying equity securities on the grant date.

The 2009 Plan and the 2023 Plan are administered by our chief executive officer and chief financial officer, who act on the recommendation of managers of the Company to select the individuals to whom the awards will be granted and to determine the amount and vesting period for the grants. All grants are subject to approval by the board of directors.

As of December 31, 2023, the balances under the two plans are below.

	December 31, 2023		
	Authorized	Outstanding	Available for Issue
2009 Plan	1,596,529	1,596,529	—
2023 Plan	5,585,008	2,069,705	3,515,303
Total	7,181,537	3,666,234	3,515,303

2009 Equity Incentive Plan

As of December 31, 2023 and 2022, there were in total 1,532,356 and 1,671,076, respectively, stock options issued and outstanding under the 2009 Plan. The 2009 Plan was originally set to expire on July 28, 2019, the ten-year anniversary of its establishment, however, the ten-year life automatically renews each time the plan is amended to increase the authorized shares. The most recent amendment was on September 15, 2022, so the revised expiration date of the 2009 Plan is September 15, 2032. During the year ended December 31, 2023, we granted 279,306 options with a weighted average fair value of $5.60. At December 31, 2023, no options to purchase shares of common stock were available for grant.

Stock options are granted with an exercise price equal to the estimated fair value of the stock at the date of grant. Prior to the Business Combination, the fair value was determined by a third-party valuation performed in accordance with IRS Section 409A. No awards have been granted subsequent to the Business Combination, as the 2009 Plan was frozen and replaced by the 2023 Plan (see below). Options generally have a ten-year contractual term and typically have graded vesting over one to four years.

The following table summarizes activity for options issued to employees, consultants, and directors under the 2009 Plan:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Options outstanding at January 1, 2022	1,307,080	$ 1.22	8.4
Granted	550,049	2.43	—
Exercised	(82,879)	0.81	—
Forfeiture	(103,174)	1.22	—
Options outstanding at December 31, 2022	1,671,076	1.62	8.2
Granted	279,306	10.30	—
Exercised	(222,627)	0.94	—
Forfeiture	(195,399)	5.46	—
Options outstanding at December 31, 2023	1,532,356	2.78	7.5

The following table summarizes certain information about all options outstanding under the 2009 Plan as of December 31, 2023.

	Options outstanding		Options Exercisable
Exercise Price	Number outstanding at December 31, 2023	Weighted average remaining contractual life	Number exercisable at December 31, 2023
$0.41	326,589	7.03	272,169
$1.22	200,832	4.18	200,832
$2.03	7,415	3.55	7,415
$2.43	810,855	8.19	307,567
$3.65	4,250	2.89	4,250
$10.30	182,415	9.38	5,002
Total	1,532,356	7.50	797,235

2009 Plan	2023	2022
Valuation assumptions:		
Expected dividend yield	—%	—%
Expected volatility	53%	32%
Expected term (years)[(1)]	6.0 – 6.2	5.6 – 6.2
Risk-free interest rate	4.2%	2.76%

(1) Our historical exercise behavior for previous grants does not provide a reasonable estimate for future exercise activity for employees who have been awarded stock options in the past three years. Therefore, the average expected term was calculated using the simplified method, as defined by GAAP, for estimating the expected term.

We granted 177,973 options to members of the Board of Directors and other non-employees during the year ended December 31, 2022.

Recognized compensation expense under the 2009 Plan for employees and nonemployees in 2023 was $245, which was predominately included in general and administrative expense in the accompanying consolidated statements of operations. As of December 31, 2023, there was $873 of unrecognized compensation expense related to unvested share-based compensation arrangements granted under the equity incentive plan. The December 31, 2023, balance will be recognized over a weighted average period of 1.5 years.

2023 Equity Incentive Plan

Under the 2023 Plan, the Company's Board may grant equity-based incentive awards to employees, consultants and other service providers of the Company and its affiliates within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended. Initially, 5,585,008 shares were authorized under the 2023 Plan. In addition, the share reserve will automatically increase on January 1 of each year for a period of ten years, commencing on January 1, 2024, and ending on January 1, 2033, in an amount equal to (1) five percent of the total number of shares of the fully diluted Common Stock determined on December 31 of the preceding year, or (2) a lesser number of shares of Common Stock determined by our Board prior to January 1 of a given year. During the year ended December 31, 2023, we granted 2,100,307 options with a weighted average fair value of $4.08. The 2023 Plan will expire on August 10, 2033, unless modified by the Board of Directors or a duty authorized committee thereof.

Our Board, or a duly authorized committee thereof, administers the 2023 Plan. Our Board may also delegate to one or more of our officers the authority to, among other things, (1) designate employees (other than officers) to receive specified stock awards and (2) determine the number of shares subject to such stock awards. Under the 2023 Plan, the Board has the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value and exercise price, and the provisions of each stock award, including the exercise period and the vesting schedule applicable to a stock award, subject to the limitations of the 2023 Plan.

Stock options are granted with an exercise price no less than 100% of the estimated fair value of a share of Common Stock at the date of grant.

The following table summarizes certain information about all options outstanding under the 2023 Plan as of December 31, 2023.

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Options outstanding at January 1, 2022	—	$ —	—
Granted	—	—	—
Exercised	—	—	—
Forfeiture	—	—	—
Options outstanding at December 31, 2022	—	—	—
Granted	2,100,307	7.32	—
Exercised	—	—	—
Forfeiture	(30,602)	4.79	—
Options outstanding at December 31, 2023	2,069,705	7.36	9.7

We granted 278,000 options to members of the Board of Directors and other non-employees during the year ended December 31, 2023.

The following table summarizes certain information about all options outstanding under the 2023 Plan as of December 31, 2023.

	Options outstanding		Options Exercisable
Exercise Price	Number outstanding at December 31, 2023	Weighted average remaining contractual life	Number exercisable at December 31, 2023
$4.60	150,556	9.83	—
$4.78	866,000	9.69	—
$4.95	112,649	9.77	1,324
$6.70	195,000	9.66	—
$7.92	40,000	9.97	—
$11.34	245,000	9.61	—
$11.51	172,500	9.62	—
$12.00	288,000	9.61	—
Total	**2,069,705**	**9.68**	**1,324**

2023 Plan	2023
Valuation assumptions:	
Expected dividend yield	—%
Expected volatility	53 %
Expected term (years)[(1)]	6.0 - 6.2
Risk-free interest rate	4.2%

Recognized compensation expense under the 2023 Plan for employees and nonemployees in 2023 was $724, which was predominately included in general and administrative expense in the accompanying consolidated statements of operations. As of December 31, 2023, there was $7,766 of unrecognized compensation expense related to unvested share-based compensation arrangements granted under the equity incentive plan. The December 31, 2023, balance will be recognized over a weighted average period of 3.6 years.

Restricted Stock

Pursuant to both the 2009 and 2023 Plans, we issue restricted stock unit awards ("RSUs") and satisfy such grants through the issuance of new shares. RSUs are share awards that, upon vesting, will deliver to the holder shares of our

common stock at specified vesting dates. Typically, RSUs vest over four years, with 25% of the awarded units vesting at each annual anniversary of the grant date.

The following table summarize activity for RSUs issued to employees and directors under the 2009 Plan. As of December 31, 2023, no RSUs had been granted under the 2023 Plan:

Restricted Stock:	Restricted Stock Units (RSU)	Weighted-Average Grant-Date Fair Value per Share	Weighted average remaining contractual life
Beginning Outstanding	—	$ —	—
Awarded	184,018	10.30	—
Released	(25,091)	10.30	—
Forfeited	(94,754)	10.30	—
RSUs outstanding at December 31, 2023	64,173		1.8

Recognized compensation expense for RSUs for employees and nonemployees in 2023 was $433, which was predominately included in general and administrative expense in the accompanying consolidated statements of operations. As of December 31, 2023, there was $609 of unrecognized compensation expense related to unvested RSUs. The December 31, 2023, balance will be recognized over a weighted average period of 1.5 years.

(c) Employee Stock Purchase Plan

We maintain an Employee Stock Purchase Plan ("ESPP"), which provides our eligible employees and certain designated companies with an opportunity to purchase shares of Common Stock, to assist us in retaining the services of eligible employees, to secure and retain the services of new employees and to provide incentives for such persons to exert maximum efforts for our success. The ESPP will become active in 2024. There are 1,396,252 shares of Common Stock reserved for issuance under the ESPP. The number of shares of Common Stock reserved for issuance under the ESPP will automatically increase on January 1 of each year for a period of up to ten years, beginning on January 1, 2024, and continuing through and including January 1, 2033, by an amount equal to the lesser of (a) two percent (2%) of the total number of shares of the Fully Diluted Common Stock determined on December 31 of the preceding year, and (b) 200% of the Initial Share Reserve.

(16) Net Loss Per Share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. During periods where we might earn net income, we would allocate to participating securities a proportional share of net income determined by dividing total weighted-average participating securities by the sum of the total weighted-average common shares and participating securities (the “two-class method”). Our preferred stock, if any, participates in any dividends declared by us and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods where we incurred net losses, we allocate no loss to participating securities because they have no contractual obligation to share in our losses. We computed diluted loss per common share after giving consideration to the dilutive effect of stock options and warrants that are outstanding during the period, except where such nonparticipating securities would be antidilutive. Because we have reported net losses for the years ended December 31, 2023 and 2022, diluted net loss per common share is the same as basic net loss per common share for those periods.

The following potentially dilutive securities (in common stock equivalent shares) have been excluded from the computation of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported:

	December 31,	
	2023	2022
Preferred stock	4,015,002	12,330,395
Preferred stock warrants	—	2,878,519
Public and private warrants	14,215,112	—
Options to purchase common stock	3,666,234	1,671,076
	21,896,348	16,879,990

As described in Note *(14) Convertible Preferred Stock*, the triggering of the anti-dilution feature resulting from the B-2 Preferred Stock Financing decreased the conversion prices applicable to all outstanding shares for previously issued preferred stock. As a result, a deemed dividend to the preferred stockholders of $2,981 was recorded as an increase in the net loss attributable to common stockholders reflected in our consolidated statement of operations for the year ended December 31, 2023. This deemed dividend increased the net loss per common share by $0.32 for the year ended December 31, 2023.

(17) Leases

We have four property leases in effect as of December 31, 2023, which we account for as operating leases:

- A lease for our principal administrative and production facility at 6272 West 91st Avenue, Westminster, Colorado, which expires on December 31, 2026. This lease includes two options to extend the lease by five years each at the end of the current term.
- A lease for office space at 2275 Half Day Road, Bannockburn, Illinois, which expires in November 2024. This lease includes an option to extend the lease by three years at the end of the current term.
- A lease for office space at 1000 Chapel View Blvd, Cranston, Rhode Island, which expires in October 2024. This lease includes an option to extend the lease by two years at the end of the current term.
- A lease for laboratory and research space at 1 Hoppin Street, Providence, Rhode Island, which expires on February 1, 2024.

We also have four finance leases, three for copier equipment in our Westminster, Bannockburn and Cranston facilities, and one for laboratory equipment in our research space in Providence.

The components of right-of-use assets, short-term lease liabilities and long-term lease liabilities as of December 31, 2023, is as follows:

	Operating Leases	Finance Leases	
Right-of-use assets	$ 1,179	$ 233	(1)
Short-term lease liabilities	$ 275	$ 76	
Long-term lease liabilities	$ 1,156	$ 88	

(1) Net of accumulated depreciation, included in fixed assets

The components of lease expense for the year ended December 31, 2023 and 2022, were as follows:

	December 31,	
	2023	2022
Operating lease expense	$ 473	$ 443
Finance lease expense:		
Amortization of ROU assets	13	16
Interest on lease liabilities	4	4
Total finance lease expense	16	20
Total lease expense	$ 489	$ 463

Maturities of lease liabilities under noncancellable leases as of December 31, 2023, are as follows:

	Operating Leases	Finance Leases
2024	$ 380	$ 87
2025	205	77
2026	213	9
2027	219	7
2028	226	—
Thereafter	657	—
Total undiscounted lease payments	1,900	180
Less imputed interest	(470)	(16)
Total lease liabilities	$ 1,431	$ 164

In October 2022, we recorded $38 in fixed assets for a finance lease for a copier in our Westminster facility, and $6 and $32 in current liabilities and long-term liabilities, respectively, for the related lease liabilities.

In December 2022, we recorded $310 in fixed assets for a finance lease for analytical equipment in our laboratory facility in Providence, and $178 and $132 in current liabilities and long-term liabilities, respectively, for the related lease liabilities.

As of December 31, 2023, the weighted average life of our operating and finance leases is eight and three years, respectively. The weighted average discount rate for both operating and finance leases is 8.1%, which is based on interest rates we paid for our most recent term loan and convertible notes.

(18) Commitments And Contingencies

401(k) Plan

The Company maintains a salary reduction savings plan under Section 401(k) of the Internal Revenue Code, which we administer for participating employees' contributions. All full-time employees are covered under the plan after meeting minimum service requirements. We paid matching contributions of $580 and $431 to the plan for the years ended December 31, 2023 and 2022, respectively. Our contributions were based on compensation at the rate of 3%, 3.5%, and 4% for an employee's contribution of up to 3%, between 3% and 4%, and between 4% and 5%, respectively, with the match-eligible contribution being limited to 4% of the employee's eligible compensation.

Legal Matters

From time to time, we may have certain contingent liabilities, including litigation, which arise in the ordinary course of its business activities. We accrue contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. In the opinion of management, there are no pending claims for which the outcome is expected to result in a material adverse effect on our consolidated financial position, results of operations, or cash flows.

Pursuant to the Amended and Restated Registration Rights Agreement, subject to certain requirements and customary conditions, the Company also grants piggyback registration rights and demand registration rights to the parties thereto, will pay certain expenses related to such registrations and will indemnify the parties thereto against certain liabilities related to such registrations. The Company's registration obligations under the Amended and Restated Registration Rights Agreement will terminate with respect to any party thereto on the date that such party no longer holds any Registrable Securities (as defined in the Amended and Restated Registration Rights Agreement). The Amended and Restated Registration Rights Agreement does not contain liquidated damages or other cash settlement provisions resulting from delays in registering the Company's securities.

We are not a party to any legal proceedings and we are not aware of any claims or actions pending or threatened against us. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosures

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosure. As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), of the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this report to provide the reasonable assurance, as discussed above and as a result of the material weakness that existed in our internal control over financial reporting identified previously, which continues to exist as of December 31, 2023, as discussed below.

Management's Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to our determination that, due to the relatively recent closing of the Business Combination, it is impracticable to perform a comprehensive assessment that includes the identification of risks, documentation of processes, rationalization of controls, creation of a test plan that includes samples from several months and quarters, and time to assess the results. In making this determination, we have considered the timing and effects of the Business Combination, which closed in August 2023 and after which substantially all of the business of the company was that of TriSalus. We further considered the integration between the two businesses, which involved substantial changes to the board. Accordingly, we are excluding management's report on internal control over financial reporting pursuant to Section 215.02 of the SEC Division of Corporation Finance's Regulation S-K Compliance & Disclosure Interpretations. We will file our first assessment regarding internal control in the Annual Report for the year ending December 31, 2024.

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 our consolidated 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 and December 31, 2023, management identified material weaknesses in our internal control over financial reporting with respect to:

(i) 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:
   1. financial reporting,
   2. accounting for costs associated with the SEPA,
   3. patent costs, and
   4. certain R&D accruals;

(ii) inadequate controls over the accounting and financial reporting for the Business Combination;

(iii) inadequate internal controls over the valuation of the warrant and tranche rights and obligations and liabilities resulting from the series B-2 preferred stock financing; and

(iv) inadequate design and implementation of controls over the conversion of data from our legacy equity management system to our new system, and over the assumptions used to calculate fair value of certain equity awards to support the recognition of stock compensation expense.

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, 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 effective. Our management will continue to monitor the effectiveness of the remediation plan and will make the changes it determines to be appropriate.

Changes in Internal Control over Financial Reporting

No change to our internal control over financial reporting occurred during the last fiscal quarter ended December 31, 2023, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections

None

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

The following table sets forth the name, age and position of each of the directors and executive officers of the Company.

Name	Age*	Position
Executive Officers		
Mary Szela	61	Chief Executive Officer, President; Director
Sean Murphy	72	Chief Financial Officer; Director
Dr. Steven Katz	49	Chief Medical Officer
Bryan Cox	62	Chief Scientific and Manufacturing Officer
Jennifer Stevens	63	Chief Regulatory Officer
Richard Marshak	65	Senior Vice President, Corporate Development & Strategy
Jodi Devlin	62	President, Commercial Operations
Non-Employee Directors		
Mats Wahlström[(3)]	69	Chairman of the Board
Andrew von Eschenbach[(3)(4)]	82	Director
George Kelly Martin[(1)(2)]	65	Director
David J. Matlin[(1)(3)]	63	Director
Arjun Desai[(2)(4)]	43	Director
Kerry Hicks[(1)(3)]	64	Director
Anil Singhal[(2)(4)]	72	Director

* As of April 3, 2024

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

(4) Member of the science and technology committee.

Executive Officers

Mary Szela. Ms. Szela is our Chief Executive Officer and President and a member of our Board and, prior to the Business Combination, had served as the Chief Executive Officer and a director of Legacy TriSalus since January 2018. Prior to joining Legacy TriSalus, Ms. Szela was CEO of Novelion Therapeutics, a biopharmaceutical company, from January 2016 through November 2017 where she led the company through regulatory compliance and legal difficulties to a successful merger and expansion. Prior to that, Ms. Szela served as CEO of Melinta Therapeutics, a biopharmaceutical company, from August 2013 through August 2015. From 1987 to 2012, Ms. Szela held progressive leadership roles with Abbott Laboratories, a multinational medical devices and health care company, including Vice President, U.S. Commercial Operations, President of U.S. Pharmaceuticals, and culminating as Senior Vice President of Global Strategic Market and Services. In addition to her executive experience, Ms. Szela currently sits on the boards of directors of Kura Oncology, a public company, Omega Therapeutics, a public company, and Sail Biomedicines, a private company. She also previously sat on the board of directors of Prometheus Biosciences from 2021 until 2023, Alimera Sciences from 2018 until 2021, Coherus Biosciences from 2014 until 2021, and Macrolide Pharmaceuticals from 2018 until 2019. Ms. Szela received both her B.S. in Nursing and her MBA from the University of Illinois at Chicago.

Ms. Szela is qualified to serve on the Board based on her substantial business, leadership and management experience in the biotechnology sector.

Sean Murphy. Mr. Murphy is our Chief Financial Officer and a member of our Board and, prior to the Business Combination, had served as the Chief Financial Officer of Legacy TriSalus since June 2022. He was also a director of

Legacy TriSalus since August 2020 and served as the chairman of its audit committee from August 2020 through June 2022. Prior to joining Legacy TriSalus, Mr. Murphy was Executive Vice President at Malin PLC, a publicly listed company investing in life sciences companies, from April 2015 through June 2021. Mr. Murphy was a senior advisor at Evercore, an independent investment banking advisory firm, from August 2011 to June 2018. Prior to that, he held numerous positions over a 30-year career with Abbott Laboratories, a multinational medical devices and health care company, culminating as Vice President of Business Development and Licensing. Mr. Murphy has had extensive Board experience as well. He currently serves on the boards of directors of Xenex, Disinfection Services, a private company, and Prenosis, Inc. a private biotech company. In addition, Mr. Murphy previously served on the board of directors of Immucor and public company board of directors of Radius Health, where he sat on the audit committee, and Poseida Therapeutics, where he was a member of the compensation and governance committee. Mr. Murphy received his BBA in Finance and Accounting from Western Illinois University and his M.S. in Finance from University of Illinois. He is a Certified Public Accountant, State of Illinois.

We believe Mr. Murphy is qualified to serve on the Board based on his corporate finance experience and his previous experience on boards of directors.

Steven Katz. Dr. Steven Katz is our Chief Medical Officer and, prior to the Business Combination, had served as Chief Medical Officer of Legacy TriSalus since September 2020 and is Chairman of the Scientific Advisory Board, which includes leadership of our Translational Immunotherapy Laboratory. Previously, Dr. Katz served as an advisor to Legacy TriSalus from June 2014 to August 2020, and Chief Medical Advisor from January 2019 to August 2020. Since 2016, Dr. Katz also has served as a consultant for several companies developing cell therapies for solid tumors. In Dr. Katz's academic work, he is an Associate Professor of Surgery at Brown University and has been with Brown Surgical Associates in a part-time role since February 2022. From 2009 to 2021, Dr. Katz led the creation of a solid tumor immunotherapy program at CharterCare Health Partners, serving as the Director of the Office of Therapeutic Development and Complex Surgical Oncology Program Director during that time. While at CharterCare, he led a translational immunotherapy laboratory focused on immunosuppression and immunotherapy development, while serving as principal investigator for multiple immunotherapy trials which integrated novel delivery approaches. Dr. Katz received his B.A. in Government & Biochemistry from Wesleyan University and his M.D. from New York University, followed by completion of a general surgery residency at New York University. He completed Immunology Research and Surgical Oncology fellowships at the Memorial Sloan-Kettering Cancer Center.

Bryan Cox. Dr. Bryan Cox is our Chief Scientific and Manufacturing Officer and, prior to the Business Combination, had served as Chief Scientific and Manufacturing Officer of Legacy TriSalus since June 2020. Dr. Cox has also served as the Chief Executive Officer of Nephraegis Therapeutics, a biotechnology company, since November 2018. Prior to joining Legacy TriSalus, Dr. Cox served as a consultant for CoPharm Global Consulting, a boutique consultancy focuses on providing guidance for biotechnology companies, from May 2013 to June 2020. Prior to that, Dr. Cox served as the Director of Integrative Pharmacology for Abbott Laboratories, a multinational medical devices and health care company, from 1996 to 2013. Dr. Cox has served on the board of directors for Nephraegis Therapeutics since November 2018. Dr. Cox received his B.S. in Biological Sciences from North Carolina State and his Ph.D. in Pharmacology from the University of Iowa.

Jennifer Stevens. Jennifer Stevens is our Chief Regulatory Officer and also serves as our Head of Quality for Devices and Drugs. Prior to the Business Combination, she had served as Chief Regulatory Officer of Legacy TriSalus since March 2022. Previously, Ms. Stevens served as Legacy TriSalus' Senior Vice President of Regulatory Affairs from March 2021 to March 2022. Prior to joining of Legacy TriSalus, Ms. Stevens held several progressive leadership roles with EMD Serono Inc., a division of Merck KGaA focused on biopharmaceuticals, from January 2013 through March 2021, including as Acting Head of US Oncology Hub — Regulatory Affairs. Previously, Ms. Stevens was Regulatory Counsel for the U.S. Food and Drug Administration from July 2008 to December 2012. Earlier in her career, Ms. Stevens was a practicing attorney at several global law firms, achieving partnership at Kirkland & Ellis LLP. Ms. Stevens received her B.A. in Political Sciences from the University of Illinois and her J.D. from George Washington University.

Richard Marshak, VMD. Dr. Richard Marshak is our Senior Vice President, Corporate Development, Strategy and Marketing and, prior to the Business Combination, had served as Senior Vice President, Corporate Development and Strategy of Legacy TriSalus since June 2022. Prior to joining Legacy TriSalus, Dr. Marshak was Managing Principal of LF Consulting, a consulting firm for biotechnology companies, from June 2013 to June 2022. Dr. Marshak also co- founded Nephraegis Therapeutics, a biotechnology company, in September 2018 and serves as its Chief Business Officer as well as board member. Previously, Dr. Marshak served as the Chief Executive Officer of Mount Tam Biotechnologies from May 2016 to October 2019. Prior to these roles, Dr. Marshak held several progressive leadership roles in Abbott Laboratories, a multinational medical devices and health care company, from 1999 to 2013, culminating as the Head of Global Strategic

Pricing. Dr. Marshak has served on the board of directors of Nephraegis Therapeutics since August 2018 and Torcept Therapeutics since 2019. He previously served on the board of Mount Tam Biotechnologies from May 2016 to October 2019. Dr. Marshak received his B.A. in Psychology and VMD in Veterinary Medicine from the University of Pennsylvania, and his MBA from the University of Chicago

Jodi Devlin. Jodi Devlin is our President, Commercial Operations and joined our team in August 2023 as President, Therapeutics. She has more than 30 years in the biotech and pharmaceutical industry. Previously, Ms. Devlin served as CEO of AltaThera Pharmaceuticals, a specialized, hospital pharmaceutical company from May 2018 to December 2022. Ms. Devlin also spent 21 years at Abbott where she held leadership roles in pipeline planning, global launches, and management of numerous commercial organizations. Ms. Devlin also serves as Chairman of the board of directors of Fitabeo Therapeutics, a private company. Before her time in the biotech industry, she worked as a hospital nurse in New York and Missouri. Ms. Devlin received her B.S. in Nursing from University of Oklahoma and her MBA from Washington University, Olin School of Business.

Non-Employee Directors

The Company Board is composed of nine directors. In addition to Ms. Szela and Mr. Murphy, the Combined Company's directors are:

Mats Wahlström. Mats Wahlström is the Chairman of our Board and, prior to the Business Combination, had served as chairman of the board of directors of Legacy TriSalus since January 2017. Additionally, he serves as a member of our Nominating and Corporate Governance Committee. He has also served as the Co-Chairman of HW Investment Partners, LLC since July 2016, a company focused on investments in the healthcare industry, and Chairman of Leonard Capital, LLC since July 2010, a company focused on investing in the healthcare industry. In addition, Mr. Wahlström has served as the Chairman of the board of directors of Triomed AB since October 2016, as the lead independent director of Coherus Biosciences, Inc., a public biotech company, since January 2012 and as Chairman of Caduceus Medical Holdings, Inc. since August 2010. Mr. Wahlström has served on the boards of directors of Alteco Medical AB since October 2012, Circuit Clinical Solutions, Inc. since July 2016. He served as a director of Health Grades, Inc. a Nasdaq-listed healthcare ratings company, from March 2009 through its sale to a private equity firm in October 2010, as a director of Getinge AB, a Swedish Stock Exchange-listed medical device company, from March 2012 to March 2017, and as a director of Zynex Inc. an over- the-counter medical device manufacturer, from October 2010 through January 2014. From January 2004 to December 2009, Mr. Wahlström served as co-CEO of Fresenius Medical Care North America and a member of the management board at Fresenius Medical Care AG & Co. KGaA. From November 2002 to December 2009, Mr. Wahlström served as President and Chief Executive Officer of Fresenius Medical Services. Prior to that, Mr. Wahlström held various positions at Gambro AB from January 1983 to February 2000, including President of Gambro North America and Chief Executive Officer of Gambro Healthcare Inc. as well as Chief Financial Officer of the Gambro Group. Mr. Wahlström has a B.S. degree in Economics and Business Administration from the University of Lund, Sweden

We believe Mr. Wahlström is qualified to serve on the Board based on his extensive management and director experience in the life sciences and healthcare sectors.

Andrew von Eschenbach. Dr. von Eschenbach has been a member of our Board since August 2023. He serves on our Nominating and Corporate Governance Committee, as well as the chair of our Science and Technology Committee. Dr. von Eschenbach is the President and Founder at Samaritan Health Initiatives, a health care policy consultancy, a role which he has held since 2010. He is also an Adjunct Professor at the University of Texas M.D. Anderson Cancer Center ("MDACC"), a position he has held since 2009. Dr. von Eschenbach holds advisory roles as the Senior Advisor at Target RWE, a biotechnology company, since September 2020, and Medical Advisor at Datavant, a health information technology company, since January 2020. From October 2017 to June 2019, Dr. von Eschenbach served as Chief Medical Advisor at Malin Corporation PLC, a life sciences company. From 2009 to 2021, he worked on the International Advisory Council of Chugai Pharmaceutical Co., Ltd., a Japanese drug manufacturer. From 2012 to 2016, Dr. von Eschenbach was a Senior Fellow and Director of the FDA Project at the Manhattan Institute, a think tank. From 2009 to 2018, he served on the GE Healthymagination Advisory Board, a GE Healthcare initiative to provide better healthcare for more people around the world. From 2012 to 2016, he served as a global council member of Eli Lilly and Company, PACE, a global collaboration that encourages public policies and healthcare decisions that speed the development of new medicines. From September 2005 to January 2009, Dr. von Eschenbach served as Commissioner of the FDA. Previously, Dr. von Eschenbach served as Director of the National Cancer Institute at the National Institutes of Health from January 2002 to June 2006. As a researcher, clinician and administrator, Dr. von Eschenbach served in a variety of roles at MDACC, including as Director, Genitourinary Cancer Center, Vice President for Academic Affairs, and Executive Vice President and Chief Academic Officer. Dr. von Eschenbach currently serves on the board of directors of Bausch and Lomb Corporation and WaveBreak

Therapeutics. In recent years, Dr. von Eschenbach also previously served on the board of directors of Bausch Health Companies, Radius Health, Inc., Banyan Biomarkers, COTA, Histosonics, Innocrin Pharmaceuticals, and Viamet Pharmaceuticals.

Dr. von Eschenbach is qualified to serve on the Board based on his extensive experience in the pharmaceutical and healthcare industries as well as his service as Commissioner of the FDA.

George Kelly Martin. Mr. Martin has been a member of our Board since August 2023, where he serves as the chair of our Compensation Committee and a member of our Audit Committee. Mr. Martin currently serves as Chairman of Transition Bio, Inc., a molecular condensates discovery company, a role which he has held since 2020, and as Vice Chairman of Ride Therapeutics, Inc., a molecular logistics company, a role which he has held since 2022. He also serves as Chairman of WaveBreak (formerly Wren Therapeutics, Inc.), a company that utilizes physical science and kinetics to create therapeutic solutions for protein misfolding diseases, since 2018. Mr. Martin previously served as a Director and Chief Executive Officer of Radius Health, Inc., a bone and women's health company, from 2020 to 2022. Prior to that, Mr. Martin served as Director and Chief Executive Officer of Novan, Inc., a development-stage dermatology company, from 2018 to 2020. Prior to joining Novan, Inc., Mr. Martin was the Founder and Chief Executive Officer of Malin Corporation PLC, a life sciences investment company, from 2015 to 2017. Mr. Martin also served as Chief Executive Officer of Elan Corporation plc, an Ireland-based neurodegeneration research and development company, from 2003 to 2013. Mr. Martin's business career started in finance and capital markets, having spent 21 years at Merrill Lynch & Co. Inc. At the time of his departure from Merrill Lynch in 2002, he was a member of the company's Executive Operating Committee and his tenure included leadership oversight of four global divisions (debt markets, international equities, Information Technology, and International Private Banking). While at Merrill Lynch, Mr. Martin served multi- year assignments in both Tokyo and London. He previously served on the boards of directors of Questcor Pharmaceuticals, Immunocore Holdings, plc, and Kymab Ltd. Mr. Martin received his B.A. in Politics from Princeton University.

We believe Mr. Martin is qualified to serve on the Board based on his extensive executive experience in the biopharmaceutical industry.

David J. Matlin. Mr. Matlin has been a member of our Board since August 2023, where he currently serves as the chair of our Audit Committee and a member of our Nominating and Corporate Governance Committee. Mr. Matlin previously served as the Chief Financial Officer of MTAC, where he was also a director since September 2020. Mr. Matlin was also the co-founder and Chief Executive Officer of MatlinPatterson Global Advisers LLC ("MatlinPatterson"), a distressed securities investment manager, which he co-founded in July 2002, through 2021. Mr. Matlin was also Chief Executive Officer of MatlinPatterson Asset Management L.P. and its operating joint venture affiliates that managed non-distressed credit strategies, from 2015 to 2018. In 2017, MatlinPatterson began winding down its investment activities and its various funds began to return the investment proceeds to their respective investors. In conjunction with this wind-down process and to protect their investors from foreign litigation, two of the MatlinPatterson funds (Matlin Global Opportunities Partners II L.P. and Matlin Global Opportunities Partners (Cayman) II L.P.) that had been unable to settle foreign litigation, filed, along with MatlinPatterson, voluntary petitions for relief under Chapter 11 of the U.S. Bankruptcy Code in July 2021. Prior to forming MatlinPatterson, Mr. Matlin was a Managing Director at Credit Suisse, and headed their Global Distressed Securities Group upon its inception in 1994. Mr. Matlin was also a Managing Director and a founding partner of Merrion Group, L.P., an investment advisory firm, from 1988 to 1994. He began his career as a securities analyst at Halcyon Investments from 1986 to 1988. Until its November 2022 sale, Mr. Matlin also served on the board of directors of US Well Services Inc. (Nasdaq: USWS) (formerly Matlin & Partners Acquisition Corporation) and was Chief Executive Officer and Chairman of the company prior to its business combination with US Well Services LLC. He also serves on the boards of directors of Dermasensor, Inc. and Pristine Surgical LLC, which are medical device manufacturers. Mr. Matlin has served on the board of directors of Clene, Inc. (Nasdaq: CLNN), a biopharmaceutical manufacturer, since December 2020, and has served as the Chairman of its Board of Directors since May 2021. Since 2021 he also serves on the Board of Directors of Empyrean Neuroscience, a private biotechnology company. Previously, he served on the board of directors of Flagstar Bank FSB, a federally charted savings bank, and Flagstar Bancorp, Inc. (NYSE: FBC), a savings and loan holding company from 2009 to May 2021, CalAtlantic Group, Inc. (NYSE: CAA), a U.S. homebuilder, from 2009 to 2018, Global Aviation Holdings, Inc., an air charter company, from 2006 to 2012, and Huntsman Corporation (NYSE: HUN), a U.S. chemicals manufacturer, between 2005 and 2007 and Orthosensor, Inc. until the sale of the company to Stryker Corporation in December 2020. Mr. Matlin holds a JD degree from the Law School of the University of California at Los Angeles and a BS in Economics from the Wharton School of the University of Pennsylvania.

We believe Mr. Matlin is qualified to serve on the Board based on his significant public company board experience.

Arjun Desai. Dr. Desai has been a member of our Board since August 2023, where he also serves on our compensation committee. Dr. Desai has served as the Chief Strategic Innovation Officer at Insightec, a medical device

company, from 2018 to 2023. From 2016 to 2018, he served as the Global Vice President and Chief Operating Officer of Johnson & Johnson Innovation, a company that collaborates with innovators to incorporate science into healthcare solutions. Additionally, Dr. Desai is the chairman of the board of directors of Obvius Robotics, Inc., a private medtech company. He also currently serves on the board of directors of Tympa Health Technologies Ltd, a medical device company, Pathology Watch, a private laboratory company, Empyrean Neuroscience, a private company, Openwater Software, Inc., a private SaaS company, and Wespe, a private medical device company. Dr. Desai received his B.S. degree in Economics from the University of Oklahoma and his M.D. from the University of Miami. He also completed his residency and advanced training in Anesthesiology at Stanford University.

We believe Dr. Desai is qualified to serve on the Board based on his extensive experience in the biotech industry.

Anil Singhal. Dr. Singhal has been a member of our Board since August 2023 and serves as a member of our Compensation Committee. Dr. Singhal has served as the President and Chief Executive Officer of Trishula Therapeutics, a biotechnology company, since January 2021. From May 2019 to September 2020, he served as President and Chief Executive Officer of Adicet Bio, a publicly-traded biotechnology company, and from September 2020 to February 2021, he served as an advisor to Adicet. Dr. Singhal also served as Vice President, Early Oncology Development, of AbbVie Inc., a publicly-traded pharmaceutical company, from January 2013 to March 2018. Dr. Singhal is a member of the American Association of Cancer Research, which he joined in 2005, and a member of the American Society of Clinical Oncology, which he joined in 2007. Dr. Singhal has been a member of the board of directors of Legacy TriSalus since 2018. Dr. Singhal received his B.Sc Honours degree in Biochemistry from Panjab University in India, his MBA in Business Administration from the University of Washington and his PhD in Biochemistry from Rutgers University.

We believe Dr. Singhal is qualified to serve on the Board based on his extensive experience cancer research and development and his extensive experience in the biotechnology and pharmaceutical industries.

Kerry Hicks. Mr. Hicks has been a member of our Board since August 2023, where he serves on our Audit Committee, as well as the chair of our Nominating and Corporate Governance Committee. Mr. Hicks serves as Partner, Chief Executive Officer, and President of KMG Capital Partners LLC, a boutique healthcare venture capital company, since April 2012. He also currently serves as Executive Chairman of Circuit Clinical, an integrated research organization, and Co-Chairman and Partner of Breakout Investment Partners, LLC, a venture capital firm that focuses on investing in healthcare companies, both positions which he has held since 2016. He also currently serves on the board of directors of Caduceus Medical Holdings, Inc. Prior to joining KMG Capital Partners, Mr. Hicks served as Chief Executive Officer of Healthgrades, a healthcare information and services company, from 2000 to 2012, Chairman of Healthgrades from 2000 to 2010 and 2012 to 2013, and as President, Chief Executive Officer and Chairman of Specialty Care Network, a predecessor company to Healthgrades, from 1995 to 2000. Mr. Hicks has been a member of the board of directors of Legacy TriSalus since April 2021. Mr. Hicks received his B.S. degree in Management and his MBA in Business Administration from Colorado State University.

We believe Mr. Hicks is qualified to serve on the Board based on his extensive experience in the healthcare industry and knowledge regarding TriSalus and its products and operations.

Family Relationships

There are no family relationships among any of the Company’s directors and executive officers.

Board Composition

The Company’s business and affairs is organized under the direction of the Board. The Board consists of nine members. Mats Wahlström serves as Chairman of the Board. The primary responsibilities of the Board are to provide oversight, strategic guidance, counseling and direction to the Company’s management. The Board will meet on a regular basis and additionally as required.

In accordance with the terms of the Company's Second Amended and Restated Certificate of Incorporation (the "Charter"), the Board is divided into three classes, Class I, Class II and Class III, with only one class of directors being elected in each year and each class serving a three-year term. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors. The Board is divided into the following classes:

- Class I, which consists of Anil Singhal, Kerry Hicks, and Sean Murphy, whose terms will expire at the Company’s annual meeting of stockholders to be held in 2024;

- Class II, which consists of David Matlin, Mats Wahlström, and Andrew von Eschenbach, whose terms will expire at the Company's annual meeting of stockholders to be held in 2025; and
- Class III, which consists of Mary Szela, Arjun "JJ" Desai, and George Kelly Martin, whose terms will expire at the Company's annual meeting of stockholders to be held in 2026.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election and until their successors are duly elected and qualified, or their earlier resignation, removal, retirement or death. This classification of the Board may have the effect of delaying or preventing changes in the Company's control or management. The Company's directors may be removed for cause by the affirmative vote of the holders of at least 66 ⅔% of the Company's voting stock.

Role of the Board in Risk Oversight/Risk Committee

One of the key functions of the Board will be informed oversight of the Company's risk management process. The Board does not anticipate having a standing risk management committee, but rather anticipates administering this oversight function directly through the Board as a whole, as well as through various standing committees of the Board that address risks inherent in their respective areas of oversight. In particular, the Board will be responsible for monitoring and assessing strategic risk exposure and the Company's audit committee will have the responsibility to consider and discuss the Company's major financial risk exposures and the steps its management will take to monitor and control such exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee will also monitor compliance with legal and regulatory requirements. The Company's compensation committee will assess and monitor whether the Company's compensation plans, policies and programs comply with applicable legal and regulatory requirements.

Board Committees

The Board has established an audit committee, a compensation committee, a nominating and corporate governance committee, and science and technology committee. The Board has adopted a charter for each of these committees, which comply with the applicable requirements of current Nasdaq rules, as applicable. In addition, from time to time, special committees may be established under the direction of the Board when the board deems it necessary or advisable to address specific issues. The Company intends to comply with future requirements to the extent they will be applicable to the Company. Copies of the charters for each committee are available on the investor relations portion of the Company's website.

Audit Committee

The Company's audit committee consists of David Matlin, Kerry Hicks, and George Kelly Martin. The Board has determined that each of the members of the audit committee satisfy the independence requirements of Nasdaq listing rules and Rule 10A-3 under the Exchange Act. Each member of the audit committee can read and understand fundamental financial statements in accordance with applicable audit committee requirements. In arriving at this determination, the Board examined each audit committee member's scope of experience and the nature of their prior and/or current employment.

Mr. Matlin serves as the chair of the audit committee. The Board has determined that Mr. Matlin qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of Nasdaq listing rules. In making this determination, the Board considered Mr. Matlin's formal education and previous experience in financial roles. Both the Company's independent registered public accounting firm and management periodically meet privately with the Company's audit committee.

The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of the Company's independent auditors and determining whether to retain the Company's existing independent auditors or engage new independent auditors;
- reviewing the Company's financial reporting processes and disclosure controls;
- reviewing and approving the engagement of the Company's independent auditors to perform audit services and any permissible non-audit services;
- reviewing the adequacy and effectiveness of the Company's internal control policies and procedures, including reviewing, with the independent auditors, management's plans with respect to the responsibilities, budget, staffing

and effectiveness of the Company's internal audit function, and reviewing and approving the Company's head of internal audit (if established);

- reviewing with the independent auditors the annual audit plan, including the scope of audit activities and all critical accounting policies and practices to be used by the Company;
- obtaining and reviewing at least annually (if required by applicable stock exchange listing requirements) or as otherwise determined, a report by the Company's independent auditors describing the independent auditors' internal quality-control procedures and any material issues raised by the most recent internal quality-control review, peer review, or any inquiry or investigation by governmental or professional authorities;
- monitoring the rotation of partners of the Company's independent auditors on the Company's engagement team as required by law;
- at least annually, reviewing relationships that may reasonably be thought to bear on the independence of the committee, receiving and reviewing a letter from the independent auditor affirming their independence, discussing the potential effects of any such relationship, and assessing and otherwise taking the appropriate action to oversee the independence of the Company's independent auditor;
- reviewing the Company's annual and quarterly financial statements and reports, including the disclosures contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors," and discussing the statements and reports with the Company's independent auditors and management;
- reviewing with the Company's independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of the Company's financial controls and critical accounting policies;
- reviewing with management and the Company's independent auditors any earnings announcements, disclosures and other financial information and guidance;
- establishing procedures for the review, retention and investigation of complaints received by the Company regarding financial controls, accounting, auditing or other matters;
- preparing the report that the SEC requires in the Company's annual proxy statement;
- reviewing and providing oversight of any related party transactions in accordance with the Company's related party transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including the Company's code of business conduct and ethics;
- reviewing and discussing with management risks related to data privacy, technology and information security, including cybersecurity, back-up of information systems, and policies and procedures that the Company has in place to monitor and control such exposures;
- reviewing the Company's major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;
- reviewing any analyses prepared by management or the independent auditors setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of alternative GAAP methods on the financial statements;
- reviewing with management and the independent auditors any disagreement between them regarding financial reporting, accounting practices or policies, or other matters, that individually or in the aggregate could be significant to the Company's financial statements or the independent auditor's report, reviewing management's response, and resolving any other conflicts or disagreements regarding financial reporting;
- considering and reviewing with management, the independent auditors, and outside advisors or accountants any correspondence with regulators or governmental agencies and any published reports that raise material issues regarding the Company's financial statements or accounting policies;
- reviewing with management legal and regulatory compliance and any material current, pending or threatened legal matters; and
- reviewing and evaluating on an annual basis the performance of the audit committee and the audit committee charter.

The composition and function of the audit committee complies with all applicable requirements of the Sarbanes-Oxley Act, SEC rules and regulations and Nasdaq listing rules.

Compensation Committee

The Company's compensation committee consists of George Kelly Martin, Arjun "JJ" Desai, and Anil Singhal. Mr. Martin serves as the chair of the compensation committee. The Board has determined that each of the members of the compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act and satisfy the independence requirements of Nasdaq. The functions of the committee include, among other things:

- reviewing and approving the corporate objectives that pertain to the Company's overall compensation strategy and policies;
- reviewing and approving annually the compensation and other terms of employment of the Company's executive officers and other members of senior management, in the compensation committee's discretion;
- reviewing and approving the type and amount of compensation to be paid or awarded to the Company's non-employee board members;
- administering the Company's equity incentive plans and other benefit plans;
- reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections, indemnification agreements and any other material arrangements with the Company's executive officers and other members of senior management, in the compensation committee's discretion;
- reviewing and establishing appropriate insurance coverage for the Company's directors and officers;
- reviewing and discussing with management the Company's disclosures under the caption "Compensation Discussion and Analysis" in the Company's periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- preparing an annual report on executive compensation that the SEC requires in the Company's annual proxy statement;
- reviewing the Company's practices and policies for employee compensation as related to risk management and risk-taking incentives to determine if such compensation policies and practices are reasonably likely to have a material adverse effect on the Company;
- establishing and monitoring stock ownership guidelines for directors and executive officers of the Company, if and as determined to be necessary or appropriate;
- providing recommendations to the Board on compensation-related proposals to be considered at the Company's annual meeting of stockholders;
- reviewing and discussing with management, if appropriate, the independence of and any conflicts of interest raised by the work of a compensation consultant, outside legal counsel, or advisor hired by the compensation committee or management and how such conflict is being addressed for disclosure in the appropriate filing or report;
- annually reviewing and discussing with management the Company's human capital management practices with respect to its employees and, where applicable, independent contractors;
- approving and modifying, as needed, clawback policies allowing the Company to recoup improper compensation paid to employees; and
- reviewing and evaluating on an annual basis the performance of the compensation committee and recommending such changes as deemed necessary with the Board.

The composition and function of the compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act, SEC rules and regulations and Nasdaq listing rules.

Nominating and Corporate Governance Committee

The Company's nominating and corporate governance committee consists of Kerry Hicks, Mats Wahlström, Andrew von Eschenbach, and David Matlin. Mr. Hicks serves as the chair of the nominating and corporate governance committee. The Board has determined that each of the members of the Company's nominating and corporate governance committee satisfies the independence requirements of Nasdaq. The functions of this committee include, among other things:

- determining the qualifications, qualities, skills and other expertise required to be a director of the Company, and developing and recommending to the Board for approval criteria to be considered in selecting nominees for director;

- identifying, reviewing and making recommendations of candidates to serve on the Board, including incumbent directors for reelection;
- evaluating the performance of the Board, committees of the Board and individual directors and determining whether continued service on the Board is appropriate;
- periodically reviewing and making recommendations to the Board regarding the Company's process for stockholder communications with the Board, and making such recommendations to the Board with respect thereto;
- evaluating nominations by stockholders of candidates for election to the Board;
- evaluating the structure and organization of the Board and its committees and making recommendations to the Board for approvals;
- considering possible conflicts of interest of officers and directors as set forth in the Company's code of business conduct and ethics;
- reviewing and considering environmental, social responsibility and sustainability and governance matters as it determines appropriate and making recommendations to the Board regarding, or taking action with respect to, such matters;
- periodically reviewing the Company's corporate governance guidelines and code of business conduct and ethics and recommending to the Board any changes to such policies and principles;
- developing and periodically reviewing with the Company's Chief Executive Officer the plans for succession for the Company's Chief Executive Officer and other executive officers, as it sees fit, and making recommendations to the Board with respect to the selection of appropriate individuals to succeed to these positions;
- considering the Board's leadership structure, including the separation of the roles of chairperson of the Board and the Chief Executive Officer and/or the appointment of a lead independent director;
- periodically reviewing the processes and procedures used by the Company to provide information to the Board and its committees and the scope of such information and making recommendations to the Board and management for improvement as appropriate; and
- reviewing periodically the nominating and corporate governance committee charter and recommending any proposed changes to the Board, including undertaking an annual review of its own performance.

The composition and function of the nominating and corporate governance committee complies with all applicable requirements of the Sarbanes-Oxley Act, SEC rules and regulations and Nasdaq listing rules.

Science and Technology Committee

The Company's science and technology committee consists of Andrew Von Eschenbach, Anil Singhal and Arjun Desai. Mr. Von Eschenbach serves as the chair of the science and technology committee. The functions of the committee include, among other things:

- reviewing, evaluating and advising the Board and management on matters relating to the overall strategy, direction, and effectiveness of the Company's research and development strategy and related investments and on the Company's progress in achieving its long-term strategic research and development goals and objectives;
- reviewing the Company's planned or ongoing research activities and plans;
- evaluating and monitoring, on its own or in conjunction with external experts engaged by the committee, plans as well as individual project progress and performance of the Company's research and development pipeline;
- evaluating and advising the Board and management on the opportunities and risks associated with the products, programs and technologies in which the Company is, or is considering, investing its research and development efforts;
- providing the Board with strategic advice on emerging regulatory, clinical and scientific issues that are relevant to the Company and in alignment with the Company's strategy and on areas that are important to the success of the Company's R&D activities;
- assess and advise the Board, from time to time, on the committee's view of the overall quality and expertise of medical and scientific talent in the Company's R&D organization; and

- assisting the Board in understanding the Company's intellectual property position in connection with the foregoing and otherwise.

Compensation Committee Interlocks and Insider Participation

None of the members of the Company's compensation committee has ever been an executive officer or employee of the Company. None of the Company's executive officers currently serve, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers that will serve as a member of the Board or compensation committee.

Limitation on Liability and Indemnification of Directors and Officers

The Charter eliminates the liability of the Company's officer and directors for monetary damages to the fullest extent permitted by applicable law. The applicable law, the General Corporation Law of the State of Delaware ("DGCL") provides that officers and directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties, except for liability:

- for any transaction from which the director or officer derives an improper personal benefit;
- for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- for any unlawful payment of dividends or redemption of shares by directors; or
- for any breach of a director's or officer's duty of loyalty to the corporation or its stockholders.

If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of officers and directors, then the liability of the Company's officers and directors will be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

The Company Amended and Restated Bylaws (the "Company Bylaws") require the Company to indemnify and advance expenses to, to the fullest extent permitted by applicable law, its directors, officers and agents. The Company maintains a directors' and officers' insurance policy pursuant to which the Company's directors and officers are insured against liability for actions taken in their capacities as directors and officers. Finally, the Charter prohibits any retroactive changes to the rights or protections or increase the liability of any officer or director in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

In addition, the Company has entered into separate indemnification agreements with the Company's directors and executive officers. These agreements, among other things, require the Company to indemnify its directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of the Company's directors or executive officers or any other company or enterprise to which the person provides services at the Company's request.

We believe these provisions in the Charter and Company Bylaws are necessary to attract and retain qualified persons as directors and officers.

Code of Business Conduct and Ethics for Employees, Executive Officers and Directors

The Board has adopted a Code of Business Conduct and Ethics (the "Code of Conduct"), applicable to all of the Company's employees, executive officers and directors. The Code of Conduct is available on the Company's website under the "Governance Overview" section of the "Investors" tab at *www.trisaluslifesci.com*. The nominating and corporate governance committee of the Board will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. The Company expects that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on its website.

Item 11. Executive Compensation

As used in this section, "TriSalus" refers to Legacy TriSalus prior to the closing of the Business Combination and TriSalus after the closing of the Business Combination. Upon the closing of the Business Combination, the executive officers of Legacy TriSalus became executive officers of TriSalus.

Throughout this section, unless otherwise noted, "we," "us," "our," "the Company" and similar terms refer to TriSalus and its subsidiaries prior to the Closing, and to TriSalus and its subsidiaries after the Business Combination. Unless otherwise stated, references to share numbers and exercise prices are reflected after giving effect to the Business Combination. This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of the Business Combination may differ materially from the currently planned programs summarized in this discussion.

For the fiscal year ended December 31, 2023, TriSalus' named executive officers ("NEOs") were:

- Mary Szela, Chief Executive Officer and President;
- Sean Murphy, Chief Financial Officer; and
- Dr. Steven Katz, Chief Medical Officer.

As required by SEC rules, our NEOs also include the Christopher Dewey who was the former chief executive officer of MTAC until the closing of the Business Combination. Mr. Dewey did not receive any employee compensation during the fiscal year ended December 31, 2023, and, as a result, this Item 11 is focused on the compensation of our current NEOs.

Summary Compensation Table

The following table sets forth information concerning the compensation of TriSalus' NEOs for the fiscal years ended December 31, 2023 and 2022:

Name, Principal Position	Fiscal Year	Salary[1]	Stock Awards	Option Awards[2]	Non-Equity Incentive Plan Compensation[3]	All Other Compensation[3]	Total
Mary Szela *CEO and President*	2023	$518,077	$ 378,772	$ 1,433,387	$ 340,819	$ 21,775	$2,692,830
	2022	$463,630	$ —	$ 52,841	$ 123,750	$ 1,680	$ 641,901
Steven Katz, M.D. *Chief Medical Officer*	2023	$486,769	$ 171,433	$ 591,684	$ 342,461	$ 20,658	$1,613,005
	2022	$468,197	$ —	$ 85,720	$ 227,850	$ 17,379	$ 799,146
Sean Murphy *Chief Financial Officer*	2023	$471,539	$ 171,433	$ 593,066	$ 156,158	$ 1,050	$1,393,246
	2022	$207,462	$ —	$ 122,066	$ —	$ 69	$ 329,597

(1) Salary amounts represent actual amounts earned during applicable fiscal year. See "*Narrative Disclosure to Summary Compensation Table — Base Salaries*" below.

(2) This column reflects the aggregate grant date fair value of the stock and option awards granted during the applicable fiscal year computed in accordance with ASC Topic 718 for stock-based compensation transactions. Assumptions used in the calculation of these amounts are included in the notes to our audited financial statements included elsewhere in this Annual Report. These amounts do not reflect the actual economic value that will be realized by the NEO upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(3) See "*Narrative Disclosure to Summary Compensation Table — Non-Equity Incentive Plan Compensation*" below for a description of the material terms of the non-equity incentive plans for the fiscal years 2022 and 2023.

Narrative Disclosure to Summary Compensation Table

Base Salaries

Our NEOs receive an annual base salary to compensate them for the services they provide to the Company. The annual base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

As of December 31, 2023, Ms. Szela, Dr. Katz, and Mr. Murphy had annual base salaries of $600,000, $515,000 and $530,000, respectively.

Prior to the Business Combination, Ms. Szela, Dr. Katz and Mr. Murphy had annual base salaries of $466,875, $469.125 and $435,000, respectively. Post-Business Combination salary adjustments were approved in connection with the transition from operating a private corporation to a publicly-traded corporation. These salary adjustments were effective beginning as of August 10, 2023, and were not retroactive to any period prior to such date.

Bonuses

TriSalus has at times provided, and may in the future provide, cash bonuses to certain members of its executive team on an ad hoc basis as deemed appropriate, in the form of spot bonuses or for achievement of certain milestones or as individually negotiated in a NEO's employment agreement or offer letter.

Non-Equity Incentive Plan Compensation

We develop a performance-based cash bonus program annually. Under the 2023 program, each NEO was eligible to be considered for an annual performance bonus based on (1) the individual's target bonus, as a percentage of base salary pursuant to their respective employment agreements, which are described in "*Employment Arrangements with Executive Officers*" below and (2) the percentage attainment of 2023 corporate goals established by TriSalus' board of directors in its sole discretion and communicated to each officer. Each NEO is assigned a maximum target performance bonus expressed as a percentage of their base salary, which for 2023 was 55% for Ms. Szela, and 50% for each of Dr. Katz and Mr. Murphy. For the fiscal year ended December 31, 2023, the TriSalus board of directors determined that Ms. Szela was entitled to receive 95% of her target bonus and each of Dr. Katz and Mr. Murphy were entitled to receive 97% of his target bonus.

Equity-Based Incentive Awards

Our equity award program is the primary vehicle for offering long-term incentives to our executives. We believe that equity awards provide our executive officers with a strong link to long-term performance, create an ownership culture and help to align the interests of our executive officers with our stockholders. TriSalus has historically granted both incentive stock options and nonstatutory stock options to executive officers. We have used options as an incentive for long-term compensation to our executive officers because these grants allow our executive officers to realize value from this form of equity compensation only if the value of the underlying equity securities increase relative to the option's exercise price, which exercise price is set at the fair market value of the underlying equity securities on the grant date. In 2023, we also began to grant restricted stock units ("RSUs") to executive officers. Some RSUs granted have contained both a performance and time-based requirement for vesting. We have used this approach to align the interests of our stockholder with the interests of our executive officers, which incentives performance and retention while providing more tangible equity compensation compared to options. We believe that equity awards are an important retention tool for our executive officers, as well as for our other employees. We grant equity awards broadly to our employees, including to our non-executive employees. The Board is responsible for approving equity grants.

We currently maintain the 2023 Plan, which our Board and stockholders approved in connection with the Business Combination for purposes of granting equity-based incentive awards to our employees and consultants, including our NEOs. See "— *2023 Equity Incentive Plan*" below for further information. Prior to the Business Combination, TriSalus granted equity incentive awards under the 2009 Amended and Restated Equity Incentive Plan (the "**2009 Plan**"). The 2009 Plan will not be used following the Business Combination. See "— *2009 Equity Incentive Plan*" below for further information.

On May 19, 2023, TriSalus granted options to Ms. Szela, Dr. Katz and Mr. Murphy to purchase 58,409, 31,040 and 31,287 shares of our common stock, respectively, at an exercise price of $10.30 per share. The options must satisfy both time-based and performance-based requirements in order to vest. The time-based requirement is satisfied as follows: one fourth (1/4th) of the total number of options will satisfy time-based requirement on the vesting start date, which is May 19, 2023, and one forty-eighth (1/48th) of the total number of options will satisfy the time-based

requirement each month thereafter over the following three years. Ms. Szela, Dr. Katz and Mr. Murphy satisfied the performance-based vesting requirement upon TriSalus' consummation of the Business Combination.

On May 19, 2023, TriSalus awarded Ms. Szela, Dr. Katz and Mr. Murphy RSUs covering 36,774, 16,664 and 16,644 shares of our common stock, respectively. The RSUs must satisfy both time-based and performance-based requirements in order to vest. The time-based requirement is satisfied as follows: one fourth (1/4th) of the total number of RSUs will satisfy the time-based requirement on each anniversary of the vesting start date, which is October 5, 2022 for each of Ms. Szela, Dr. Katz and Mr. Murphy. The RSUs satisfied the performance-based requirement upon TriSalus' consummation of the Business Combination. .

Following the Business Combination, on August 11, 2023, TriSalus granted to each of Dr. Katz and Mr. Murphy an option to purchase 62,500 shares of our common stock at an exercise price of $12.00 per share. On August 14, 2023, TriSalus granted an option to purchase 172,500 shares of our common stock to Ms. Szela at an exercise price of $11.51 per share. Each of these options have a vesting schedule as follows: one-fourth (1/4th) of the shares subject to the option shall vest on the one-year anniversary of August 10, 2023, and 1/36th of the remaining shares shall vest each month thereafter on the 10th day of each month. TriSalus approved these option grants in connection with the transition from operating a private corporation to a publicly-traded corporation.

Health and Welfare and Retirement Benefits

All of TriSalus' named executive officers are eligible to participate in TriSalus' employee benefit plans, including medical, dental, vision, disability and life insurance plans, in each case on the same basis as all of TriSalus' other full-time employees. TriSalus pays approximately 80% of the premiums for medical, dental, vision, group term life, disability and accidental death and dismemberment insurance for all of its employees, including its named executive officers. TriSalus generally does not provide perquisites or personal benefits to its named executive officers, except in limited circumstances.

401(k) Plan

TriSalus' NEOs are eligible to participate in a defined contribution retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax-advantaged basis. Eligible employees may defer eligible compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the Code. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. In 2023, contributions made by participants, including the NEOs, to the 401(k) plan were matched by the Company up to a specified percentage of the employees' contribution. These matching contributions are fully vested when made.

Outstanding Equity Awards at December 31, 2023

The following table presents information regarding outstanding equity awards held by TriSalus' NEOs as of December 31, 2023. All awards granted prior to August 10, 2023, were granted pursuant to the 2009 Plan. All awards granted after August 10, 2023, were granted pursuant to the 2023 Plan.

	Option Awards					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares of units of stock that have not vested ($)(1)
Mary Szela	01/30/18	177,973	—	$ 1.22	01/29/28		
	10/06/20	13,698	3,604 (1)	$ 0.41	10/05/30		
	04/21/21	101,345	—	$ 0.41	04/20/31		
	11/03/21	37,748	21,942 (2)	$ 2.43	11/02/31		
	11/03/21	74,901	81,696 (2)	$ 2.43	11/02/31		
	04/20/22	—	37,080 (3)	$ 2.43	04/18/32		
	04/20/22	—	18,536 (3)	$ 2.43	04/18/32		
	05/19/23	—	46,989 (4)	$ 10.30	05/18/33		
	05/19/23	—	11,420 (4)	$ 10.30	05/18/33		
	05/19/23	—	—	$ —	10/25/26	27,581 (9)	235,542
	08/14/23	—	3,242 (5)	$ 11.51	08/13/33		
	08/14/23	—	169,258 (5)	$ 11.51	08/13/33		

Steven Katz, M.D.	05/17/16	593	—	$	3.65	05/17/26			
	01/18/17	2,471	—	$	3.65	01/17/27			
	04/18/18	2,471	—	$	1.22	04/16/28			
	01/22/19	2,471	—	$	1.22	01/21/29			
	10/06/20	93,991	21,691 (6)	$	0.41	10/06/30			
	11/03/21	17,018	15,659 (2)	$	2.43	11/03/31			
	04/20/22	—	26,485 (3)	$	2.43	04/19/32			
	04/20/22	—	63,737 (3)	$	2.43	04/19/32			
	05/19/23	—	18,276 (4)	$	10.30	05/18/33			
	05/19/23	—	12,764 (4)	$	10.30	05/18/33			
	05/19/23	—	—	$	—	10/25/26	12,483 (9)		106,605
	08/11/23	—	5,558 (5)	$	12.00	08/10/33			
	08/11/23	—	56,942 (5)	$	12.00	08/10/33			
Sean Murphy	11/03/21	2,677	2,266 (2)	$	2.43	11/03/31			
	01/19/22	5,917	6,442 (7)	$	2.43	01/19/32			
	07/13/22	2,625	—	$	2.43	07/12/32			
	07/13/22	41,152	79,815 (8)	$	2.43	07/12/32			
	05/19/23	—	17,734 (4)	$	10.30	05/18/33			
	05/19/23	—	13,553 (4)	$	10.30	05/18/33			
	05/19/23	—	—	$	—	10/25/26	12,483 (9)		106,605
	08/11/23	—	5,536 (5)	$	12.00	08/10/33			
	08/11/23	—	56,964 (5)	$	12.00	08/10/33			

(1) 1/48 of the shares subject to this option vest each month following the vesting commencement date (October 6, 2020) on the same day of the month as the vesting commencement date, subject to Ms. Szela's continuing to be a Service Provider (as defined in the 2009 Plan) through each such date.

(2) 1/48 of the shares subject to this option vest each month on the same day of the month as the vesting commencement date (November 3, 2021), subject to the executive's continuing to be a Service Provider through each such date, subject to continued service at each vesting date.

(3) 1/12 of the shares subject to this option vest each month following the first anniversary of the vesting commencement date (April 20, 2022) on the same day of the month as the vesting commencement date for three years, subject to the executive's continuing to be a Service Provider.

(4) 25% of the total shares underlying the option vested on the vesting commencement date (May 19, 2023), and 1/48th of the total number of option shares vest each month thereafter on the same day of the month as the vesting commencement date, subject to the executive's continuing to be a Service Provider through each such date.

(5) 25% of the total shares underlying this option will vest on the first anniversary of the vesting commencement date (August 10, 2023, for Dr. Katz and Mr. Murphy, and August 14, 2023, for Ms. Szela) and 1/48th of the total number of option shares shall vest each month thereafter on the same day of the month as the vesting commencement date, subject to the executive's continuing to be a Service Provider through each such date.

(6) 1/48 of the shares subject to this option vest each month on the same day of the month as the vesting commencement date (September 21, 2020), subject to Dr. Katz's continuing to be a Service Provider through each such date.

(7) 1/48 of the shares subject to this option vest each month on the same day of the month as the vesting commencement date (January 19, 2022), subject to Mr. Murphy's continuing to be a Service Provider through each such date.

(8) 1/48 of the shares subject to this option vest each month on the same day of the month as the vesting commencement date (July 13, 2022), subject to Mr. Murphy's continuing to be a Service Provider through each such date.

(9) 25% of the total RSUs vest on each anniversary of the vesting commencement date (October 5, 2022), subject to the executive's continuing to be a Service Provider through each such date.

Employment Arrangements with Executive Officers

Each of TriSalus' NEOs is an at-will employee. TriSalus entered into amended and restated executive employment agreements with each of its NEOs in November 2022, which are summarized below.

Mary Szela

In March 2023, TriSalus entered into an amended and restated executive employment agreement with Ms. Szela. Pursuant to the amended and restated executive employment agreement, Ms. Szela's annual base salary was $466,875 and she was eligible to receive an annual performance bonus of a target amount equal up to 50% of her base salary, based upon certain profitability or other financial objectives of the Company, business initiatives and other criteria to be determined by the Board, with such bonus subject to review and adjustment by the Board. Following the consummation of the Business Combination, the Board approved an increase of Ms. Szela's annual base salary to $600,000 and a revised target bonus of 55% of her base salary. Ms. Szela is also eligible to participate in TriSalus' benefit plans generally available to similarly situated employees.

Ms. Szela is entitled to certain severance benefits as described below in "— *Potential Payments Upon Termination or Change in Control*."

Steven Katz, M.D.

In February 2023, TriSalus entered into an amended and restated executive employment agreement with Dr. Katz. Pursuant to the amended and restated executive employment agreement, Dr. Katz received an annual base salary of $469,125, and is eligible to receive an annual performance bonus of a target amount equal to up to 50% of his base salary, based upon certain profitability or other financial objectives of the Company, business initiatives and other criteria to be determined by the Board, with such bonus subject to review and adjustment by the Board. Following the consummation of the Business Combination, the Board approved an increase of Dr. Katz's annual base salary to $515,000. Dr. Katz is also eligible to participate in TriSalus' benefit plans generally available to similarly situated employees.

Dr. Katz's executive employment agreement also provides that he is eligible for two cash payments of $500,000 each, which are payable upon achievement of certain corporate milestones, subject to his continued employment through such milestone date, except as otherwise provided below (the "Milestone Payments").

Dr. Katz is entitled to certain severance benefits as described below in "— *Potential Payments Upon Termination or Change in Control*."

Sean Murphy

In March 2023, TriSalus entered into an amended and restated executive employment agreement with Mr. Murphy. Pursuant to the amended and restated executive employment agreement, Mr. Murphy received an annual base salary of $435,000 and is eligible to receive an annual performance bonus of a target amount equal to up to 50% of his base salary, based upon certain profitability or other financial objectives of the Company, business initiatives and other criteria to be determined by the Board, with such bonus subject to review and adjustment by the Board. Following the consummation of the Business Combination, the Board approved an increase in Mr. Murphy's annual base salary to $530,000. Mr. Murphy is also eligible to participate in TriSalus' benefit plans generally available to similarly situated employees.

Mr. Murphy is entitled to certain severance benefits as described below in "— *Potential Payments Upon Termination or Change in Control*."

Potential Payments Upon Termination or Change in Control

Each of Ms. Szela, Dr. Katz, and Mr. Murphy are entitled to any accrued obligations, which include accrued but unpaid salary through the date of termination, unreimbursed expenses, and benefits owed to such executive officer under retirement or health plans in which such executive officer was a participant ("Accrued Benefits"), in the event of any termination of their employment. In addition, each executive is eligible to receive the following severance benefits under their employment agreements if their employment is terminated by TriSalus pursuant to a "Discharge Without Cause" (as such term is defined in each of their respective employment agreements)) or if individual experiences a "Resignation For Good Reason" (as such term is defined in each of their respective employment agreements), and provided such executive officer timely executes and does not revoke a release of claims in TriSalus' favor: (a) continuing payments of the executive's then-current annual base salary for 12 months for Ms. Szela, Dr. Katz and Mr.

Murphy, and (b) if Ms. Szela's, Dr. Katz's or Mr. Murphy's "Discharge Without Cause" occurs in the fourth calendar quarter of a year and the Company achieves it financial objectives on which such executive's bonus for that year is based, such executive would also be entitled to a pro rata annual bonus for such year.

In addition to the foregoing, Dr. Katz is also entitled to receive an applicable Milestone Payment(s) if he experiences a "Discharge Without Cause" or a "Resignation For Good Reason" within 60 days of the achievement of the applicable qualifying milestone or milestones.

Further, if Ms. Szela, Dr. Katz, or Mr. Murphy experiences a "Discharge Without Cause" or a "Resignation For Good Reason" within the one-year period following a "Change in Control" (as such term is defined in each of their respective employment agreements) and provided each executive officer timely executes and does not revoke a release of claims in TriSalus' favor, they will instead be entitled to a lump sum payment equal to: (a) 12 months of their annual base salary, (b) their annual bonus for the year of termination, assuming performance was met at the "target" level, (c) the cost of one year of continued medical, dental and vision benefits at the same level as if the executive remained actively employed by TriSalus, and (d) full vesting of all outstanding stock options and other equity incentives that are subject to vesting over time and based on length of service with TriSalus.

Equity Compensation Plan Information

The following table summarizes our equity compensation plan information as of December 31, 2023. Information is included for equity compensation plans approved by our stockholders. We do not have any equity compensation plans not approved by our stockholders.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
	(a)	(b)	(c)
Equity compensation plans approved by security holders			
2009 Plan[(1)]	1,596,529	2.78	—
2023 Plan[(2)]	2,069,705	7.36	3,515,303
2023 ESPP[(3)]	—	N/A	1,396,252
Equity compensation plans not approved by security holders[(4)]	—		—
Total	**3,666,234**		**4,911,555**

a. Upon adoption of our 2023 Plan, we restricted future grants from our 2009 Plan. Shares of our common stock reserved for issuance under the 2009 Plan that are repurchased, forfeited, expired, or cancelled do not increase the number of shares of our common stock reserved for issuance under the 2023 Plan and are returned to our authorized but unallocated shares of common stock.

b. Under the terms of our 2023 Plan, the number of shares of our common stock reserved for issuance under our 2023 Plan will automatically increase on January 1 of each year through January 1, 2033, by a number of shares equal to (i) 5% of the total number of shares of our capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or (ii) a lesser amount determined by our Board of Directors.

c. Under the terms of our 2023 Employee Stock Purchase Plan (our "ESPP"), the number of shares of our common stock reserved for issuance under our ESPP will automatically increase on January 1 of each calendar year through January 1, 2033, by a number of shares equal to the lesser of (i) 2% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year; (ii) 2,792,503 shares; or (iii) a lesser amount determined by our Board of Directors.

d. As of December 31, 2023, we did not have any equity compensation plans that were not approved by our stockholders.

Non-Employee Director Compensation

Following the consummation of the Business Combination, our Board adopted the Non-Employee Director Compensation Policy, which establishes cash and equity-based compensation designed to align compensation with TriSalus' business objectives and stockholder value, while enabling TriSalus to attract, retain, incentivize and reward directors who contribute to the success of the company. Our board of directors will review director compensation periodically to ensure that director compensation remains competitive such that the we are able to recruit and retain qualified directors.

The following table sets forth information concerning the compensation of TriSalus' directors for fiscal year 2023. Ms. Szela, our Chief Executive Officer, and Sean Murphy, our Chief Financial Officer, did not receive additional

compensation for their service as a director in fiscal year 2023, and therefore are not included in the Director Compensation table below. All compensation paid to Ms. Szela and Mr. Murphy is reported above in the "*Summary Compensation Table.*" Additionally, prior to the closing of the Business Combination, none of the directors of MTAC received any cash compensation or equity awards for their service as a director of MTAC, and therefore, are not included in the Director Compensation table below to the extent such director's service was terminated in connection with the closing of the Business Combination.

Name	Fees earned or paid in Cash	Option Awards ($)[1][2]	Total ($)
Christopher C. Dewey	$ —	$ —	$ —
Robert H. Weiss	$ —	$ —	$ —
Karim Karti	$ —	$ —	$ —
Martin W. Roche, MD	$ —	$ —	$ —
Thierry Thaure	$ —	$ —	$ —
Manny Aguero	$ —	$ —	$ —
David Treadwell	$ —	$ —	$ —
Mats Wahlström	$ 102,083	$ 221,200	$ 323,283
Andrew von Eschenbach	$ 13,750	$ 221,200	$ 234,950
Anil Singhal	$ 47,500	$ 221,200	$ 268,700
Arjun Desai	$ 10,833	$ 221,200	$ 232,033
David J. Matlin	$ 12,917	$ 221,200	$ 234,117
George Kelly Martin	$ 25,000	$ 221,200	$ 246,200
Kerry Hicks	$ 42,500	$ 221,200	$ 263,700

(1) This column reflects the aggregate grant date fair value of the stock options granted to the directors during fiscal year 2023. The aggregate grant date fair value is computed in accordance with ASC Topic 718 for stock-based compensation transactions. Assumptions used in the calculation of these amounts are included in the notes to our financial statements included elsewhere in this Annual Report. In accordance with ASC Topic 718, recognition of compensation expense is deferred until consummation of the Business Combination. This amount does not reflect the actual economic value that may be realized by the director.

(2) As of December 31, 2023, our non-employee directors held the following number of options to purchase shares of our common stock: Mr. Wahlström, 170,945; Messrs. von Eschenbach, Desai, Matlin and Martin, 35,000 each; Mr. Singhal, 54,278; and Mr. Hicks, 59,222; none of the foregoing held other stock awards. None of Messrs. Dewey, Weiss, Karti, Thaure, Aguero, Treadwell or Dr. Roche held any options to purchase shares of our common stock or other stock awards.

Non-Employee Director Compensation

Our Board reviews director compensation periodically to ensure that director compensation remains competitive such that we are able to recruit and retain qualified directors. In August 2023, our Board approved a non-employee director compensation policy (the "Non-Employee Director Policy") consisting of annual cash retainers of $50,000 for each non-employee director and an additional $30,000 for the chairperson of the Board; an additional $20,000 and $7,500 for the chairperson and each other member of the audit committee of the Board, respectively; an additional $15,000 and $7,500 for the chairperson and each other member of the compensation committee of the Board, respectively; an additional $15,000 and $7,500 for the chairperson and each other member of the nominating and corporate governance committee of the Board, respectively; and an additional $25,000 and $7,500 for the chairperson and each other member of the science and technology committee of the Board, respectively. The Non-Employee Director Policy also provides for an initial grant of a stock option for 35,000 shares on the date an eligible director is first elected or appointed to the Board (vesting in equal annual installments over three years) and an annual stock option grant for 15,000 shares on the date of each annual stockholder meeting for each eligible director who continues to serve as a non-employee member of the Board as of such date (vesting on the earlier of the one year anniversary of the date of grant or our next annual stockholder meeting). The non-employee directors serving on the Board as of

immediately following the closing of the Business Combination also received a one-time stock option grant for 35,000 shares immediately following the closing of the Business Combination.

TriSalus' policy is to reimburse directors for reasonable and necessary out-of-pocket expenses incurred in connection with attending TriSalus Board and committee meetings or performing other services in their capacities as directors.

The Non-Employee Director Policy was developed with input from an independent compensation consultant regarding practices and compensation levels at comparable companies. It is designed to align compensation with our business objectives and the creation of stockholder value, while enabling us to attract, retain, incentivize and reward directors who contribute to our long-term success

Equity Incentive Plans

Equity-based compensation has been and will continue to be an important foundation in executive compensation packages as we believe it is important to maintain a strong link between executive incentives and the creation of stockholder value. We believe that performance and equity-based compensation can be an important component of the total executive compensation package for maximizing stockholder value while, at the same time, attracting, motivating and retaining high-quality executives. Equity-based compensation is an important element of our compensation arrangements for both executive officers and directors. Executive officers are also eligible to participate in the 2023 Employee Stock Purchase Plan ("ESPP"). Below is a description of the 2009 Plan, the 2023 Plan and the ESPP.

2009 Plan

The following summary describes the material terms of the 2009 Plan, an amendment of which was last adopted by the TriSalus Board on July 13, 2022 and last approved by the stockholders of TriSalus on July 19, 2022. No further awards have been, or will be made, under the 2009 Plan following the effective date of our 2023 Plan.

Awards. The 2009 Plan provided for the grant of incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), restricted stock, restricted stock units ("RSU"s), and stock appreciation rights (collectively, "Awards") to TriSalus' employees, directors, and consultants who provide services to TriSalus.

Authorized Shares. The aggregate number of shares of Common Stock that may be issued pursuant to the 2009 Plan was 1,596,529 shares. The maximum number of shares of Common Stock that may be issued pursuant to the exercise of options and RSUs under the 2009 Plan was 1,532,356 and 64,173 shares, respectively.

Plan Administration. The 2009 Plan is administered by the Board, or a duly authorized committee of the TriSalus Board and is referred to as the "administrator" in the 2009 Plan. Subject to the provisions of the 2009 Plan, the administrator determines in its discretion the persons to whom Awards are granted, the sizes of such Awards and all of their terms and conditions. The administrator has the authority to construe and interpret the terms of the 2009 Plan and Awards granted under it.

Outstanding Awards. Awards are granted under forms of award agreements adopted by the administrator. The administrator determines the exercise price for stock options, within the terms and conditions of the 2009 Plan, provided that the exercise price of a stock option cannot be less than 100% of the fair market value of Common Stock on the date of grant. Options and RSUs granted under the 2009 Plan vest at the rate specified in the grant agreement as determined by the administrator.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of Common Stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year under all of TriSalus' stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of TriSalus' total combined voting power or that of any of its affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (ii) the term of the ISO does not exceed five years from the date of grant.

Changes to Capital Structure. In the event there is a specified type of change in TriSalus' capital structure, such as a recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, combination, repurchase, or exchange of shares, appropriate adjustments will be made to the number and class of shares that may be delivered under the 2009 Plan and/or number, class, and the exercise price of shares covered by each outstanding Award.

Merger or Change in Control. The 2009 Plan provides that in the event of a merger or change in control Awards will be treated as the administrator determines, and the administrator may take one or more of the following actions with respect to such Awards:

- arrange for the assumption or substitution of an Award by a surviving or acquiring corporation;
- terminate the Awards;
- accelerate the vesting of the Award and, to the extent the administrator determines, provide for termination if not exercised (if applicable) at or before the effective time of the merger or change in control; or
- terminate the Award in exchange for an amount of cash and/or property, if any, equal to the amount that would have been attained upon the exercise of such Award or realization of the participant's rights as of the date of the occurrence of the transaction or the replacement of such Award with other rights or property selected by the administrator in its sole discretion.

The administrator is not obligated to treat all Awards or portions of Awards in the same manner and is not obligated to treat all participants in the same manner.

In the event that the successor corporation does not assume or substitute for the Award, the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, including shares as to which such Awards would not have otherwise been vested or exercisable, all restrictions on restricted stock and restricted stock units will lapse, and, with respect to Awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. In addition, if an option or stock appreciation right is not assumed or substituted in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that the option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion, and the option or stock appreciation right will terminate upon the expiration of such period.

Under the 2009 Plan, a change in control means the occurrence of any of the following events: (i) a change in ownership of TriSalus, which occurs on the date that any one person, or more than one person acting as a group, acquires ownership of the stock of TriSalus that constitutes more than 50% of the total voting power of the stock of TriSalus, except that any changes in the ownership of the stock of TriSalus as a result of a private financing of TriSalus that is approved by the Board will not be considered a change in control, (ii) a change in the effective control of TriSalus, which occurs on the date the majority of the members of the Board is replaced during any twelve month period by directors whose appointment or election is not endorsed by a majority of members of the Board prior to the date of the appointment or election, or (iii) a change in the ownership of a substantial portion of TriSalus' assets, which occurs on the date that any person acquires (or has acquired during the twelve month period ending on the date of the most recent acquisition by such person) assets from TriSalus that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of the assets of TriSalus immediately prior to such acquisition.

Plan Amendment or Termination. The Board has the authority to amend, alter, suspend, or terminate the 2009 Plan, provided that such action does not impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of TriSalus stockholders. No stock awards may be granted under the 2009 Plan while it is suspended or after it is terminated.

At the close of the Business Combination, outstanding TriSalus Options under the 2009 Plan were assumed by TriSalus and converted into options to purchase Common Stock. The stock options continued to be governed by the terms of the 2009 Plan and the stock option agreements thereunder, until such outstanding options are exercised or until they terminate or expire by their terms. At the close of the Business Combination, outstanding RSUs under the 2009 Plan were assumed by TriSalus and converted into restricted stock units covering shares of Common Stock. The restricted stock units will continue to be governed by the terms of the 2009 Plan.

2023 Plan

The following summary describes the material terms of the 2023 Plan, which was adopted by the TriSalus Board on August 10, 2023.

Awards. The 2023 Plan provided for the grant of incentive stock options, nonstatutory stock options, restricted stock, restricted stock units, and stock appreciation rights (collectively, "Awards") to TriSalus' employees, directors, and consultants who provide services to TriSalus.

Authorized Shares. Subject to certain capitalization adjustments, as of December 31, 2023, the aggregate number of shares of Common Stock that may be issued pursuant to stock awards under the 2023 Plan was 5,585,008 shares. The aggregate number of shares that may be issued under the 2023 Plan will automatically increase on January 1 of each year for a period of ten years commencing on January 1, 2024, in an amount equal to 5% of the total number of shares of fully diluted common stock determined on each preceding December 31, or such smaller number as may be determined by our Board prior to January 1 of a given year.

Plan Administration. The 2023 Plan is administered by the Board, or a duly authorized committee of the Board and is referred to as the "administrator" in the 2023 Plan. Subject to the provisions of the 2023 Plan, the administrator determines in its discretion the persons to whom Awards are granted, the sizes of such Awards and all of their terms and conditions. The administrator has the authority to construe and interpret the terms of the 2023 Plan and Awards granted under it.

Outstanding Awards. Awards are granted under forms of award agreements adopted by the administrator. The administrator determines the exercise price for stock options, within the terms and conditions of the 2023 Plan, provided that the exercise price of a stock option cannot be less than 100% of the fair market value of Common Stock on the date of grant. Options and RSUs granted under the 2023 Plan vest at the rate specified in the grant agreement as determined by the administrator.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of Common Stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year under all of TriSalus' stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of TriSalus' total combined voting power or that of any of its affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (ii) the term of the ISO does not exceed five years from the date of grant.

Changes to Capital Structure. In the event there is a specified type of change in TriSalus' capital structure, such as a recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, combination, repurchase, or exchange of shares, appropriate adjustments will be made to the number and class of shares that may be delivered under the 2023 Plan and/or number, class, and the exercise price of shares covered by each outstanding Award.

Merger or Change in Control. The 2023 Plan provides that in the event of a merger or change in control Awards will be treated as the administrator determines, and the administrator may take one or more of the following actions with respect to such Awards:

- arrange for the assumption or substitution of an Award by a surviving or acquiring corporation;
- terminate the Awards;
- accelerate the vesting of the Award and, to the extent the administrator determines, provide for termination if not exercised (if applicable) at or before the effective time of the merger or change in control; or
- terminate the Award in exchange for an amount of cash and/or property, if any, equal to the amount that would have been attained upon the exercise of such Award or realization of the participant's rights as of the date of the occurrence of the transaction or the replacement of such Award with other rights or property selected by the administrator in its sole discretion.

The administrator is not obligated to treat all Awards or portions of Awards in the same manner and is not obligated to treat all participants in the same manner.

In the event that the successor corporation does not assume or substitute for the Award, the participant will fully vest in and have the right to exercise all of his or her outstanding options and stock appreciation rights, including shares as to which such Awards would not have otherwise been vested or exercisable, all restrictions on restricted stock and restricted stock units will lapse, and, with respect to Awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. In addition, if an option or stock appreciation right is not assumed or substituted in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that the option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion, and the option or stock appreciation right will terminate upon the expiration of such period.

Under the 2023 Plan, a change in control means the occurrence of any of the following events: (i) a change in ownership of TriSalus, which occurs on the date that any one person, or more than one person acting as a group, acquires ownership of the stock of TriSalus that constitutes more than 50% of the total voting power of the stock of TriSalus, except that any changes in the ownership of the stock of TriSalus as a result of a private financing of TriSalus that is approved by the Board will not be considered a change in control, (ii) a change in the effective control of TriSalus, which occurs on the date the majority of the members of the Board is replaced during any twelve month period by directors whose appointment or election is not endorsed by a majority of members of the Board prior to the date of the appointment or election, or (iii) a change in the ownership of a substantial portion of TriSalus' assets, which occurs on the date that any person acquires (or has acquired during the twelve month period ending on the date of the most recent acquisition by such person) assets from TriSalus that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of the assets of TriSalus immediately prior to such acquisition.

Plan Amendment or Termination. The Board has the authority to amend, alter, suspend, or terminate the 2023 Plan, provided that such action does not impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of TriSalus stockholders. No stock awards may be granted under the 2023 Plan while it is suspended or after it is terminated.

ESPP

In June 2023 our Board adopted and in August 2023 our stockholders approved the ESPP. The ESPP became effective immediately upon the closing of the Business Combination. A summary description of the material features of the ESPP is set forth below. This summary is not a complete description of all provisions of the ESPP and is qualified in its entirety by reference to the ESPP, the form of which is attached as an exhibit to the registration statement of which this prospectus forms a part and incorporated by reference in its entirety.

The purpose of the ESPP is to provide a means by which our eligible employees and certain designated companies may be given an opportunity to purchase shares of Common Stock, to assist us in retaining the services of eligible employees, to secure and retain the services of new employees and to provide incentives for such persons to exert maximum efforts for our success. The ESPP includes two components: a 423 Component and a Non-423 Component. We intend that the share purchase rights under the 423 Component will qualify as options issued under an "employee stock purchase plan" as that term is defined in Section 423(b) of the Code. The share purchase rights under the Non-423 Component will not qualify as options that are subject to Section 423(b) of the Code. Except as otherwise provided in the ESPP or determined by the Board, the Non-423 Component will operate and be administered in the same manner as the 423 Component.

Share Reserve. The initial number of shares of Common Stock reserved for issuance under the ESPP 1,396,252 shares of Common Stock. This number is referred to herein as the "Initial Share Reserve", subject to adjustment for specified changes in our capitalization. The number of shares of Common Stock reserved for issuance under the ESPP will automatically increase on January 1 of each year for a period of up to ten years, beginning on January 1, 2024, and continuing through and including January 1, 2033, by an amount equal to the lesser of (x) two percent (2%) of the total number of shares of the Fully Diluted Common Stock determined on December 31 of the preceding year, and (y) 200% of the Initial Share Reserve. Notwithstanding the foregoing, the Board may act prior to January 1st of a given year to provide that the increase for such year will be a lesser number of shares. Shares issuable under the ESPP may be shares of authorized but unissued or reacquired Common Stock, including shares purchased by us on the open market. Shares subject to purchase rights granted under the ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the ESPP.

Administration. Our Board, or a duly authorized committee thereof, administers the ESPP.

Eligibility. Our employees and the employees of any of our designated affiliates, are eligible to participate in the ESPP, provided they may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by the administrator: (1) customary employment with us or one of our affiliates for more than 20 hours per week and more than five months per calendar year or (2) continuous employment with us or one of our affiliates for a minimum period of time, not to exceed two years, prior to the first date of an offering. In addition, the Board may also exclude from participation in the ESPP or any offering, employees who are "highly compensated employees" (within the meaning of Section 423(b)(4)(D) of the Code) or a subset of such highly compensated employees.

An employee may not be granted rights to purchase stock under the 423 Component of the ESPP (a) if such employee immediately after the grant would own stock (including stock issuable upon exercise of all such employee's

purchase rights) possessing 5% or more of the total combined voting power or value of all classes of Common Stock or (b) to the extent that such rights would accrue at a rate that exceeds $25,000 worth of Common Stock for each calendar year that the rights remain outstanding. The Board may approve different eligibility rules for the Non-423 Component.

Offerings. The 423 Component of the ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Code. The administrator may specify offerings under the 423 Component with a duration of not more than 27 months and may specify one or more shorter purchase periods within each offering. For the Non-423 Component, the administrator may specify offerings, and purchase periods within each offering, as determined by the administrator. Each offering will have one or more purchase dates on which shares of Common Stock will be purchased for the employees who are participating in the offering. The administrator, in its discretion, will determine the other terms of offerings under the ESPP. The administrator has the discretion to structure an offering so that if the fair market value of a share of Common Stock on any purchase date during the offering period is less than or equal to the fair market value of a share of Common Stock on the first day of the offering period, then that offering will terminate immediately, and the participants in such terminated offering will be automatically enrolled in a new offering that begins immediately after such purchase date.

A participant may not transfer purchase rights under the ESPP other than by will, the laws of descent and distribution, or as otherwise provided under the ESPP.

Payroll Deductions. The ESPP permits participants to purchase shares of Common Stock through payroll deductions, subject to such limitations as the administrator specifies. The administrator may limit a participant's payroll deductions to a certain percentage or amount of pay, or by limiting the number of shares that may be purchased during the offering.

Purchase Price. Unless otherwise determined by the administrator, the purchase price of the shares will be 85% of the lesser of the fair market value of Common Stock on the first day of an offering or on the applicable date of purchase.

Withdrawal. Participants may withdraw from an offering by delivering a withdrawal form to us and terminating their contributions. Such withdrawal may be elected at any time prior to the end of an offering, except as otherwise provided by the administrator. Upon such withdrawal, we will distribute to the employee such employee's accumulated but unused contributions without interest (unless otherwise required by law), and such employee's right to participate in that offering will terminate. However, an employee's withdrawal from an offering does not affect such employee's eligibility to participate in any other offerings under the ESPP.

Termination of Employment. A participant's rights under any offering under the ESPP will terminate immediately if the participant either (i) is no longer employed by us or any of our parent or subsidiary companies (subject to any post-employment participation period required by law) or (ii) is otherwise no longer eligible to participate. In such event, we will distribute to the participant such participant's accumulated but unused contributions, without interest (unless otherwise required by law).

Corporate Transactions. In the event of certain specified significant corporate transactions, such as a merger or change in control, a successor corporation may assume, continue, or substitute each outstanding purchase right. If the successor corporation does not assume, continue, or substitute for the outstanding purchase rights, the offering in progress will be shortened and a new purchase date will be set. The participants' purchase rights will be exercised on the new purchase date and such purchase rights will terminate immediately thereafter.

Amendment and Termination. The Board has the authority to amend, suspend, or terminate the ESPP, at any time and for any reason, provided certain types of amendments will require the approval of our stockholders. Any benefits, privileges, entitlements and obligations under any outstanding purchase rights granted before an amendment, suspension or termination of the ESPP will not be materially impaired by any such amendment, suspension or termination except (i) with the consent of the person to whom such purchase rights were granted, (ii) as necessary to facilitate compliance with any laws, listing requirements, or governmental regulations, or (iii) as necessary to obtain or maintain favorable tax, listing, or regulatory treatment. The ESPP will remain in effect until terminated by our Board in accordance with the terms of the ESPP.

Emerging Growth Company Status

As an emerging growth company, we are exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation or golden parachute payments, and to provide information relating to the ratio of total compensation of our CEO to the median of the

annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Item 12. Security Ownership of Certain Beneficial Owner and Management and Related Stockholder Matters

The following table sets forth information regarding the beneficial ownership of shares of our Common Stock, as applicable, as of April 3, 2024 (the "Ownership Date") by:

- each person or "group" (as such term is used in Section 13(d)(3) of the Exchange Act) known by us to be the beneficial owner of more than 5% of our Common Stock as of the Ownership Date;
- each of our current executive officers and directors;
- all of our current executive officers and directors as a group.

Beneficial ownership is determined in accordance with SEC rules, which generally provides that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power with respect to the security. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of our Common Stock that they beneficially own, subject to applicable community property laws. Under SEC rules, beneficial ownership includes securities that the individual or entity has the right to acquire, such as through exercise of stock options or warrants, within 60 days of the Ownership Date and are deemed to be outstanding and beneficially owned by the persons holding those options or warrants for the purpose of computing the number of shares beneficially owned and the percentage ownership of that person. They are not, however, deemed to be outstanding and beneficially owned for the purpose of computing the percentage ownership of any other person.

The beneficial ownership of shares of our Common Stock is based on 26,758,295 shares of Common Stock outstanding as of the Ownership Date.

Unless otherwise indicated, we believe that all persons named in the table below have sole voting and investment power with respect to the voting securities beneficially owned by them.

	Number of Shares	
Name and Address of Beneficial Owner[1]	**Number of Shares Beneficially Owned**	**Approximate % of Outstanding Common Stock**
Mary Szela[2]	688,148	2.5 %
Sean Murphy[3]	600,239	2.2 %
Steven Katz, M.D., FACS[4]	160,035	*
Mats Wahlström[5]	2,764,040	10.3 %
David J. Matlin[6]	2,272,421	7.9 %
Arjun "JJ" Desai[7]	449,794	1.7 %
Andrew von Eschenbach	—	*
George Kelly Martin[8]	247,185	*
Anil Singhal[9]	14,133	*
Kerry Hicks[10]	2,189,091	8.2 %
All executive officers and directors as a group (14 individuals)	*9,560,407*	*31.7 %*
Christopher Dewey[14]	1,522,789	5.5 %
Five Percent or More Stockholders		
Frankenius Equity AB[11]	6,408,254	23.7 %
Unique Diamond Investments Limited[12]	1,546,569	5.8 %
HW Investment Partners, LLC[13]	1,370,028	5.1 %

* Less than one percent.

(1) Unless otherwise noted, the business address of each of the following entities or individuals is c/o TriSalus Life Sciences, Inc., 6272 W. 91st Avenue, Westminster, Colorado 80031.

(2) Consists of (i) 243,189 shares held by Ms. Szela and (ii) 429,997 shares of Common Stock issuable pursuant to TriSalus Options that are exercisable within 60 days of the Ownership Date.

(3) Consists of (i) 357,535 shares held by Murphy Family Trust 2012, (ii) 167,732 shares held by Sean E Murphy TTEE U/A 2/4/2004 ("Sean Murphy Trust") and (iii) 64,216 shares of Common Stock issuable pursuant to TriSalus Options that are exercisable within 60 days of the Ownership Date. Lisa Murphy, Mr. Murphy's spouse, has voting and

investment discretion with respect to the shares held of record by Murphy Family Trust 2012 and thus Mr. Murphy may be deemed to have beneficial ownership of the shares held directly by Murphy Family Trust 2012. Mr. Murphy is the trustee of the Sean Murphy Trust and thus Mr. Murphy may be deemed to have beneficial ownership of the shares held directly by the Sean Murphy Trust.

(4) Consists of (i) 17,799 shares held by Dr. Katz and (ii) 132,059 shares of Common Stock issuable pursuant to TriSalus Options that are exercisable within 60 days of the Ownership Date.

(5) Consists of (i) 1,254,259 shares held by Leonard Capital, LLC, (ii) 52,278 shares of Common Stock issuable upon conversion of shares of Series A Convertible Preferred Stock held by Leonard Capital LLC, (iii) 1,370,028 shares held by HW Investment, and (iii) 85,673 shares of Common Stock exercisable pursuant to options that are exercisable within 60 days of the Ownership Date. Mr. Wahlström has sole voting and investment discretion with respect to the shares held directly by Leonard Capital LLC and shared voting and investment discretion with respect to the shares held by HW Investment and may be deemed to have beneficial ownership of the shares held by each of them.

(6) Consists of (i) 931,903 shares held directly by Mr. Matlin of which 215,055 shares are vested and 716,848 shares are subject to vesting and forfeiture pursuant to a sponsor support agreement, (ii) 1,240,518 shares underlying private warrants, which are exercisable for shares of Common Stock commencing 30 days after the closing of the Business Combination and (iii) 100,000 shares of Common Stock issuable upon conversion of shares of Series A Convertible Preferred Stock held by Mr. Matlin.

(7) Consists of (i) 203,127 shares held directly by Dr. Desai of which 46,875 shares are vested and 156,252 shares are subject to vesting and forfeiture pursuant to the Sponsor Support Agreement and (ii) 246,667 shares underlying private warrants, which are exercisable for shares of Common Stock commencing 30 days after the Closing of the Business Combination.

(8) Consists of 247,185 shares of Common Stock held by Varka LLC. Mr. Martin may be deemed to have beneficial ownership of the shares held directly by the Varka LLC.

(9) Consists of 13,876 shares of Common Stock issuable for Anil Singhal pursuant to TriSalus Options that are exercisable within 60 days of the Ownership Date.

(10) Consists of (i) 514,589 shares held directly by Mr. Hicks, (ii) 1,254,460 shares held by HW Investment, (iii) 81,845 shares held by the Millennium Trust Company, LLC for which Mr. Hicks acts as custodian, (iv) 322,737 shares held by The Kerry Raymond Hicks Dynasty Trust, for which Mr. Hicks serves as trustee, and (v) 14,997 shares of Common Stock issuable pursuant to TriSalus Options that are exercisable within 60 days of the Ownership Date. Mr. Hicks has shared voting and investment discretion with respect to the shares held of record by HW Investment and may be deemed to have beneficial ownership of the shares held by each of them.

(11) Consists of (i) 6,167,776 shares held by Frankenius Equity AB ("Frankenius Equity") and (ii) 240,478 shares of Common Stock issuable upon conversion of shares of Series A Convertible Preferred Stock held by Frankenius Equity. Frankenius Equity's principal place of business is Box 984, 501 10 Boras, Sweden. Paul Frankenius has sole voting and investment discretion with respect to the shares held of record by Frankenius Equity and may be deemed to have beneficial ownership of the shares held by Frankenius Equity.

(12) Consists of 1,546,569 shares held by Unique Diamond Investments Limited. Unique Diamond's principal place of business is C/O Room Nos.,4727-34 Sun Hung Kai Centre, 30 Harbour Road, Wan Chai, Hong Kong. ORI Capital Inc, which is a general partner of ORI Healthcare Fund, L.P, has sole voting and investment discretion with respect to the shares held of record by Unique Diamond Investment, Ltd. Ms Song, Hong Fan, who owns ORI Capital Inc. may be deemed to have beneficial ownership of the shares held by Unique Diamond Investment Limited.

(13) Consists of 1,370,028 shares held by HW Investment. Messrs. Wahlström and Mr. Hicks and have shared voting and investment discretion with respect to the shares held of record by HW Investment and may be deemed to have beneficial ownership of the shares held by each of them.

(14) Consists of (i) 573,690 shares held directly by the Christopher C Dewey Trust DTD 5/3/18, (ii) 881,599 shares underlying private warrants, which are exercisable for shares of Common Stock commencing 30 days after the Closing of the Business Combination held by the Christopher C Dewey Trust DTD 5/3/18 and (iii) 67,500 shares of Common Stock issuable upon conversion of shares of Series A Convertible Preferred Stock held by the Christopher C Dewey Trust DTD 5/3/18. Mr. Dewey is the trustee of the Christopher C Dewey Trust DTD 5/3/18 and thus Mr. Dewey may be deemed to have beneficial ownership of the shares held directly by the Christopher C Dewey Trust DTD 5/3/18.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Other than the compensation arrangements for TriSalus' directors and executive officers, which are described in the section entitled "*Executive Compensation*", below is a description of transactions since January 1, 2022, to which TriSalus was a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal year; and
- any of TriSalus' directors, executive officers or holders of more than 5% of TriSalus' capital stock, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

Compensation Arrangements and Stock Option Grants for Executive Officers and Directors

TriSalus has employment arrangements with its NEOs that, among other things, provide for certain change in control benefits, as well as severance benefits. For a description of these agreements, see "*Executive Compensation*."

TriSalus has granted stock options and RSUs to its executive officers and stock options to certain of its directors. For a description of these equity awards, see "*Executive Compensations — Employment Arrangements with Executive Officers*" and "*Executive Compensation — Outstanding Equity Awards as of December 31, 2023*."

Indemnification Agreements

TriSalus has entered into indemnification agreements with its executive officers and directors. The indemnification agreements require TriSalus to indemnify its executive officers and directors to the fullest extent permitted by Delaware law.

TriSalus has also entered into an indemnification agreement with Dr. Katz with respect to legal fees, judgments and awards in relation to third party claims arising out of the prior consulting services on behalf of TriSalus pursuant to a consulting agreement with SCKMD Consulting, under which Dr. Katz provided consulting services to TriSalus prior to his becoming an employee.

Series B-1 Preferred Stock Financing

In September 2021, with subsequent closings through July 2022, Legacy TriSalus entered into a Stock Purchase Agreement, as amended, with a group of investors (the "Series B-1 SPA") pursuant to which it issued and sold an aggregate of 1,659,672 shares of its series B-1 preferred stock ("Series B-1 Stock") to such investors at a purchase price of $14.16 per share, for aggregate gross proceeds of approximately $23.5 million.

Pursuant to the Series B-1 SPA, Legacy TriSalus issued and sold to Frankenius 1,059,365 shares of Series B-1 Stock, resulting in aggregate gross proceeds of approximately $15.0 million to Legacy TriSalus.

Series B-2/B-3 Preferred Stock Financing

In October 2022, Legacy TriSalus entered into a Preferred Stock and Warrant Purchase Agreement (the "Series B-2/B-3 Purchase Agreement") pursuant to which it issued and sold an aggregate of 706,243 shares of its series B-2 preferred shares ("Series B-2 Stock") to investors at a purchase price of $14.16 per share, for aggregate gross proceeds of approximately $10 million. For each such share of Series B-2 Stock sold under the Series B-2/B-3 Purchase Agreement, Legacy TriSalus also issued a warrant to purchase four shares of its series B-3 preferred stock ("Series B-3 Stock") for no additional consideration (for an aggregate of 2,824,974 warrants issued in connection with the initial issuance of Series B-2 Stock). The strike price of the warrants issued in the financing was $2.03 per share. The Series B-2/B-3 Purchase Agreement included, at the option of Legacy TriSalus, a second tranche for the sale of up to 518,854 shares of Series B-2 Stock for approximately $7.3 million (which could be increased up to an aggregate of 706,243 shares of Series B-2 Stock for approximately $10.0 million), with each such share of Series B-2 Stock accompanied by a warrant to purchase four shares of Series B-3 Stock at a strike price of $2.03 per share (warrants to purchase up to an aggregate of 2,824,974 shares of Series B-3 Stock may be issued in second tranche closings assuming the full $10.0 million is sold); and a third tranche, at the election of investors who participated in the second tranche, for the sale of up to 306,053 shares of Series B-2 Stock for approximately $4.3 million (which could be increased up to an aggregate of 353,121 shares of Series B-2 Stock for approximately $5.0 million), with each such share of Series B-2 Stock accompanied by a warrant to purchase eight shares of Series B-3 Stock at a strike price of $2.03 per share (warrants to purchase up to an aggregate of 2,824,974 shares of Series B-3 Stock may be issued in the third tranche closing assuming the full $5.0 million is sold).

In March 2023, Legacy TriSalus effectuated two closings of the second tranche under the Series B-2/B-3 Purchase Agreement whereby (i) 207,541 shares of Series B-2 Stock and accompanying warrants to purchase 830,167 shares of Series B-3 Stock, representing 40% of the shares committed in the second tranche, were sold for an aggregate purchase price of approximately $2.9 million, and (ii) 17,656 shares of Series B-2 Stock and accompanying warrants to purchase 70,624 shares of Series B-3 Stock, none of which were shares committed in the second tranche, were sold for an aggregate purchase price of $0.2 million. The series B-2/B-3 preferred stock financing was deemed to be non-compensatory to the participating directors and officers because (i) the issuance was not associated to services, (ii) the participating directors and officers participated on the same terms as all parties, and (iii) the participating parties who were non-insiders (i.e., non-service providers) represented greater than 50% of the participation.

In June 2023, Legacy TriSalus effectuated two closings of the second tranche under the Series B-2/B-3 Purchase Agreement whereby (i) 257,779 shares of Series B-2 Stock and accompanying warrants to purchase 1,031,116 shares of Series B-3 Stock, representing approximately 49.7% of the shares committed in the second tranche, were sold for an aggregate purchase price of approximately $3.7 million, and (ii) 165,967 shares of Series B-2 Stock and accompanying warrants to purchase 663,868 shares of Series B-3 Stock, none of which were shares committed in the second tranche, were sold for an aggregate purchase price of approximately $2.3 million. The Series B-2/B-3 preferred stock financing was deemed to be non-compensatory to the participating directors and officers because (i) the issuance was not associated to services, (ii) the participating directors and officers participated on the same terms as all parties, and (iii) the participating parties who were non- insiders (i.e., non-service providers) represented greater than 50% of the participation.

Pursuant to the Series B-2/B-3 Purchase Agreement, Legacy TriSalus issued and sold to Frankenius an aggregate of 655,909 shares of Series B-2 Stock and warrants purchase 2,623,637 shares of Series B-3 Stock, resulting in aggregate gross proceeds of $9.3 million to Legacy TriSalus.

Pursuant to the Series B-2/B-3 Purchase Agreement, Legacy TriSalus issued and sold shares to various entities associated with Mr. Wahlström, one of its directors, including (i) 104,742 shares of Series B-2 Stock and warrants to purchase 418,970 shares of Series B-3 Stock to Leonard Capital and (ii) 109,470 shares of Series B-2 Stock and warrants to purchase 437,882 shares of Series B-3 Stock to HW Investment, resulting in aggregate gross proceeds of approximately $3.1 million to Legacy TriSalus.

Pursuant to the Series B-2/B-3 Purchase Agreement, Legacy TriSalus issued and sold shares to various entities associated with Mr. Hicks, including (i) 71,902 shares of Series B-2 Stock and warrants to purchase 287,608 shares of Series B-3 Stock to Mr. Hicks in his individual capacity and (ii) 109,470 shares of Series B-2 Stock and warrants to purchase 437,882 shares of Series B-3 Stock to HW Investment, resulting in aggregate gross proceeds of approximately $2.6 million to Legacy TriSalus.

Pursuant to the Series B-2/B-3 Purchase Agreement, Legacy TriSalus issued and sold to various entities associated with Sean Murphy, one of its executive officers, including (i) 87,397 shares of Series B-2 Stock and warrants to purchase 349,590 shares of Series B-3 Stock to the Murphy Family Trust 2012 and (ii) 17,656 shares of Series B-2 Stock and warrants to purchase 70,624 shares of Series B-3 Stock to the Sean E Murphy TTEE U/A 2/4/2004, resulting in aggregate gross proceeds of approximately $1.5 million to Legacy TriSalus.

Pursuant to the Series B-2/B-3 Purchase Agreement, Legacy TriSalus issued and sold to Ms. Szela, one of its executive officers, 32,116 shares of Series B-2 Stock and warrants to purchase 128,466 shares of Series B-3 Stock, resulting in aggregate gross proceeds of approximately $454,754 to Legacy TriSalus.

Pursuant to the Series B-2/B-3 Purchase Agreement, Legacy TriSalus issued and sold to Mr. McGrevin 33,490 shares of Series B-2 Stock and warrants to purchase 133,961 shares of Series B-3 Stock, resulting in aggregate gross proceeds of approximately $474,205 to Legacy TriSalus.

Pursuant to the Series B-2/B-3 Purchase Agreement, Legacy TriSalus issued and sold to Dr. Katz, one of its executive officers, 2,411 shares of Series B-2 Stock and warrants to purchase 9,645 shares of Series B-3 Stock, resulting in aggregate gross proceeds of $34,143 to Legacy TriSalus.

Pursuant to the Series B-2/B-3 Purchase Agreement, Legacy TriSalus issued and sold to Dr. Cox, one of its executive officers, 1,674 shares of Series B-2 Stock and warrants to purchase 6,698 shares of Series B-3 Stock, resulting in aggregate gross proceeds of $23,710 to Legacy TriSalus.

Pursuant to the Series B-2/B-3 Purchase Agreement, Legacy TriSalus issued and sold to Richard Marshak, one of its executive officers, 1,674 shares of Series B-2 Stock and warrants to purchase 6,698 shares of Series B-3 Stock, resulting in aggregate gross proceeds of $23,710 to Legacy TriSalus.

In July 2023, holders of warrants to purchase 2,306,471 shares of Series B-3 Stock exercised their warrants, resulting in gross proceeds of approximately $4.5 million. The list below sets forth the number of shares of Series B-3 Stock purchased by related parties pursuant to the exercise of warrants to purchase Series B-3 Stock.

- Leonard Capital, associated with Mr. Wahlström, purchased 249,471 shares of Series B-3 Stock for $504,625.
- Sean E Murphy TTEE U/A 2/4/2004, associated with Mr. Murphy, purchased 134,186 shares of Series B-3 Stock for $271,428.
- HW Investment, associated with Mr. Wahlström and Mr. Hicks, purchased 122,680 shares of series B-3 Stock for $248,155.
- Mr. McGrevin purchased 63,337 shares of Series B-3 Stock for $128,118.
- Cox purchased 3,166 shares of Series B-3 Stock for $6,406.
- Mr. Marshak purchased 3,166 shares of Series B-3 Stock for $6,406.

Amended and Restated Registration Rights Agreement

On the Closing Date, in connection with the consummation of the Business Combination and as contemplated by the Merger Agreement, TriSalus, Sponsor, the members of the Sponsor, and the directors and officers and certain former stockholders of Legacy TriSalus entered into an amended and restated registration rights agreement (the "Amended and Restated Registration Rights Agreement"). Pursuant to the Amended and Restated Registration Rights Agreement, the Company agreed to file, not later than 45 days after the Closing Date, a registration statement to register for resale, pursuant to Rule 415 under the Securities Act, certain TriSalus securities that are held by the parties thereto (the "Registrable Securities"). Pursuant to the Amended and Restated Registration Rights Agreement, subject to certain requirements and customary conditions, the Company also grants piggyback registration rights and demand registration rights to the parties thereto, will pay certain expenses related to such registration and will indemnify the parties thereto against certain liabilities related to such registration. The Amended and Restated Registration Rights Agreement will terminate with respect to any party thereto, on the date that such party no longer holds any Registrable Securities.

Placement Agent Services from Ceros

We engaged Ceros, an SEC registered broker/dealer and FINRA member firm, to act as our placement agent for the non-institutional equity financing component of the Future PIPE Investment that resulted in our entry into the Subscription Agreements as part of the Preferred Stock PIPE Investment. Christopher Dewey, our former Chief Executive Officer and director, as well as a Managing Member of the Sponsor, is a Managing Director of Ceros. In consideration for its services as placement agent, Ceros received a fee from the Sponsor equal to 10% of the gross proceeds received by us in the Preferred Stock PIPE Investment (excluding amounts raised from stockholders or members of the Company, the Sponsor, Legacy TriSalus, or their affiliates and certain designees) plus expense reimbursement. As part of the engagement, the Sponsor paid the entirety of such placement agent fees and Ceros has agreed that we shall not be responsible or liable for any portion of such payment. Ceros' placement agent fees were contingent upon the completion of the Preferred Stock PIPE Investment, which closed in connection with the Business Combination.

Promissory Notes — Related Party

On December 30, 2021, we issued an unsecured promissory note to the Sponsor (as amended, the "2021 Promissory Note"), pursuant to which we could borrow up to an aggregate principal amount of $544,000. The 2021 Promissory Note was non-interest bearing. On December 2, 2022, the 2021 Promissory Note was amended to clarify that no amount shall be due under the note if a business combination is not consummated on or before the outside date to consummate a business combination pursuant to the Existing Charter.

On January 28, 2022, we issued an unsecured promissory note to the Sponsor (as amended, the "January 2022 Promissory Note") in principal amount of up to $400,000. The January 2022 Promissory Note was non-interest bearing. On December 2, 2022, he January 2022 Promissory Note was amended to clarify that no amount shall be due under the note if a business combination is not consummated on or before the outside date to consummate a business combination pursuant to the Existing Charter.

On May 24, 2022, we issued a promissory note in the principal amount of up to $1,500,000 to the Sponsor for working capital requirements and payment of certain expenses in connection with a potential business combination transaction (the "Convertible Sponsor Note"). The Convertible Sponsor Note was non-interest bearing and became payable on the date of the Closing of the Business Combination. At any time prior to payment in full of the principal balance of the Convertible

Sponsor Note, the Sponsor was permitted to elect to convert all or any portion of the unpaid principal balance into that number of warrants, each exercisable for one share of Common Stock (the "Conversion Warrants"), equal to: (x) the portion of the principal amount of the Convertible Sponsor Note being converted, divided by (y) $1.50, rounded up to the nearest whole number of warrants. Each Conversion Warrant entitles the holder to purchase one share of Common Stock at $11.50 per share, subject to adjustment. The Conversion Warrants and their underlying securities are entitled to certain demand and piggyback registration rights as set forth in the Convertible Sponsor Note. On August 10, 2023, the Convertible Sponsor Note was converted into 1,000,000 Conversion Warrants.

On December 16, 2022, we issued an unsecured promissory note to the Sponsor (the "December 2022 Promissory Note", together with the 2021 Promissory Note and the January 2022 Promissory Note, the "Sponsor Promissory Notes") in principal amount of up to $1,000,000. The December 2022 Promissory Note was non-interest bearing. At the Closing of the Business Combination, we repaid the Sponsor Promissory Notes out of the proceeds of the Trust Account released to us (subject to the MTAC Transaction Expenses Cap (as defined in the Merger Agreement)).

Working Capital Loans

In order to fund working capital deficiencies or finance transaction costs in connection with negotiating and consummating an initial business combination, the Sponsor or an affiliate of the Sponsor, or certain of our officers and directors loaned to us additional funds as may be required ("Working Capital Loans"). At the Closing of the Business Combination, we repaid the Working Capital Loans out of the proceeds of the Trust Account released to us (subject to the MTAC Transaction Expenses Cap).

Promissory Notes — Related Party Extension Loans

At the special meeting of MTAC stockholders held on December 12, 2022 (the "First Extension Meeting"), the stockholders approved an amendment to MTAC's then-current charter (the "First Extension Amendment"), which extended the date by which MTAC was required to (i) consummate an initial business combination or (ii) dissolve and liquidate, from December 22, 2022 to June 22, 2023. In connection with the First Extension Amendment, the Sponsor agreed to, among other things, deposit, or cause the deposit of, $0.04 for each of the 1,953,422 public shares that were not redeemed in connection with the First Extension Meeting, for a monthly contribution into the Trust Account of $78,136.88 and an aggregate contribution of $468,821.28.

At the special meeting of MTAC stockholders held on June 12, 2023 (the "Second Extension Meeting"), the stockholders approved an amendment to MTAC's then-current charter (the "Second Extension Amendment"), which extended the date by which MTAC was required to (i) consummate an initial business combination or (ii) dissolve and liquidate, from June 22, 2023 to September 22, 2023. In connection with the Second Extension Amendment, the Sponsor agreed to, among other things, deposit, or cause the deposit of, $0.04 for each of the 1,144,794 public shares that were not redeemed in connection with the Second Extension Meeting, for a monthly contribution into the Trust Account of $45,791.76 and an aggregate contribution of $91,583.52.

Pursuant to the Merger Agreement, Legacy TriSalus agreed to pay for, as a transaction expense and not as a loan, 50% of the Sponsors contributions into the Trust Account until the earliest to occur of (i) the Closing and (ii) the valid termination of the Merger Agreement.

When we completed the Business Combination, we repaid the Sponsor Notes (representing the Sponsor's allocable 50% portion of the contributions into the Trust Account) out of the proceeds of the Trust Account released to us (subject, in the case of the Business Combination, to the MTAC Transaction Expenses Cap).

Related Person Transaction Policy

Our board of directors has adopted a written related person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related person transactions." For purposes of our policy only, a "related person transaction" will be considered a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which the Company or any of its subsidiaries are participants involving an amount that exceeds $120,000, in which any "related person" has a material interest.

Transactions involving compensation for services provided to the Company as an employee, consultant or director will not be considered related person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than 5% of any class of the Company's voting securities (including the Common Stock), including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, the related person in question or, in the case of transactions with an entity holding more than 5% of any class of the Company's voting securities, an officer with knowledge of a proposed transaction, must present information regarding the proposed related person transaction to the Company's audit committee (or, where review by the Company's audit committee would be inappropriate, to another independent body of the Board) for review. To identify related person transactions in advance, the Company will rely on information supplied by the Company's executive officers, directors and certain significant stockholders. In considering related person transactions, the Company's audit committee will take into account the relevant available facts and circumstances, which may include, but are not limited to:

- The risks, costs, and benefits to the Company;
- The impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- The terms of the transaction;
- The availability of other sources for comparable services or products; and
- The terms available to or from, as the case may be, unrelated third parties.

The Company's audit committee will approve only those transactions that it determines are fair and in the Company's best interests. All of the transactions described above were entered into prior to the adoption of such policy.

Director Independence

Based on information provided by each director concerning his or her background, employment and affiliations, each of the directors on the Board, other than Mary Szela and Sean Murphy, qualify as independent directors, as defined under the Nasdaq Stock Exchange ("Nasdaq") listing rules (the "Nasdaq listing rules"), and the Board consists of a majority of "independent directors," as defined under the rules of the SEC and Nasdaq listing rules relating to director independence requirements. In addition, the Company is subject to the rules of the SEC and Nasdaq relating to the membership, qualifications and operations of the audit committee.

Item 14. Principal Accounting Fees and Services

For the years ended December 31, 2023 and 2022, KPMG LLP ("KPMG") and WithumSmith+Brown, PC ("Withum") performed professional services for us. The professional services provided by KPMG and the fees billed for those services are set forth below.

Audit Fees

The aggregate fees billed by KPMG for the audit and related services of our annual financial statements for the fiscal years ended December 31, 2023 and 2022, were $2,407,078 and $590,254, respectively.

Audit-Related Fees

The aggregate fees billed by Withum for assurance and related services that were reasonably related to the audit or review of our financial statements for the fiscal years ended December 31, 2023, were $102,960.

Tax Fees

The aggregate fees billed by KPMG for tax services for the fiscal years ended December 31, 2023 and 2022, were $67,643 and $55,750, respectively.

All Other Fees

No fees were billed by KPMG or Withum for services other than those reported above for each of the fiscal years ended December 31, 2023 and 2022.

Audit Committee's Pre-Approval Policies and Procedures

The Audit Committee must pre-approve the audit and non-audit services rendered by our independent registered public accounting firm. The Audit Committee has adopted a policy and procedures for the pre-approval of such audit and non-audit services. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services with the fee levels for such services to be established periodically by the Audit Committee . Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide such service.

The pre-approval authority may be delegated to one or more of the Audit Committee's members, but any pre-approval decisions must be reported to the full Audit Committee at its next scheduled meeting. Pursuant to the policy, the Audit Committee has delegated pre-approval authority to its Chair.

The Audit Committee has determined that the rendering of services other than audit services by KPMG is compatible with maintaining the principal accountant's independence.

Part IV

Item 15. Exhibit and Financial Statement Schedules

(a) The following documents are filed as part of this Form 10-K:

(1) Financial Statements:

Our Consolidated Financial Statements are listed in the "Index to Consolidated Financial Statements" under Part II. Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules:

Financial statement schedules have been omitted in this report because they are not applicable, not required under the instructions, or the information requested is set forth in the consolidated financial statements or related notes thereto.

(3) Exhibits

The exhibits filed as part of the Annual Report on Form 10-K are listed in Item 15(b).

(b) Exhibits

The following exhibits are filed as part of this Annual Report on Form 10-K:

		Incorporated by Reference			
Exhibit	Description	Schedule/ Form	File Number	Exhibits	Filing Date
2.1#	Agreement and Plan of Merger, dated as of November 11, 2022, by and among MedTech Acquisition Corporation, MTAC Merger Sub, Inc., and TriSalus Life Sciences, Inc.	Form 8-K	001-39813	2.1	November 14, 2022
2.2	First Amendment to Agreement and Plan of Merger, dated as of April 4, 2023, by and among MedTech Acquisition Corporation, MTAC Merger Sub, Inc., and TriSalus Life Sciences, Inc.	Form 8-K	001-39813	10.1	April 5, 2023
2.3	Second Amendment to Agreement and Plan of Merger, dated as of May 13, 2023, by and among MedTech Acquisition Corporation, MTAC Merger Sub, Inc., and TriSalus Life Sciences, Inc.	Form 8-K	001-39813	10.1	May 13, 2023
2.4	Third Amendment to Agreement and Plan of Merger, dated as of July 5, 2023, by and among MedTech Acquisition Corporation, MTAC Merger Sub, Inc., and TriSalus Life Sciences, Inc.	Form 8-K	001-39813	10.1	July 6, 2023
3.1	Second Amended and Restated Certificate of Incorporation of TriSalus Life Sciences, Inc.	Form 8-K	001-39813	3.1	August 16, 2023
3.2	Amended and Restated Bylaws of TriSalus Life Sciences, Inc.	Form S-4/A	333-251037		June 8, 2023

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
3.3	Form of Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock of TriSalus Life Sciences, Inc.	Form S-4/A	333-251037		June 8, 2023
4.1	Description of Capital Stock				
4.2	Reference is made to Exhibit 3.1 and 3.2.				
4.3	Form of Amended and Restated Registration Rights Agreement, by and among TriSalus Life Sciences, Inc., MedTech Acquisition Sponsor LLC, and certain former stockholders of TriSalus Life Sciences, Inc.	Form 8-K	001-39813	10.1	November 14, 2022
4.4	Warrant Agreement, dated December 17, 2020, by and between MTAC and Continental Stock Transfer & Trust Company.	Form 8-K	001-39813	4.1	December 23, 2020
4.5	Specimen Common Stock Certificate	Form 8-K	001-39813	4.1	August 16, 2023
4.6	Specimen Warrant Certificate	Form 8-K	001-39813	4.2	August 16, 2023
10.1*	TriSalus Life Sciences, Inc. 2023 Equity Incentive Plan	Form 8-K	001-39813	10.2	August 16, 2023
10.2*	TriSalus Life Sciences, Inc. 2023 Employee Stock Purchase Plan	Form 8-K	001-39813	10.2	June 8, 2023
10.3*	Letter Agreement, dated December 17, 2020, by and among MedTech Acquisition Corporation, its officers and directors and	Form 8-K	001-39813	10.1	December 23, 2020
10.4*	Surefire Medical, Inc. 2009 Amended and Restated Equity Incentive Plan.	Form 8-K	001-39813	10.15	August 16, 2023
10.5*	Form of Stock Option Grant Notice and Form of Stock Option Agreement under Surefire Medical, Inc. 2009 Amended and Restated Equity Incentive Plan (Pre-2020).	Form 8-K	001-39813	10.16	August 16, 2023
10.6*	Form of Early Exercise Stock Option Grant Notice and Form of Stock Option Agreement under Surefire Medical, Inc. 2009 Amended and Restated Equity Incentive Plan (for grants prior to 2020).	Form 8-K	1-39813	10.17	August 16, 2023
10.7*	Form of Stock Option Grant Notice and Form of Stock Option Agreement under Surefire Medical, Inc. 2009 Amended and Restated Equity Incentive Plan (for grants after 2020).	Form 8-K	001-39813	10.18	August 16, 2023
10.8*	Form of Early Exercise Stock Option Grant Notice and Form of Stock Option Agreement under Surefire Medical, Inc. 2009 Amended and Restated Equity Incentive Plan (for grants after 2020).	Form 8-K	001-39813	10.19	August 16, 2023

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
10.9*	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Agreement under Surefire Medical, Inc. 2009 Amended and Restated Equity Incentive Plan.	Form 8-K	001-39813	10.20	August 16, 2023
10.10*	Form of Stock Option Grant Notice and Form of Stock Option Agreement under 2023 Equity Incentive Plan.	Form 8-K	001-39813	10.22	August 16, 2023
10.11*	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Agreement under 2023 Equity Incentive Plan.	Form 8-K	001-39813	10.23	August 16, 2023
10.12*	Form of Indemnification Agreement by and between the Company and its directors and executive officers.	Form 8-K	001-39813	10.25	August 16, 2023
10.13*	Non-Employee Director Compensation Policy.	Form 8-K	001-39813	10.26	August 16, 2023
10	Standby Equity Purchase Agreement, by and between TriSalus Life Sciences, Inc. and YA II PN, LTD.	Form 10-Q	333-269138	10.10	November 14, 2023
10.15##	Asset Purchase Agreement, dated as of July 31, 2020, by and between Dynavax Technologies Corporation and Surefire Medical Inc. d/b/a TriSalus Life Sciences.	Form S-4/A	333-269138	10.13	April 21, 2023
10.16*##	Amended and Restated Employment Agreement, dated November 11, 2022, by and between TriSalus Life Sciences, Inc. and Mary Szela.	Form S-4/A	333-269138	10.14	April 21, 2023
10.17*##	Amended and Restated Employment Agreement, dated November 12, 2022, by and between TriSalus Life Sciences, Inc. and Steven C. Katz, MD.	Form S-4/A	333-269138	10.15	April 21, 2023
10.18*##	Executive Employment Agreement, dated July 9, 2022, by and between TriSalus Life Sciences, Inc. and Sean Murphy.	Form S-4/A	333-269138	10.16	April 21, 2023
10.19*##	Amended and Restated Executive Employment Agreement, dated October 11, 2022, by and between TriSalus Life Sciences, Inc. and Richard Marshak.	Form S-4/A	333-269138	10.17	April 21, 2023
10.20*##	Executive Employment Agreement, dated November 11, 2022, by and between TriSalus Life Sciences, Inc. and Jennifer L. Stevens.	Form S-4/A	333-269138	10.18	April 21, 2023
10.21*##	Executive Employment Agreement, dated November 4, 2022, by and between TriSalus Life Sciences, Inc. and Bryan F. Cox, Ph.D.	Form S-4/A	333-269138	10.19	April 21, 2023
10.22*##	Executive Employment Agreement, Dated August 28, 2023, by and between TriSalus Life Sciences, Inc. and Jodi Devlin	Form S-1/A	333-269138	10.14	October 19, 2023

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
10.23*##	Strategic Collaboration Agreement, dated March 2, 2021, by and between Surefire Medical Inc. d/b/a TriSalus Life Sciences and The University of Texas M.D.	Form S-4/A	333-269138	10.20	April 21, 2023
10.24*##	Distribution and Collaboration Agreement, dated May 7, 2019, between Hangzhou Ruizhen Therapeutics Co., Ltd. and Surefire Medical, Inc. d/b/a TriSalus Life	Form S-4/A	333-269138	10.24	June 8, 2023
10.25*##	Office/Warehouse Lease, dated February 4, 2014 between Colorado Industrial Portfolio LLC and Surefire Medical, Inc., as amended.	Form S-4/A	333-269138	10.25	July 6, 2023
21.1	List of Subsidiaries.	Form S-4	333-269138	21.1	January 6, 2023
23.1	Consent of KPMG LLP, independent registered public accounting firm of TriSalus.				
24.1	Power of Attorney (see signature page).				
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
97.1	TriSalus Life Sciences, Inc. Incentive Compensation Recoupment Policy.				
101.INS	Inline XBRL Instance Document – the instance documents does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.				

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
101.SCH	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents.				
104	Cover Page (formatted as Inline XBRL and contained in Exhibit 101)				

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* Indicates management contract or compensatory plan or arrangement.

\# Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request; provided, however, that the Registrant may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act, as amended, for any schedule or exhibit so furnished.

\## Certain portions of this Exhibit have been omitted in accordance with Regulation S-K Item 601(b)(10)(iv) because they are not material and are the type of information that the Registrant treats as private or confidential. The Registrant agrees to furnish supplementally an unredacted copy of the Exhibit, or any section thereof, to the SEC upon request.

^ The certifications attached as Exhibits 32.1 and 32.2 are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Form 10-K), irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this Annual Report on Form 10-K statement to be signed on its behalf by the undersigned, thereunto duly authorized, on the 11th day of April, 2024.

TriSalus Life Science, Inc.

By: /s/ Mary Szela
Name: Mary Szela
Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mary Szela and Sean Murphy, and each of them, his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Mary Szela Mary Szela	Chief Executive Officer and Director *(Principal Executive Officer)*	April 11, 2024
/s/ Sean Murphy Sean Murphy	Chief Financial Officer and Director *(Principal Financial and Accounting Officer)*	April 11, 2024
/s/ Mats Wahlström Mats Wahlström	Chairman	April 11, 2024
/s/ Arjun "JJ" Desai Arjun "JJ" Desai	Director	April 11, 2024
/s/ Andrew von Eschenbach Andrew von Eschenbach	Director	April 11, 2024
/s/ Kerry Hicks Kerry Hicks	Director	April 11, 2024
/s/ George Kelly Martin George Kelly Martin	Director	April 11, 2024
/s/ David J. Matlin David J. Matlin	Director	April 11, 2024
/s/ Anil K. Singhal Anil K. Singhal	Director	April 11, 2024

CORPORATE INFORMATION

EXECUTIVE OFFICERS

Mary Szela
Chief Executive, President, and Director

Sean Murphy
Chief Financial Officer and Director

Dr. Steven Katz
Chief Medical Officer, Scientific Advisory Board Chairman

Bryan Cox
Chief Scientific and Manufacturing Officer

Jennifer Stevens
Chief Regulatory Officer

Richard Marshak
Senior Vice President, Corporate Development and Strategy

Jodi Devlin
President, Commercial Operation

BOARD OF DIRECTORS

Mats Wahlström
Chairman of the Board,
TriSalus Life Sciences, Inc
Co-Chairman,
HW Investment Partners, LLC
Partner and Executive Chairman,
KMG Capital Partners, LLC

Andrew von Eschenbach
President and Founder,
Samaritan Health Initiatives, Inc.

George Kelly Martin
Chairman,
Transition Bio, Inc.
Wave Break (formerly Wren Therapeutics, Inc.)
Vice Chairman,
Ride Therapeutics, Inc.

David J. Matlin
Co-founder and Chief Executive Officer
MatlinPatterson Global Advisers, LLC

Dr. Arjun Desai
Chief Strategic Innovation Officer
Insightec

Kerry Hicks
Partner, Chief Executive Officer, and President,
KMG Capital Partners, LLC
Executive Chairman and Partner,
HW Investment Partners, LLC

Dr. Anil Singhal
President and Chief Executive Officer,
Trishula Therapeutics

Liselotte Hyveled
Chief Patient Officer
Novo Nordisk

ANNUAL REPORT

Included in this Annual report is a copy of TriSalus Life Sciences, Inc. Form 10-K filed with the U.S. Securities and Exchange Commission for the fiscal year ended December 31, 2023. Additional copies of the Company's Form 10-K and other information are available at https://trisaluslifesci.com/ or upon written request to:

James Young
Senior Vice President, Investor Relations, and Treasurer
TriSalus Life Sciences, Inc.
6272 W. 91st Avenue
Westminster, CO 80031 USA
Email: investor.relations@trisaluslifesci.com

ANNUAL MEETING

All shareholders are invited to attend TriSalus's Annual Meeting of Shareholders to be held virtually via live webcast on Thursday, August 13th, 2024, at 8 A.M Central Time.

STOCK TRANSFER AGENT/REGISTRAR

Continental Stock Transfer & Trust
1 State Street, 30th Floor
New York, N.Y. 10004-1561
T: (800) 509-5586
https://continentalstock.com/

MARKET INFORMATION

TriSalus's common stock is traded on the NASDAQ Global Select Market System under the symbol "TLSI".

INDEPENDENT ACCOUNTING FIRM

Grant Thornton, LLP
171 N. Clark Street
Suite 200
Chicago, IL 60601

LEGAL COUNSEL

Cooley, LLP
Corporate and Securities Counsel
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