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, 2024

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: (888) 321-5212	**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 $82,407,511 as of June 28, 2024 (the last trading day of the registrant's most recently completed second quarter), based on the closing price of $5.52 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 32,272,462 shares of common stock as of March 31, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2025 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than April 30, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ending December 31, 2024, ("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, the plans and objectives of management for future operations, statements regarding future economic conditions or performance and statements of belief and any statement of assumptions underlying any of the foregoing. 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. You should not place undue reliance on these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A, "Risk Factors" of this

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Annual Report. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. 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. 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 need for additional capital raises substantial doubt about our ability to continue as a going concern. 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.
- 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.
- We may not be able to generate sufficient cash to service our indebtedness or borrow additional funds pursuant to our Loan Facility.
- 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 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 for nelitolimod, and 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 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.
- 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

Unless the context indicates otherwise, references in this Annual Report to the "Company," "TriSalus," "we," "us," "our" and similar terms refer to TriSalus Life Sciences, Inc. (f/k/a MedTech Acquisition Corp.), a Delaware corporation and its consolidated subsidiaries.

Overview

We are a growing, oncology focused medical technology business seeking to transform outcomes for patients with solid tumors by integrating our innovative delivery technology with standard-of-care therapies, and with our investigational immunotherapeutic, nelitolimod, a class C Toll-like receptor 9 ("TRL9") agonist, for a range of different therapeutic and technology applications. Our ultimate goal is to transform the treatment paradigm for patients battling solid tumors. We have developed an innovative technology 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) off target delivery. Nelitolimod, specifically, combined with our technology aims to address the immunosuppressive properties of tumor immune cells in liver, pancreas and other solid tumors. By systematically addressing these barriers, we aim to improve response to therapies and to enable improved patient outcomes.

Background

Many solid tumors, especially desmoplastic tumors like pancreatic ductal adenocarcinoma (PDAC), have high interstitial fluid pressure which creates a physical barrier preventing therapeutics from penetrating the tumor. Beyond penetration issues, the blood vessels that supply these tumors are leaky and disorganized, leading to poor distribution of the therapeutic within the tumor.

We have developed a platform approach to address the unique challenges of drug delivery to solid tumors with the goal of overcoming the two primary barriers described above that limit therapeutic delivery and inhibits treatment success:

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 thereby increasing 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 primary liver cancer or in patients with liver metastases. TriNav is a highly innovative and novel device that is FDA-cleared and has undergone peer-reviewed studies at multiple clinical sites. The PEDD method has now been used in over 21,000 procedures, primarily TACE and TARE. TriNav achieved $29.4 million in revenue in 2024 representing growth of 59.0% 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 and has completed enrollment in a Phase 1 clinical trial. Although FDA-cleared, the PRVI device has not yet been commercialized and commercial sale is not anticipated before 2026.

We are currently studying the ability of nelitolimod, an investigational class C 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.

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 or other classes of immunotherapeutics, such as cell therapeutics, and, based on published clinical and preclinical data, may prove beneficial when co-administered with currently approved chemotherapeutics and radiation.

We are in the early stages of our development efforts and have only one product candidate, nelitolimod, in early clinical development. We have initiated Phase 1 and Phase 1b clinical trials for nelitolimod, each of which are focused on a different target indication, specifically: uveal melanoma, intrahepatic cholangiocarcinoma and hepatocellular carcinoma ("UMLM", "ICC" and "HCC", respectively), and pancreatic cancer. We expect that any continued investigation for ICC and HCC may continue through Investigator Initiated Trials (IITs). Based on the changing landscape for second line treatment of UMLM, we do not intend to proceed to Phase II trials for that indication on our own, but we are looking for potential partners to advance that indication. Our Phase I PERIO-03 clinical trial in pancreatic cancer is enrolled and we anticipate data from the study will be available by the end of 2025, depending on when treatment is completed.

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 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.

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 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 ($88.7 \pm 10.6\%$ vs 55.3 ± 32.7 %; $p=0.002$)

Real-world Support

TriSalus recently published a Health Economic and Outcome Research ("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 603 PEDD patients with those of 16,210 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 showed reduced rates of post-procedure fatigue compared to non-TriNav patients
- 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 TACE 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.
- In patients with HCC, TriNav patients showed lower rates of post-procedural gastric ulcers and jaundice.

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.

TriNav Market Opportunity

TACE and TARE are widely used locoregional therapies for HCC, colorectal liver metastases ("CRLM"), and neuroendocrine tumor ("NET") liver metastases. However, significant unmet medical needs remain. One major challenge is inconsistent drug delivery; traditional embolization techniques often result in suboptimal drug penetration due to high intratumoral pressure and poor perfusion, limiting treatment efficacy. Additionally, tumor heterogeneity and vascular variability can lead to uneven distribution of therapeutic agents, reducing overall response rates. Another key limitation is treatment resistance and recurrence, as embolization alone does not fully eradicate microscopic disease, necessitating repeat procedures that may compromise liver function over time. Furthermore, post-embolization syndrome, characterized by pain, fever, and liver dysfunction, impacts patient quality of life and may delay subsequent treatments.

TriNav is focused on improved therapeutic delivery and reduction of off target effects on a range of liver tumors including HCC, colorectal liver metastasis and neuro endocrine tumors. The incidence of primary and metastatic liver tumors has been increasing, presenting a large opportunity given the poor outcomes associated with liver cancers, whether primary or metastatic. According to the American Cancer Society, primary liver tumors, including ICC and HCC, currently represent more than 42 thousand 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 60% of these patients are eligible for TACE or TARE procedures and that between 75% and 80% are appropriate candidates for our current TriNav device, representing a potential market opportunity of approximately 62 thousand units, or approximately $494.0 million, based on our current price of $7,983.

TriSalus recently expanded its portfolio of PEDD devices with the launch of the TriNav LV Infusion System ("TriNav LV") and TriGuide Guiding Catheter to optimize therapeutic delivery for patients with larger vessels. The TriNav LV is suitable for patients with vessels sized between 3.5 and 5.0mm and is expected to allow us to meaningfully expand our addressable liver embolization market. The TriGuide Guiding Catheter has a larger inner diameter, lubricious inner lining, and reverse curve design to support femoral access for the TriNav LV, which we believes will enhance procedural efficiency. These new products are eligible for the same Healthcare Common Procedure Coding System ("HCPCS") reimbursement codes as existing TriNav products, enabling seamless integration into current billing structures.

One potential new application for TriNav LV is the use of the technology for uterine fibroid embolizations ("UFEs"). Roughly 10% of women aged 18-65 lives with uterine fibroid today and current treatment approaches include hysterectomy, endometrial ablation and uterine fibroid embolizations. We estimate TriNav LV is applicable for 20 thousand UFEs per year, expanding the market opportunity by approximately $160.0 million.

TriSalus also initiated a registry study called PROTECT (Pressure Enabled Retrograde Occlusive Therapy with Embolization for Control of Thyroid Disease) and intends to enroll 100 patients across at least five leading academic sites. It is estimated that approximately 5% of adults have multinodular goiters, and the prevalence in adults over 50 is estimated to be up to 50%. We estimate that this could expand the addressable market for TriNav by approximately 50 thousand procedures, representing an incremental $400.0 million market opportunity. This new procedure utilizing the TriNav system is also eligible for the same HCPCS reimbursement code allowing for seamless integration into current billing approaches.

Additionally, through our pancreas infusion technology we believe we can deliver to the site of disease (pancreatic tumor) in combination with systemic therapy allowing for maximum concentration of the therapeutic directly to the tumor with potential reduced toxicity. We believe that this technology potentially could treat 2 thousand patients annually adding an additional market expansion of $400.0 million.

Another potential application of TriNav is for the use in prostate embolization's. Current treatment options for men with enlarged prostate include prostatectomy, trans-urethral prostate resection, alpha blockers and 5-alpha reductase inhibitors and other options. Prostate embolization's offer a minimally invasive alternative to pharmaceutical side effects or surgical complications. We estimate that TriNav has potential in 25 thousand patients of the 100 thousand patients diagnosed with the disease.

The estimated total addressable market for TriSalus PEDD technology in the U.S. is project to exceed $1.6 billion annually. The market is divided into a current market valued at $900.0 million and an additional market opportunity estimated at $700.0 million. The analysis is based on patient population estimates for various conditions where PEDD may be applicable, including liver cancer, multinodular goiter, locally advanced pancreatic cancer, UFEs and prostate embolization.

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 (≥ 5 cm);
- Multiple comorbidities; and
- Hypovasular tumors.

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 Centers for Medicare & Medicaid Services ("CMS"), C9797, which has been assigned to APC 5194 (Level 4 Endovascular Procedures) for calendar year 2025 with a payment rate of $17,957. 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 code, reimbursement for TriNav has continued uninterrupted from the launch year. The 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. Effective April 1, 2025, TriNav received a second unique and permanent HCPCS code from CMS, C8004, which has been assigned to APC 5193 (Level 3

Endovascular Procedures) for the calendar year 2025 with a payment rate of $11,341. This new code provides reimbursement clarity for mapping procedures conducted prior to TARE.

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 ("VAC") 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 with 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. 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 sales 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. Our sales and marketing team totals 53 professionals as of December 31, 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 sales representatives. 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.

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 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 (e.g., Y90). However, standard microcatheters do not have the ability to modulate pressure and flow or to improve the T:N ratio, 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 Merit Medical's Swift NINJA.

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 Product Improvements

We are committed to advancing our technology to improve patient outcomes. Major areas of product enhancement underway at the Company includes incorporation of sensing and machine learning into our technology to improve patient outcomes while also exploring potential new applications outside of our current core focus on liver and pancreatic cancer. These include:

- **Precision therapeutic delivery** – By more accurately measuring both pressure and flow within blood vessels feeding tumors, we expect healthcare providers will be able to more efficiently and precisely overcome mechanical barriers in the tumor microenvironment.
- **Reduced treatment toxicity** – Fine-tuning treatment regimens based on real-time pressure and flow data may help minimize treatment toxicity by delivering therapeutic agents more precisely to the tumor while sparing healthy tissues. Current PEDD™ devices are able to significantly outperform conventional microcatheters in delivering more dose to the tumor while sparing normal tissue (improving the T:N Ration), and we are focused on enhancing this capability.
- **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.
- **Additional applications** – TriSalus continues to explore opportunities to improve patient outcomes in interventional radiology procedures beyond the liver and pancreas. Potential areas where PEDD™ devices may be able to improve outcomes and/or reduce post-embolization complications include benign goiter, UFE, geniculate artery embolization for osteoarthritis of the knee, and prostate embolization for prostatic hyperplasia, among others.

We are committed to enhancing our technology by incorporating new technologies that provide meaningful improvements in treatment outcomes and where we can gather new data to support continued product development. Most importantly, we are focused on improving personalized treatment strategies and improving patient outcomes in a range of disease areas. Research and development efforts are currently underway on a variety of different technologies with plans for future product launches within the next several years.

Pancreatic Retrograde Venous Infusion Device

Additionally, we are advancing our 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, pancreatic 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 not anticipated before 2026.

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.

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 and drive revenue growth.
- ***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 in collaborations designed to improve targeted 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 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 have initiated Phase 1 and Phase 1b clinical trials for nelitolimod, each of which are focused on a different target indication, specifically UMLM, ICC and HCC, and pancreatic cancer. We expect that any continued investigation for ICC and HCC will only continue through IITs. Based on the changing landscape for second line treatment of uveal melanoma, we do not intend to proceed to Phase II trials for that indication on our own, but we are looking for potential partners to advance that indication. Our Phase I PERIO-03 clinical trial in pancreatic cancer is enrolled and we anticipate data from the study will be available in sometime in 2025, depending on when treatment is completed.

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 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. Based on published clinical and preclinical data, TLR9 agonists may also have beneficial effects when combined with chemotherapeutics and/or radiation.

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 three thousand 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 tebentafusp (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.

Market Opportunity for 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 thousand new cases of primary and secondary liver cancers diagnosed annually in the U.S. alone, and more than 60 thousand cases of pancreatic cancer diagnosed each year. Of these, more than 80 thousand 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 thousand 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: UMLM

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. Kimmtrak was approved by the FDA 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. Based on the changing landscape of second line treatment of uveal melanoma, we do not intend to proceed to Phase II trials for that indication on our own, but we are looking for potential partners to advance that indication.

Clinical Site Partnership

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 have been 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 $8.0 million towards these studies. 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.

Nelitolimod Competition

We expect nelitolimod to compete primarily with a number of therapeutics that are now, or will soon be, approved for use in UMLM with liver metastases and locally advanced PDAC. These therapeutics include a range of immunotherapeutics (e.g., tebentafusp for HLA-A*02:01 positive metastatic uveal melanoma patients.

Uveal Melanoma

There are currently two FDA-approved therapies for uveal melanoma liver metastases, Immunocore's Kimmtrak® (tebentafusp) and Delcath's Hepzato Kit™. Kimmtrak 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. Hepzato Kit is designed to deliver high-dose chemotherapy to the liver while limiting systemic exposure. Hepzato Kit carries several black box warnings, is only available at select institutions through a Risk Evaluation and Management Strategy ("REMS"), and is associated with a high rate of Grade 3 or 4 adverse events. We believe that even with the availability of the Hepzato Kit, as an alternative for some uveal melanoma liver metastases patients, significant unmet needs remains for these patients.

Ideaya's Darovasertib, in combination with crizotinib, is currently being studied in HLA:A*02:01 negative patients in a potential 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.

Pancreatic Ductal Adenocarcinoma

Current preferred therapy for PDAC is either a clinical trial or chemotherapy (commonly the FOLFIRINOX regimen, ± subsequent chemoradiation with a more recent approval of NALIRIFOX which uses liposomal irinotecan rather than standard irinotecan). These chemotherapeutic treatments have significant toxicities and limited efficacy, leaving significant unmet medical need in this disease. In December 2024, the FDA approved BIZENGRI (Zenocutuzamab)for pancreatic adenocarcinoma that harbors NRG1 gene fusions and are advanced unresectable or metastatic. Revolution Medicine is in a Phase 3 registrational trial for RMC-6236, a RAS multi-selective inhibitor. Revolutions trial is anticipated to enroll approximately 460 patients who have received prior PDAC therapy and harbor RAS mutations. Other clinical trials for PDAC are early stage and are evaluating combinations of targeted therapies and immunotherapy.

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 $5.0 million, and on December 30, 2020, made an additional payment of $4.0 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 $170.0 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 $80.0 million. As of December 31, 2024 and 2023, we have made three milestone payments of $1.0 million each, totaling $3.0 million; no payments were made in the twelve months ended December 31, 2024.

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 $1.0 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

Manufacturing

We manufacture TriNav at our facility in Westminster, Colorado, and have adequate capacity to meet anticipated commercial and clinical demands through 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.

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 December 31, 2024, we owned at least 79 registered patents expiring between 2030 and 2040, with at least an additional 86 pending patent applications.

For our TriNav device, we are the sole owner of five granted U.S. patents, five pending U.S. patent applications, eight foreign patents (counting national validations in Europe) and two pending foreign patent applications in Canada and Europe 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 eight granted foreign patent expire 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, five pending U.S. patent applications, 12 granted foreign patents (counting national validations in Europe) and two pending foreign patent applications in China and Europe 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 awaiting three pending U.S. patent application, two pending PCT patent applications, 16 pending foreign patent applications relating to immunostimulatory sequence oligonucleotides and methods of using the oligonucleotides and specifically nelitolimod. However, we jointly own with Merck Sharp & Dohme LLC two granted US and 14 granted foreign patents (counting national validations in Europe) that expire in 2036 and related 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.

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.

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 18 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 delivered via PEDD through the 505(b)(1) regulatory approval pathway, as part of a combination regimen with other therapeutics. 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 thousand 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.

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 began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare drug price negotiation program. 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 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,, particularly given the recent change in administration. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create

additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan, and directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. 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. In December 2023, CMS granted a New Technology HCPCS code for procedures involving TriNav. This 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.

TriSalus has been in active discussion with CMS with the goal of clarifying that the current code used for TriNav procedures, C9797, covers both "mapping" or "simulation" procedures. These procedures precede the actual Y90 delivery, usually from several days to several weeks, are critical for determining the optimal dose to be delivered and are an essential component of the treatment plan for patients receiving Y90 therapy. Specifically, we have asked for minor changes in the language of the code to make it clearer that simulation procedures, commonly referred to as mappings, are reimbursed when a TriNav is used. Effective April 1, 2025, TriNav received a second unique and permanent HCPCS code from CMS, C8004, which has been assigned to APC 5193 (Level 3 Endovascular Procedures). This new code provides reimbursement clarity for mapping procedures conducted prior to TARE.

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 thousand square feet of office, manufacturing, and warehouse space pursuant to a lease that expires on December 31, 2031. The lease includes one extension option, for five years. We have not yet determined if we will exercise the extension option. We also lease office facilities in Bannockburn, Illinois, and 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 December 31, 2024, we had approximately 110 full-time employees, including six employees who held Ph.D. or M.D. degrees.

None of our employees are 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

We were incorporated in Delaware in September 2020. 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. We intend to announce material information to the public through filings with the SEC, the investor relations page on our website, press releases, public conference calls and public webcasts. Information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only. For additional information, see Item 7- Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report, and *(3) Business Combination* of our audited consolidated financial statements for the year ended December 31, 2024, included in Item 8 of this Annual Report.

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.

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 $30.0 million and $59.4 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $279.5 million. We anticipate incurring increased sales 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.

Our need for additional capital raises substantial doubt about our ability to continue as a going concern. Until we are able to generate significant revenues or achieve profitability through product sales, we will require substantial additional capital to finance our operations and continue development of our product candidates. We cannot be certain that such additional financing will be available on terms favorable to us, or at all, which could limit our ability to grow and jeopardize our ability to continue our business operations.

This Annual Report includes disclosures regarding management's assessment of our ability to continue as a going concern as our current liquidity position and recurring losses from operations since inception and negative cash flows from operating activities raise substantial doubt about our ability to continue as a going concern. As of December 31, 2024, we had $8.5 million in cash and cash equivalents. Based on our sales, operations, and research and development plans, we expect that our existing cash and cash equivalents will not be sufficient to fund operations for at least the next 12 months from the issuance date of this Annual Report. As a result, there is substantial doubt about our ability to continue as a going concern. We expect to incur significant expenses and operating losses for the foreseeable future as we continue to invest in the commercialization of TriNav, and clinical trials and other development, manufacturing and regulatory activities for TriNav, nelitolimod, and our other product candidates, and discovery research and development. Based on our history of losses, we do not expect that we will be able to fund our longer-term capital and liquidity needs through our cash balances, operating cash flow, and the proceeds from the OrbiMed Credit Agreement alone.

Until we can generate a sufficient amount of revenue, we will need to finance our operations through strategic alliance and licensing arrangements and/or public or private debt and equity financings. We anticipate needing to obtain substantial additional funding in connection with our continuing operations and planned activities to expand our business, to respond to competitive pressure and to make acquisitions. The amount of capital we will need may change depending on, among other things, the success of our efforts to grow revenue, our efforts to continue to effectively manage expenses, the results of our research and development and clinical trials for product candidates, and costs arising from seeking regulatory approvals. We may not succeed in raising additional funds in a timely manner. The timing of our need for additional funds will depend on many factors, which are difficult to predict or may be outside of our control, including to continue the clinical development of, and seek regulatory approval for, nelitolimod in any indication. These factors include:

- the revenue received from sales of TriNav;
- the costs and timing of research and development programs, including for additional Pressure- Enabled Drug Delivery ("PEDD") devices;
- our ability to access the remaining available loan amount under our OrbiMed Credit Agreement if and when needed;
- the scope, progress, results, resources, time and costs of preclinical development, laboratory testing and clinical trials for our current and future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our ability to establish collaborations on favorable terms, if at all;
- the costs, timing and outcome of the regulatory review and approval of nelitolimod and any future product candidate;
- the timing of any milestone payments or royalties due to Dynavax; and
- the costs of operating as a public company.

If our estimates and predictions relating to any of these factors are incorrect, we may need to modify our business plans. Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales for nelitolimod or any of our product candidates. In addition, nelitolimod and any future product candidates, if approved, may not achieve commercial success.

Our ability to raise additional capital in the equity and debt markets, should we choose to do so, will depend upon many factors, including but not limited to, the market demand for our Common Stock, which itself is subject to a number of development and business risks and uncertainties, as well as investor perception of our creditworthiness and prospects. It will also depend on a number of factors, including market conditions, interest rates, our operating performance and our credit rating. If we are unable to raise funds on acceptable terms, we may not be able to execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements. This may seriously harm our business, financial condition and results of operations. If we are not able to continue operations, investors may suffer a complete loss of their investments in our securities.

If we raise additional funds through future issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of Common Stock. Subject to limited exception, we are prohibited from incurring indebtedness without the prior written consent of OrbiMed pursuant to the OrbiMed Credit Agreement. Regardless, any debt financing that we may secure in the future could involve significant fixed payment obligations and restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. We may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when needed, we may need to delay, reduce the scope of or put on hold one or more research and development programs or commercialization efforts while we seek strategic alternatives, and our ability to continue to support our business growth and to respond to business challenges and opportunities could be significantly impaired.

We may also need to seek collaborators for nelitolimod and any future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to nelitolimod and any future product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition, and results of operations and cause the price of Common Stock to decline. Further, our ability to raise additional capital and the interest rate of our term loans under the OrbiMed Credit Agreement may be adversely impacted by potential worsening global economic conditions, and the continued disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from geopolitical events, including the wars in Ukraine and the Middle East, and disruptions to the U.S. banking system due to bank failures. 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 or other preferences that adversely affect the rights of existing stockholders. Thus, existing holders of our Common Stock bear the risk of our future offerings reducing the market price of our Common Stock and diluting their shareholdings in us. For instance, in October 2023, we entered into a standby equity purchase agreement (the "SEPA") with YA II PN, LTD., a Cayman Islands exempt limited partnership ("Yorkville"), whereby we have the right, but not the obligation, to sell to Yorkville up to $30.0 million of our Common Stock at our request, subject to terms and conditions specified in the SEPA. We have, and in the future may continue to, sell shares of our Common stock to Yorkville under the SEPA. In addition, the OrbiMed Credit Agreement requires us to make payments of interest and principal and subject us to a number of restrictive covenants, including among others, limitations on our ability to incur additional debt; create liens and encumbrances; merge, dissolve, merge, dissolve, liquidate or consolidate; make acquisitions, investments, advances or loans; dispose of or transfer assets; pay dividends or make other payments in respect of our capital stock; amend certain material documents; redeem or repurchase certain debt; engage in certain transactions with our affiliates; enter into certain restrictive agreements; and license intellectual property rights. If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

Because our decision to issue additional equity or debt securities in any future offering or to enter into any strategic partnership or licensing arrangement will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, nature or success of our future capital raising efforts or partnership and licensing arrangements. In addition, a significant decline in the trading price of our Common Stock could potentially impact our ability to use equity securities as consideration in acquisitions. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, or grant rights to develop and market products or product candidates that we would otherwise develop and market ourselves.

We may not be able to generate sufficient cash to service our indebtedness or borrow additional funds pursuant to our Loan Facility.

We have entered into the OrbiMed Credit Agreement, pursuant to which we may borrow up to $50.0 million in senior secured term debt. Our obligations under the OrbiMed Credit Agreement are secured by substantially all of our assets.

We are subject to a number of affirmative and restrictive covenants pursuant to the OrbiMed Credit Agreement, which limit or restrict our ability to, among others (subject to certain qualifications and exceptions): create liens and encumbrances; incur additional indebtedness; merge, dissolve, liquidate or consolidate; make acquisitions, investments, advances or loans; dispose of or transfer assets; pay dividends or make other payments in respect of our capital stock; amend certain material documents; redeem or repurchase certain debt; engage in certain transactions with our affiliates; and enter into certain restrictive agreements. In addition, we are required to maintain at least $5.0 million of unrestricted cash and cash equivalents at all times (which requirement will increase to $10.0 million at all times after March 31, 2025). Our obligations under the OrbiMed Credit Agreement are subject to acceleration upon the occurrence of an event of default (subject to applicable notice and grace periods). We are currently in compliance with the OrbiMed Credit Agreement covenants; however, we currently expect that we expect that we will need to raise additional capital to remain in compliance with the minimum cash threshold. If we are unable to achieve certain milestones, generate sufficient revenue and maintain certain minimum cash threshold, we may fall out of compliance with these covenants, which could constitute an event of default. We may also enter into other debt agreements in the future which may contain similar or more restrictive terms.

Our ability to make scheduled monthly payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these

actions, or that these actions would permit us to meet our scheduled debt service obligations. Failure to comply with the conditions of or covenants in the OrbiMed Credit Agreement could result in an event of default, which could result in an acceleration of amounts due under the OrbiMed Credit Agreement. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and OrbiMed could seek to enforce security interests in the collateral securing such indebtedness, which would materially harm our business and our stock price.

In addition, the OrbiMed Credit Agreement provides up to $15.0 million will be made available on or prior to December 31, 2025, subject to certain revenue requirements. If we are unable to achieve the revenue requirements by the applicable dates, we would be unable to borrow additional funds pursuant to the Loan Facility, which could negatively impact our ability to fund our operations.

We may issue additional Common Stock from time to time under our equity incentive plans. Any such issuances would dilute the interest of our stockholders and likely present other risks.

We may issue additional Common Stock from time to time under our equity incentive plans. Common Stock reserved for future issuance under our equity incentive plans will become eligible for sale in the public market once those shares are issued, subject to provisions relating to time-based and performance-based vesting conditions, lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. We have filed a registration statement on Form S-8 under the Securities Act to register additional shares we may issue pursuant to our 2023 Equity Incentive Plan (the "2023 Plan") and 2023 Employee Stock Purchase Plan. In addition, we may file one or more registration statements on Form S-8 under the Securities Act to register additional Common Stock or securities convertible into or exchangeable for Common Stock issued pursuant to our equity incentive plans. Any future Form S-8 registration statements will automatically become effective upon filing. Accordingly, Common Stock registered under such registration statements may be immediately available for sale in the open market.

Any acquisitions, strategic investments, entries into new businesses, joint ventures, divestitures, and other transactions could fail to achieve strategic objectives, disrupt our ongoing operations, result in operating difficulties, liabilities and expenses, harm our business, or negatively impact our results of operations.

We may evaluate and consider strategic transactions, combinations, acquisitions, dispositions, joint ventures or similar transactions. These transactions could be material to our financial condition and results of operations if consummated. If we 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.

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 on Form 10-K, we have paid Dynavax $12.0 million to date and we may be required to pay Dynavax up to an additional $158.0 million upon the achievement of certain development and regulatory milestones with respect to nelitolimod. We will also be required to pay up to $80.0 million upon achieving certain commercial milestones once sales of nelitolimod have begun. The Dynavax Agreement also obligates us to pay royalties based on potential future net sales of products containing nelitolimod compound 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.

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 account for primarily all of our revenue and will continue to account for primarily all of our revenue going forward. Our ability to execute our growth strategy and become profitable will therefore depend upon the adoption of TriNav by physicians and hospitals, among others, and for various conditions where PEDD may be applicable, including liver cancer, multinodular goiters, locally advanced pancreatic cancer, UFEs and prostate embolization.

TriNav is a relatively new drug delivery platform designed to overcome the barriers of the high pressure tumor microenvironment. As a result, physician awareness of TriNav, and experience with TriNav, is limited. A number of factors that are outside of our control may contribute to fluctuations in our financial results, including:

- physician experience and hospital demand for our products and the extent of adoption of TriNav, including the rate at which physicians recommend TriNav for use on their patients;

- delays in, or failure to supply product, component and material deliveries by our third-party suppliers;
- positive or negative media coverage, or public, patient and/or physician perception, of TriNav or competing products and procedures;
- any safety or effectiveness concerns that arise regarding TriNav;
- the extent of reimbursement by the Centers for Medicare & Medicaid Services ("CMS") for purchases of TriNav; and
- introduction of new products or procedures for delivering drugs into the tumor microenvironment that compete with TriNav.

There is no assurance that TriNav will achieve broad market acceptance among physicians and hospitals or in the conditions for which PEDD maybe applicable. Any failure of TriNav to satisfy physician or hospital demand or to achieve meaningful market acceptance will harm our business and future prospects. Further, to the extent broad market acceptance is achieved in the future, there is no assurance that such acceptance will be sustained.

Our business is dependent upon the continued adoption of TriNav by hospitals and physicians.

Our future growth and profitability largely depend on our ability to increase physician awareness and adoption of TriNav for the different conditions for which PEDD may be applicable and on the willingness of physicians to recommend the device to more of their patients. Physicians may not use our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our product provides a safe and effective treatment alternative for drug delivery. Even if we are able to raise awareness and increase adoption of TriNav among physicians, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select TriNav for recommendation to patients for a variety of reasons, including:

- Long-standing relationships with competing companies and distributors that sell competitive products;
- Competitive response and negative selling efforts from providers of alternative catheter products;
- Perceived liability risk generally associated with the use of new products and procedures;
- Lack of sufficient clinical evidence, including long-term data, supporting the clinical benefits of TriNav in the different conditions for which PEDD may be applicable;
- Reluctance to change to or use new products and procedures; and
- Time commitment and skill development that may be required to gain familiarity and proficiency with TriNav.

Physicians play a significant role in determining the course of a patient’s treatment and, as a result, the type of treatment that will be recommended or provided to a patient. We focus our sales, marketing, and education efforts primarily on interventional radiologists with the goal of educating these physicians regarding the patient population that we believe would benefit from TriNav. However, we cannot assure you that we will achieve broad education or market acceptance among these practitioners. For example, if treating physicians are not made aware of TriNav, they may not treat patients using our product, and those patients may instead not seek treatment at all or may be treated with alternative products or procedures. In addition, some physicians may choose to utilize TriNav on only a subset of their total patient population or may not adopt TriNav at all. If a physician experiences an adverse event in one or more of their TriNav patients or if any issues with the safety or efficacy of TriNav develop, physicians may not continue offering TriNav as a drug delivery method at the same rate or at all. If we are not able to effectively demonstrate that TriNav is beneficial in a broad range of patients, adoption of TriNav will be limited and may not occur as rapidly as we anticipate, which would have a material adverse effect on our business, financial condition, and results of operations. We cannot assure you that TriNav will achieve broad market acceptance among hospitals and physicians. Any failure of TriNav to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations.

In addition, the medical device industry’s interactions and relationships with health care providers, including physicians and hospitals are under increasing scrutiny by the U.S Department of Health and Human Services Office of the Inspector General (“OIG”), the Department of Justice (“DOJ”), state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with health care providers, including physicians and hospitals, or an investigation into our compliance by the OIG, DOJ, state attorneys general or other government agencies, could significantly harm our business.

In most cases, before physicians can use our products for the first time, our products must be approved for use by a hospital's new product or value analysis committee, or the staff of a hospital or health system. Following such approval, we may be required to enter into purchase contracts with such hospital or health system. Such approvals or requirements to enter into a purchase contract could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals, enter into purchase contracts, or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations.

Any change to TriNav's reimbursement status that reduces our level of reimbursement could cause TriNav sales to materially decline and impede market adoption.

In December 2023, CMS granted a New Technology Healthcare Common Procedure Coding System Code ("HCPCS") for both mapping and therapeutic procedures involving TriNav. This code, HCPCS C9797, has been assigned to the Ambulatory Payment Classification ("APC") 5194 - Level 4 Endovascular Procedures. The code became effective on January 1, 2024, and may be reported by hospital outpatient departments and ambulatory surgical centers. Effective April 1, 2025, TriNav received a second unique and permanent HCPCS code from CMS, C8004, which has been assigned to APC 5193 (Level 3 Endovascular Procedures). This new code provides reimbursement clarity for mapping procedures conducted prior to TARE. Although CMS approved a reimbursement amount increase for 2025, there can be no assurance that continuing reimbursement will be available at similar reimbursement rates or at all.

Any reduction in the amount of the reimbursement for TriNav will negatively impact the revenue we are able to generate from the sale of TriNav and may hinder our ability to recoup our total investment in TriNav notwithstanding regulatory approval of the product. If we are unable to maintain coverage and profitable payment rates from hospital budgets or government-funded and private purchasers for TriNav or any future products, we may sell fewer units or need to sell them at a lower price. Such changes in revenues would have a material adverse effect on our operating results and our overall financial condition.

We currently have a limited marketing, sales and distribution organization. If we are unable to successfully grow our marketing, sales and distribution capabilities, then our product revenues related to TriNav, our results of operations and financial condition will suffer.

We currently have limited in-house sales and marketing capabilities. 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.

In addition, we have an agreement with a partner in China for the distribution and commercialization of TriNav, if approved in China. Foreign organizations may be subject to U.S. legislation, including the proposed BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory requirements which could have an adverse effect on our ability to expand certain foreign jurisdictions.

Increases in costs, disruption of supply or shortage of materials could harm our business.

We manufacture TriNav internally, and certain materials necessary to produce our products are sourced from a limited number of suppliers. Any disruption in the supply of materials from such suppliers could disrupt production of our products until such time as a different supplier is fully qualified. As a result, we may experience an increase in costs or inability to meet customer demand. Furthermore, shortages or increased demand of such materials and other economic conditions, like inflation, may cause us to experience significant increases in the cost of materials. In the case of TriNav, substantial increases in the prices for materials used in our production would increase our operating costs and could reduce our margins if we cannot recoup any such increased costs through increased product pricing. Any attempts to increase product prices in response to increased material costs could result in cancellations of product orders and therefore materially and adversely affect our brand, business, prospects and results of operations.

Risks Related to Nelitolimod and Product Development

We are early in our pharmaceutical development efforts for nelitolimod, and if we are unable to advance our product candidates, including nelitolimod in clinical development for any reason (including due to lack of funding), obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business, results of operations, financial condition and prospects may be materially adversely affected.

We are in the early stages of our development efforts and have only one product candidate, nelitolimod, in early clinical development. We have initiated Phase 1 and Phase 1b clinical trials for nelitolimod, each of which are focused on a different target indication, specifically UMLM, ICC and HCC, and pancreatic cancer. We expect that any continued investigation for ICC and HCC will only continue through IITs. Based on the changing landscape for second line treatment of uveal melanoma, we do not intend to proceed to Phase II trials for that indication on our own, but we are looking for potential partners to advance that indication. Our Phase I PERIO-03 clinical trial in pancreatic cancer is enrolled and we anticipate data from the study will be available by the end of 2025, depending on when treatment is completed. We will need to progress the pancreatic carcinoma indication through IND-enabling studies and submit Investigational New Drug applications ("INDs") to the FDA prior to initiating their clinical development. Our ability to generate product revenues from our product candidate, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidate. The success of this product candidate will depend on several factors, including the following:

- successful enrollment in clinical trials and completion of clinical trials and preclinical studies with favorable results;
- clearance of INDs by the FDA or similar regulatory filings by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidate and our proposed design of future clinical trials;
- demonstrating the safety and efficacy in the proposed indications for use of our product candidate to the satisfaction of applicable regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including New Drug Applications ("NDAs") from the FDA and maintaining such approvals;
- making arrangements with third-party manufacturers for, or establishing, clinical and commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our product candidate, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidate;
- maintaining an acceptable safety profile of our products following approval; and
- building and maintaining an organization of people who can successfully develop our product candidate.

The success of our business depends in part on the successful development, regulatory approval, and commercialization of our product candidate, nelitolimod, as well as any other future product candidates, which may never occur. We have not yet succeeded in, and we may not succeed in, obtaining marketing approval for nelitolimod. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate any revenue from our pharmaceutical development efforts and this may have a material adverse effect on our business, results of operations, financial condition and prospects.

Clinical trials of our product candidates or potential product candidates may fail to produce results necessary to support regulatory clearance or authorization.

We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will ever result in commercial gains. We may experience significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical development process. Our products may produce undesirable adverse effects that could cause us, institutional review boards ("IRBs") or regulatory authorities to interrupt, delay or halt clinical trials. We, IRBs, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks. Our clinical trials may produce negative or inconclusive results or may demonstrate a lack of effect of our product candidates. Additionally, the FDA may disagree with our interpretation of the data from our pilot studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety or effectiveness, and may require us to pursue additional clinical trials, which could further delay the clearance or authorization of our product candidates. If we are unable to demonstrate the safety and

effectiveness of product candidates in our clinical trials, we will be unable to obtain the regulatory clearances or authorizations we need to commercialize new products.

Interim, "topline" and preliminary data from clinical trials of our product candidates may change as more patient data becomes available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data is available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

Clinical development is a lengthy and expensive process with an uncertain outcome. In addition, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. Failure can occur at any stage of clinical development.

Clinical testing is expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or efficacy profiles and flaws in trial design, among others. To obtain the requisite regulatory approvals or clearances to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. The results of preclinical studies and early clinical trials of nelitolimod and any future drug candidates may not be predictive of the results of later-stage clinical trials, making it impossible to predict when or if any of our product candidates will prove safe or effective in humans or receive regulatory approval or clearance. The results generated to date in preclinical studies for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier-stage clinical trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier-stage clinical trials. Several companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Changing treatment landscapes may also diminish the opportunities for our product candidates leading to termination of their development in general or for certain indications. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval or clearance of these product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If the trials result in negative or inconclusive results, we or our collaborators or partners may decide, or regulators may require them, to discontinue trials of our drug candidates or conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval or clearance and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

Also, we cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including challenges resulting from 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.

Use of toll-like receptor (TLR) agonist, including nelitolimod, may negatively impact the immune system. Serious adverse event data relating to TLR agonists may require us to reduce the scope of or discontinue certain of our pre-clinical or clinical activities.

Nelitolimod, an investigational agent in development, is 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, antigen-presenting immune cells and other immune cells. TLRs play a key role in the innate immune system and create a bridge to adaptive immunity. It is believed that activating TLR9 primes immune cells to promote anti-tumor T-cells. If nelitolimod or any of our future product candidates in clinical trials or similar products from competitors produce serious adverse event data, we may be required to delay, discontinue, or modify many of our clinical trials or our clinical trial strategy. If a safety risk based on mechanism of action or the molecular structure were identified, it may hinder our ability to develop our product candidates or enter into potential collaboration or commercial arrangements. Rare diseases and a numerical imbalance in cardiac adverse events have been observed in patients in our clinical trials. If adverse event data are found to apply to our TLR agonist and/or inhibitor technology as a whole, we may be required to significantly reduce the scope of or discontinue certain of our pre-clinical or clinical activities.

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 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 area of sales and marketing. 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 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 December 31, 2024, we had approximately 110 full-time employees, six of whom hold advanced degrees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the area of sales and marketing. 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 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 have not and may not in the future, however, detect and remediate all such vulnerabilities on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities, which could be exploited and resulted in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon which we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon which we rely) to provide our services. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Additionally, applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon which we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, including government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm (including but not limited to damage to our patient, partner, or employee relationships); monetary fund diversions; interruptions in our operations (including availability of data and interruptions to our clinical trial operations); financial loss; delay in the development and commercialization of our products and product candidates; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Natural or man-made disasters and other similar events may significantly disrupt our business, and negatively impact our business, financial condition and results of operations.

Our ability to make, move and sell products in coordination with our suppliers, manufacturers and business partners is critical to our success. Damage or disruption to our collective supply, manufacturing or distribution capabilities resulting from weather, any potential effects of climate change, natural disasters, pandemics or other outbreaks of contagious diseases, fire, explosion, cyber-attacks, terrorism, strikes, repairs or enhancements at facilities manufacturing or delivering TriNav or other reasons could impair our ability to manufacture, sell or timely deliver TriNav to customers and patients.

Further, such damage or disruption to the supply, manufacturing, or trial sites of nelitolimod could impair our ability to complete our clinical trials on a timely basis, if at all.

We rely on a limited number of third-party suppliers and manufacturers. Adverse events affecting such suppliers or manufacturers may limit our ability to obtain the materials they supply or manufacture for us, or alternatives at competitive prices, or at all. Competitors can be affected differently by weather conditions and natural disasters depending on the location of their suppliers and operations. Failure to take adequate steps to reduce the likelihood or mitigate the potential impact of such events, or to effectively manage such events if they occur, particularly when materials are sourced from a single location or supplier or produced by a single manufacturer, could adversely affect our business, financial condition, results of operations and/or require additional resources to restore our supply chain or manufacturing capabilities, as applicable.

Risks Related to Our Legal and Regulatory Environment

We are subject to numerous complex regulatory requirements, and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.

The research, pre-clinical testing, clinical trials, manufacturing, marketing and distribution of medical devices, human drugs and biologics and combination products are subject to regulation by numerous governmental authorities in the United States and other jurisdictions, if we desire to export the resulting products to such other jurisdictions. These regulations govern or affect the testing, manufacture, safety, effectiveness, labeling, storage, record-keeping, approval or clearance, distribution, advertising and promotion of product candidates, as well as safe working conditions. In some cases, the FDA requirements have increased the amount of time and resources necessary to develop new products and bring them to market in the United States. The FDA and foreign regulatory authorities have substantial discretion to require additional testing, to delay or withhold registration and marketing approval or clearance and to otherwise preclude distribution and sale of a product. In addition, regulatory approval or clearance could impose limitations on the indicated or intended uses for which product candidates may be marketed, and impose post- approval requirements. Our failure to obtain approval or clearance, significant delays in the approval or clearance process, or our failure to maintain approval or clearance in any jurisdiction will prevent us from selling any applicable products in that jurisdiction. We would not be able to realize revenues for those new products in any jurisdiction where we do not have approval or clearance.

Even after a product candidate has been approved or cleared, the FDA and comparable governmental authorities subject such product to continuing review and regulatory requirements including, for example, the reporting of safety issues or adverse events associated with use of an approved drug or cleared or approved device.

These authorities may, in certain circumstances, require us to conduct and report the results of certain clinical studies or trials and to commit to voluntarily conducting additional clinical trials. Developments following regulatory approval or clearance may adversely affect sales of our products.

Failure to comply with, or changes to applicable regulatory requirements may result in a variety of consequences, including the following:

- restrictions on our products or the manufacturing processes of such products;
- warning letters, untitled letters and cyber letters;
- withdrawal of a product from the market;
- voluntary or mandatory recall of a product;
- fines;
- suspension or withdrawal of regulatory approvals or clearances for a product;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our products;
- refusal to clear or approve pending applications or supplements to cleared or approved applications that we submit; requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization;
- denial of permission to file an application or supplement in a jurisdiction;

- debarment, exclusion from participation in federal healthcare programs, exclusion or debarment from government contracting, consent decrees, or corporate integrity agreements;
- seizure or detention of products; and
- injunctions or the imposition of civil or criminal penalties against us.

More stringent oversight by the FDA and other agencies in recent years has resulted in increased enforcement activity, which increases our compliance risk.

To the extent that our partners or we do not perform particular regulated functions themselves but contract out to third parties, including contract manufacturers, contract research organizations, clinical trial sites, and laboratories, our partners or we may be held responsible for such third parties' failure to follow the applicable regulatory requirements.

The complexity of a combination product that includes a drug and a medical device presents additional, unique development and regulatory challenges, which may adversely impact our development plans and our ability to obtain regulatory approval or clearance of our product candidates.

We may decide to pursue marketing authorization for a combination product comprised of drug candidates and medical devices. A combination product includes, among other possibilities, a combination of a drug and device intended to be used together, according to their proposed labeling where both are required to achieve the intended use, indication or effect.

Developing and obtaining regulatory approval or clearance for combination products pose unique challenges because they involve components that are regulated by the FDA pursuant to different regulatory frameworks and by different FDA centers. As a result, such products raise regulatory, policy and review management challenges. For example, because divisions from both FDA's Center for Drug Evaluation and Research and FDA's Center for Devices and Radiological Health must review submissions concerning product candidates that are combination products comprised of drug and devices, the regulatory review and approval for these products may be lengthened. In addition, differences in regulatory pathways for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees and post- approval modifications. Similarly, the device components of our product candidates will require any necessary approvals or clearances or other marketing authorizations or certifications in other jurisdictions, which may prove challenging to obtain.

We intend to use the FDA's expedited drug development programs for nelitolimod but may not be able to achieve expedited development or approval for this product candidate.

The FDA has established various expedited drug development programs to facilitate more rapid and efficient development, review and approval of certain types of drugs. Such programs include fast track designation, breakthrough therapy designation, accelerated approval, and priority review. We intend to use one or more expedited drug development programs for nelitolimod . The FDA has broad discretion on whether or not to admit a drug candidate for these programs, so even if we believe a particular product candidate is eligible for an expedited drug development program, we cannot assure you that the FDA would agree. Even if any of our product candidates is admitted to any of the expedited drug development programs, we may not experience a faster development process, review or approval compared to conventional FDA approval timelines, and the FDA may still decline to approve such product candidates.

Fast track designation is designed to facilitate the development and expedite the review of therapies for serious conditions that fill an unmet medical need. Programs with fast track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. If any of our product candidates receive fast track designation but do not continue to meet the criteria for fast track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply or due to other issues, we will not receive the benefits associated with the fast track program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

FDA may award breakthrough therapy designation to a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Designation as a breakthrough therapy is within the discretion of the FDA. Even if one or more of our product candidates qualify as

breakthrough therapies pursuant to FDA standards, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek breakthrough therapy designation for one or more of our current or future product candidates, there can be no assurance that we will receive breakthrough therapy designation.

If any of our programs or product candidates receive fast track or breakthrough therapy designation by the FDA or similar designations by other regulatory authorities, there is no assurance that we will receive any benefits from such programs or that we will continue to meet the criteria to maintain such designation. Even if we obtain such designations, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A fast track or breakthrough therapy designation does not ensure that a product candidate will receive marketing approval or that approval will be granted within any particular time frame. In addition, the FDA may withdraw any such designation if it believes that the designation is no longer supported by data from our clinical development program upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of nelitolimod or any future product candidates. Any marketing approval we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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.

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.

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 Reconciliation Act of 2010, or collectively the Affordable Care Act ("ACA").

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect that there will be additional challenges and amendments to the ACA in the future. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a newly established manufacturer discount program.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional congressional action is taken. .

There has been increasing legislative and enforcement interest in the U.S. with respect to prescription- pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021,the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare drug price negotiation program. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services, or CMS, Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on reimbursement price that we receive for any cleared, authorized, or approved device, or any of our product candidates in the future, if approved. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory clearance, authorization, or approval and that may affect our overall financial condition and ability to develop product candidates. Additional health reform measures may continue and affect our business in unknown ways, particularly given the recent change in administration. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan, and directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates that we may develop may lose any regulatory clearance, authorization, or approval that may have been obtained and we may not achieve or sustain profitability.

TriNav and the PRVI device must be manufactured in accordance with federal and foreign regulations, and we or any of our suppliers or third-party manufacturers could be forced to recall the products or terminate production if we fail to comply with these regulations.

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, component failures, unapproved or improper use of our products, or inadequate disclosure of risks or other information relating to the use of our products can lead to injury or other serious adverse events. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. For the FDA, the authority to require a recall must be based on a finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our international distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or another third-country competent authority. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or another third-country competent authority. If the FDA disagrees with our determinations, the FDA could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report recalls. We are also required to follow detailed recordkeeping requirements for all firm- initiated medical device corrections and removals.

If treatment guidelines for the cancer indications that we are targeting change or the standard of care evolves, we may need to redesign our preclinical or clinical trials of, or seek new marketing authorization from, the FDA for any approved products.

If treatment guidelines for the cancer indications that we are targeting change or the standard of care evolves, We may need to redesign TriNav, the PRVI device or any product candidates and seek new clearances or approvals from the FDA for any approved products. Our 510(k) clearances from the FDA for TriNav, TriNav Large and the PRVI device are based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of TriNav and the PRVI device could be diminished, and our business could suffer. Competition by other forms of cancer treatment, for example, the development of new and more efficacious systemic therapies, could reduce the use of regional therapy as a standard of care in certain indications. Changes in treatment guidelines or standard of care may also impact product coverage and/or reimbursement by payors.

Our relationships with customers, hospitals, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians and third-party payors in the United States and elsewhere, will play a primary role in the recommendation of TriNav and the PRVI device and prescription of any product candidates for which we obtain marketing approval or clearance. Our current and future arrangements with healthcare professionals, principal investigators, consultants, hospitals, customers and third-party payors subject us to various federal and state fraud and abuse laws, data privacy and security laws, transparency laws and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute TriNav and the PRVI device, and any other any future products candidates once they have obtained marketing authorization. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, a person or entity from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease order, arranging for or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, by a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, a

violation of the Anti-Kickback Statute can form the basis for a violation of the federal False Claims Act (discussed below);

- Federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, which provides for civil whistleblower or qui tam actions, that impose penalties against individuals or entities for knowingly presenting or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a referral made in violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- The Health Insurance Portability and Accountability Act ("HIPAA") which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, which impose obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses as well as their business associates and subcontractors that perform certain services involving the use or disclosure of individually identifiable health information;
- The federal transparency requirements known as the federal Physician Payments Sunshine Act, created as part of ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS information related to payments and other transfers of value made by that entity to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- Analogous local, state and foreign laws and regulations, such as state anti-kickback and false claims laws that may apply to healthcare items or services reimbursed by third-party payors, including private insurers.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

If the physicians or other providers or entities with whom we do, or expect to do, business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have a material adverse effect on our ability to compete in the marketplace.

We could be subject to litigation that could have an adverse effect on our business and operating results.

We are, from time to time, involved in litigation. The numerous operating hazards inherent in our business increase our exposure to litigation, which may involve, among other things, contract disputes, personal injury, environmental, employment, warranty and product liability claims, tax and securities litigation, patent infringement and other intellectual property claims and litigation that arises in the ordinary course of business. Our management cannot predict with certainty

the outcome or effect of any claim or other litigation matter. Litigation may have an adverse effect on us because of potential negative outcomes such as monetary damages or restrictions on future operations, the costs associated with defending the lawsuits, the diversion of management's resources and other factors.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We are developing additional sizes of, and uses for, the TriNav device. Our products and product candidates are used in connection with medical procedures in which it is important that those products function with precision and accuracy. If our existing TriNav device or our product candidates, if approved, do not function as designed, or are designed improperly, we may be forced by regulatory agencies to withdraw such products from the market. In addition, the use of our product candidates in clinical trials, the use and possible misuse of our TriNav device in medical procedures, the sale of any products and any product candidates for which we obtain marketing approval, and other liability risks that are inherent in the testing, manufacturing, marketing and sale of medical devices exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs, which may not be covered by insurance. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition and results of operations. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- injury to our reputation;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize a product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources, and the inability to commercialize any product candidate;
- decreased demand for our products and any product candidate that is approved for commercial sale; and
- loss of revenue.

Although we currently carry clinical trial insurance and product liability insurance which we believe to be reasonable, such insurance may not be adequate to cover all liability that we may incur. An inability to renew our policies or to obtain sufficient insurance at an acceptable cost could prevent or inhibit the commercialization of pharmaceutical products that we develop, alone or with collaborators.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we process sensitive data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal

Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA as amended by HITECH imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information.

In the past few years, numerous states 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 ("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 and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data maintained about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and may increase legal risk and compliance costs to us and the third parties upon which we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the EU's General Data Protection Regulation ("EU GDPR") imposes strict requirements for processing personal data, and, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20.0 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we could satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, we could face significant adverse consequences.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and we are, and may become in the future subject to such obligations in the future. We are also 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. Regulators in the United States are increasingly scrutinizing these statements and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on which we rely may fail to comply with such

obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Changes in tax law and differences in interpretation of tax laws and regulations may adversely impact our financial statements.

We operate in multiple jurisdictions and are subject to tax laws and regulations of the U.S. federal, state and local and non-U.S. governments. U.S. federal, state and local and non-U.S. tax laws and regulations are complex and subject to change and varying interpretations. For instance, the IRA imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. U.S. federal, state and local and non-U.S. tax authorities may interpret tax laws and regulations differently than we do and challenge tax positions that we have taken. This may result in differences in the treatment of revenues, deductions, credits and/or differences in the timing of these items. The differences in treatment may result in payment of additional taxes, interest or penalties that could have an adverse effect on our financial condition and results of operations. Further, future changes to U.S. federal, state and local and non-U.S. tax laws and regulations could increase our tax obligations in jurisdictions where we do business or require us to change the manner in which we conduct some aspects of our business.

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited.

We have incurred losses during our history. Unused federal net operating losses ("NOLs") for taxable years beginning before January 1, 2018, may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under current law, federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards and certain state tax credits in tax years beginning after 2023 and before 2027.These factors could limit our ability to use our NOLs and other tax attributes, which could adversely affect our future cash flows or results of operations.

Risks Related to Our Intellectual Property

Failure to obtain, adequately protect, maintain or enforce our intellectual property rights could substantially harm our business and results of operations.

Our success depends in part on our ability to obtain and maintain protection for our owned and in-licensed intellectual property rights and proprietary technology. We rely on a combination of patents, trademarks, trade secret protection and confidentiality agreements, including in-licenses of intellectual property rights of others, to protect our current or future platform technologies, products, product candidates, methods used to manufacture our current or future product candidates and methods for treating patients using our current or future product candidates.

We own or in-license patents and patent applications relating to our platform technologies, products and product candidates. There is no guarantee that any patents covering our platform technologies or product candidates will issue from the patent applications we own, in-license or may file in the future, or, if they do, that the issued claims will provide adequate protection for our platform technologies or product candidates, or any meaningful competitive advantage. Further, there cannot be any assurance that such patents issued will not be infringed, designed around, invalidated by third parties or effectively prevent others from commercializing competitive technologies, products or product candidates.

The patent prosecution process is expensive, complex and time-consuming. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in- license may fail to result in issued patents, and, even if patents are issued, such patents may not cover our current or future technologies or product candidates in the United States or in other countries or provide sufficient protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We do not have exclusive control over the preparation, filing and prosecution of patent applications under certain of our in-license agreements, and we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents that we out-licenses to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Even if our owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner.

Further, although we make reasonable efforts to ensure patentability of our inventions, we cannot guarantee that all of the potentially relevant prior art relating to our owned or in-licensed patents and patent applications has been found. For example, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, and in some cases not at all. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our product candidates, or the use of our technologies. We thus cannot know with certainty whether we or our licensors were the first to file for patent protection of such inventions. In addition, the United States Patent and Trademark Office ("USPTO") might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. There is no assurance that all potentially relevant prior art relating to our owned or in-licensed patent applications has been found. For this reason, and because there is no guarantee that any prior art search is correct and comprehensive, we may be unaware of prior art that could be used to invalidate an issued patent or to prevent our owned or in-licensed patent applications from issuing as patents. Invalidation of any of our patent rights, including in-licensed patent rights, could materially harm our business.

Moreover, the patent positions of biotechnology and medical device companies like us are generally uncertain because they may involve complex legal and factual considerations that have, in recent years, been the subject of legal development and change. The relevant patent laws and their interpretation, both inside and outside of the United States, are also uncertain. Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our platform technology or product candidates and could affect the value of such intellectual property. Our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe, misappropriate or otherwise violate our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our platform technology, product candidates, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our owned or licensed pending patent applications or with respect to any patent applications we may file or license in the future, nor can we be sure that any patents that may be granted to us or our licensors in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Additionally, third parties, including our former employees and collaborators, may challenge the ownership or inventorship of our patent rights to claim that they are entitled to ownership and inventorship interest, and we may not be successful in defending against such claims. However, we are not currently facing any such challenges. Moreover, issued patents do not guarantee the right to practice our technology in relation to the commercialization of our products. Issued patents only allow us to block —in some cases— potential competitors from practicing the claimed inventions of the issued patents.

The issuance, scope, validity, enforceability and commercial value of our pending patent rights are uncertain. The standards applied by the USPTO and foreign patent offices in granting patents are not always certain and moreover, are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in patents. Our pending and future patent applications may not result in patents

being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned or in-licensed patent applications or narrow the scope of any patent protection we may obtain from our owned or in-licensed patent applications. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Further, patents and other intellectual property rights in the pharmaceutical, biotechnology and medical device space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and any future product candidates and practicing our proprietary technology, and any issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our products, product candidates and any future product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors or other parties with similar technology. Additionally, our competitors may initiate legal proceedings, such as declaratory judgment actions in federal court or reexaminations or an *inter partes* review at the USPTO in an attempt to invalidate or narrow the scope of our patents. However, we are not currently facing any such proceedings. Furthermore, our competitors or other parties may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our products, product candidates and any future product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product candidate may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

Even if patents do successfully issue from our owned or in-licensed patent application, and even if such patents cover our current or any future products or product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any current or future products or product candidates that we may develop. Likewise, if patent applications we own or have in-licensed with respect to our development programs and current or future products or product candidates fail to issue, if their breadth or strength is threatened, or if they fail to provide meaningful exclusivity, other companies could be dissuaded from collaborating with us to develop current or future products or product candidates. Lack of valid and enforceable patent protection could threaten our ability to commercialize current or future products and could prevent us from maintaining exclusivity with respect to the invention or feature claimed in the patent applications. Any failure to obtain or any loss of patent protection could have a material adverse impact on our business and ability to achieve profitability may be unable to prevent competitors from entering the market with a product that is similar or identical to any of our products or current or potential future product candidates or from utilizing technologies similar to those in our products or current product candidates.

The filing of a patent application or the issuance of a patent is not conclusive as to our ownership, inventorship, scope, patentability, validity or enforceability. Issued patents and patent applications may be challenged in the courts and in the patent office in the United States and abroad. For example, our patent applications or patent applications filed by our licensors, or any patents that grant therefrom, may be challenged through third-party submissions, opposition or derivation proceedings. By further example, any issued patents that may result from our owned or in-licensed patent applications may be challenged through reexamination, inter partes review or post-grant review proceedings before the USPTO, or in declaratory judgment actions or counterclaims. An adverse determination in any such submission, proceeding or litigation could prevent the issuance of, reduce the scope of, invalidate or render unenforceable our owned or in- licensed patent rights, result in the loss of exclusivity, limit our ability to stop others from using or commercializing similar or identical products and product candidates, or allow third parties to compete directly with us without payment to us. In addition, if the breadth or strength of protection provided by any patents that might result from our owned or in-licensed patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, we currently co-own certain patents and patent applications with third parties and may in the future co-own additional patents and patent applications with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent application, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co-owners to enforce such patents against third parties, and such cooperation may

not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects and financial conditions.

Our in-licensed patent rights may be subject to a reservation of rights by one or more third parties, such as the U.S. government. In addition, our rights in such inventions may be subject to certain requirements to manufacture product candidates embodying such inventions in the United States. Any exercise by the U.S. government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

The expiration or loss of patent protection may adversely affect our future revenues.

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of our products and product candidates. In particular, patent protection is important in the development and eventual commercialization of our product candidates. Patents covering our product candidates normally provide market exclusivity, which is important in order to improve the probability that our product candidates are able to become profitable. Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and other countries with respect to our products and product candidates.

The patent positions of biotechnology and medical device companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the U.S. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our products and product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our products and product candidates may be impaired.

As of December 31, 2024, we owned at least 79 registered patents. Our issued U.S. patents expire between 2030 and 2040. All of our solely-owned granted U.S. and foreign patents that relate to composition of matter for nelitolimod expired in December 2023. Upon expiration of the patents covering nelitolimod, third parties, including other biopharmaceutical companies, will be able to obtain or use nelitolimod other than to the extent we have other patent protection. In addition, certain of our patents relating to the use of TriNav will expire beginning in 2031, with additional patents relating to TriNav expiring in 2036 and 2038. While we are seeking additional patent coverage, there can be no assurances that such additional patent protection will be granted, or, if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. We also intend to apply for orphan drug designation and orphan designation for nelitolimod in the U.S. and EU, respectively, which, if granted, would extend the regulatory exclusivity period beyond the initial five years of regulatory exclusivity for a New Chemical Entity ("NCE") from the date of approval in the U.S. and beyond the eight years of data exclusivity from the date of approval in Europe; however, there can be no assurance that we will ever obtain approval or orphan drug exclusivity for such product candidates. Without patent protection of our product candidates, we may be open to competition from generic versions of such products. As of December 31, 2024, we have at least 88 pending patent applications. We do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology and drugs, in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. Even if we are successful in obtaining a patent, patents have a limited lifespan. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection of our product candidates, we may be open to competition from generic versions of such drug products.

There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to our product candidates. Furthermore, as our issued patents expire, the risk that competitors may be able to circumvent our remaining patents by developing similar or alternate technologies or products in a non-infringing manner is increased.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our products and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension, or PTE, under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following expiration of our regulatory exclusivity and our patent expiration, and launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does and novel formulations of existing drugs and manufacturing processes may not be patentable in certain jurisdictions. Further, future licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products or product candidates and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology and medical device products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Furthermore, while it intends to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products and product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our products and product candidates in all of our expected significant foreign markets.

Additionally, the requirements for patentability may differ in certain countries. Generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensees or any future licensors to engage in complex, lengthy and costly litigation or other proceedings. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensees or any future licensors may have limited remedies if patents are infringed or if we and our licensees or any future licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights in some regions of the world may be inadequate to obtain a significant commercial advantage from our intellectual property.

We may be subject to claims that we or our employees, consultants, contractors or advisors have infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of the contributors to our intellectual property, including patents and applications, were previously employed at universities or other biotechnology, pharmaceutical or medical device companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our business.

In addition, while we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. To the extent that we fail to obtain such assignments, such assignments do not contain a self-executing assignment of intellectual property rights, or if such assignments are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our products or product candidates. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Our business model may require reliance on third parties and the need to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed, and if we are unable to protect the confidentiality of our trade secrets, the value of our intellectual property could be materially adversely affected and our business would be harmed.

In addition to seeking patents for some of our products and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, in seeking to develop and maintain a competitive position. Because we rely on third parties to manufacture our product candidates and we may collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, corporate collaborators, outside scientific collaborators, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective.

Since our inception, we have sought to contract with manufacturers to supply commercial quantities of pharmaceutical formulations. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers and suppliers. We believe that these disclosures, while necessary for our business, may result in the attempt by potential manufacturers and suppliers to improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing and supplier rights.

We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If we fail to prevent material disclosure of the know-how, trade secrets and other intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us.

We may not be able to prevent misappropriation of our trade secrets or other proprietary and confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Our competitors may seek to market generic versions of nelitolimod or any other product candidate for which we may in the future obtain approval by submitting abbreviated new drug applications ("ANDAs") or biosimilar applications to the FDA or new products that use our approved products as the reference listed drug or biologic, in each case where our competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with nelitolimod and any future product candidates we may develop. In these circumstances, we may need to defend or assert our patents, by means including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if patents are valid and enforceable, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Furthermore, as our issued patents expire, the risk that competitors may be able to circumvent our remaining patents by developing similar or alternate technologies or products in a non-infringing manner is increased.

Additionally, competitors could purchase TriNav or our other products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability, and our owned and licensed patents have in the past been, and in the future may be, challenged in the courts or patent offices in the United States and abroad. We may face challenges by third parties, former employees or collaborators with respect to ownership interest in the patents and intellectual property that we own or license at the time. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our products or product candidates. While it is our policy to require employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we

may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as Legacy-TriSalus owned. To the extent that we license intellectual property from a third party, such licensors may face similar obstacles. In addition, we have not updated the records in certain foreign patent offices to reflect our ownership of certain expired foreign patents relating to nelitolimod, but have recorded our ownership for at least the expired foreign patents acquired from Dynavax relating to composition of matter for nelitolimod in Australia, Canada, Austria, Germany, Denmark, Estonia, the UK, Hong Kong, Ireland, Luxembourg, Portugal, New Zealand, and Singapore. Failure to update such ownership may result in a purchaser potentially acquiring rights in such patents that are adverse to our interests. Litigation may be necessary to defend against any claims challenging inventorship or ownership and such litigation may be costly. If we fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates.

To the extent undertaken, we cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of our products and product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, certain United States patent applications can remain confidential until patents issue. Therefore, patent applications covering our products and product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our products and product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products and product candidates. We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our products or product candidates that are held to be infringing. We might, if possible, also be forced to redesign products or product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations.

Disputes may arise between us and any of these counterparties regarding intellectual property rights that are subject to such agreements, including, but not limited to:

- the scope of rights granted under the agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign our license; and
- the effects of termination.

The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations under any agreements, we may be required to pay damages and could lose intellectual property rights that are necessary or useful for developing and protecting our product candidates.

Dynavax has represented to us that we were given all intellectual property rights related to nelitolimod pursuant to the Dynavax Agreement. Pursuant to the Dynavax Agreement, we are obligated to pay up to $250.0 million upon the achievement of certain development, regulatory, and commercial milestones and low double-digit royalties based on potential future net sales of products containing the nelitolimod compound. Additionally, we are responsible for prosecution and maintenance of the acquired patents with obligations to keep Dynavax reasonably informed of the status thereof. Any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any such material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and any licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

Intellectual property rights do not necessarily address all potential threats to our business.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make formulations that are similar to our product candidates or other formulations but that are not covered by the claims of our patents that we own or have exclusively licensed;
- the patents of third parties may have an adverse effect on our business;
- we or any current or future strategic partners and/or collaborators might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own;
- we or any of our current or future strategic partners and/or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product;
- our competitors might conduct research and development activities in the United States and in other countries that provide a safe harbor from patent infringement claims for such activities, as well in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our existing or intended commercial markets;
- third parties performing manufacturing or testing for us using our product candidates could use the intellectual property of others without obtaining a proper license;

- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent application for certain technologies, trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 approve an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a paragraph IV certification of patent invalidity, unenforceability, or non-infringement to one of the patents listed in the Orange Book, with the FDA by the innovator NDA holder.

The FDC Act also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations for a previously-approved active moiety, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages, dosage forms or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and prohibits the FDA from approving an ANDA, or a Section 505(b)(2) NDA submitted by another company with overlapping conditions associated with the new clinical investigations for the three-year period. Three- year exclusivity does not prohibit the FDA from approving ANDAs for drugs containing the original conditions of use, i.e., original indications.

If we are unable to obtain such marketing exclusivity for our product candidates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our approval to obtain approval of competing products and launch their product earlier than might otherwise be the case.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We rely on trademarks as one means to distinguish any of our products or product candidates that are approved for marketing from the products of our competitors. TriNav® and Pressure-Enabled Drug Delivery™ (PEDD™) are our trademarks and, in the United States, our trademarks may be challenged, infringed, circumvented or declared descriptive or generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively.

Risks Related to the Ownership of Our Securities

We have limited experience operating as a United States public company and may not be able to adequately develop and implement the governance, compliance, risk management and control infrastructure and culture required for a public company, including compliance with the Sarbanes Oxley Act.

We have limited experience operating as a United States public company. Certain of our executive officers lack experience in managing a United States public company, which makes their ability to comply with applicable laws, rules and regulations uncertain. Our failure to comply with all laws, rules and regulations applicable to United States public companies could subject us and our management to regulatory scrutiny or sanction, which could harm our reputation and share price.

We have limited experience preparing and filing periodic or other reports with the SEC or complying with the other requirements of United States federal securities laws applicable to public companies. We also have limited experience establishing and maintaining the disclosure controls and procedures and internal controls over financial reporting applicable to a public company in the United States, including the Sarbanes-Oxley Act. Although we are in the process of developing and implementing our governance, compliance, risk management and control framework and culture required for a public company, we may not be able to meet the requisite standards expected by the SEC and/or our investors. We may also encounter errors, mistakes and lapses in processes and controls resulting in failures to meet the requisite standards expected of a public company.

As a United States public reporting company, we incur significant legal, accounting, insurance, compliance, and other expenses. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. Compliance with reporting, internal control over financial reporting and corporate governance obligations requires members of our management and our finance and accounting staff to divert time and resources from other responsibilities to ensure these new regulatory requirements are fulfilled.

If we fail to adequately implement the required governance and control framework, we could be at greater risk of failing to comply with the rules or requirements associated with being a public company. Such failure could result in the loss of investor confidence, could harm our reputation, and cause the market price of our securities to decline. Other challenges in complying with these regulatory requirements may arise because we may not be able to complete our evaluation of compliance and any required remediation in a timely fashion. Furthermore, any current or future controls may be considered as inadequate due to changes or increased complexity in regulations, our operating environment or other reasons.

Due to inadequate governance and internal control policies, misstatements or omissions due to error or fraud may occur and may not be detected, which could result in failures to make required filings in a timely manner and make filings containing incorrect or misleading information. Any of these outcomes could result in SEC enforcement actions, monetary fines or other penalties, as well as damage to our reputation, business, financial condition, operating results and share price.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management now devotes substantial time to new compliance initiatives and corporate governance practices. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act, which could result in sanctions or other penalties that would adversely impact our business.

As a public company, and particularly after we are no longer an "emerging growth company," we incur significant legal, accounting, and other expenses that we did not incur as a private company, including costs resulting from public company reporting obligations under the Securities Act and the Exchange Act, and regulations regarding corporate governance practices. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the rules of the SEC, the listing requirements of the Nasdaq Stock Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have begun to hire additional accounting, finance, and other personnel in connection with becoming a public company, and our management and other personnel devotes a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We cannot predict or estimate the amount of additional costs we will incur as a result of becoming a public company or the timing of such costs. Any changes we make to comply with these

obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the Board or committees of the Board or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Pursuant to Sarbanes-Oxley Act Section 404, we are required to furnish a report by our management on our internal control over financial reporting. In order to continue to maintain effective internal controls to support growth and public company requirements, we will need additional financial personnel, systems and resources. However, while we remain an emerging growth company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of the Sarbanes-Oxley Act within the prescribed period, we are engaged in a process to enhance our documentation and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal control over financial reporting is effective as required by Sarbanes-Oxley Act Section 404. Our management has identified material weaknesses and, in the future, our management may identify one or more material weaknesses, which could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Our management has identified material weaknesses in its internal control over financial reporting and we may identify additional material weaknesses in the future. If we fail to remediate the material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, it may adversely affect our ability to accurately and timely report our financial results, and may adversely affect investor confidence and business operations.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the financial statements would not be prevented or detected on a timely basis.

In connection with our audited consolidated financial statements for the years ended December 31, 2024 and 2023, management identified material weaknesses in its 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 financial reporting, patent costs, certain R&D accruals, certain general accruals, accounting for leases under ASC 842, accounting for revenue, and accounting for significant transactions, including costs associated with the SEPA, the Exchange Warrants, accounting for the OrbiMed Credit Agreement, including the Initial Commitment Amount and the related derivative financial instruments,; (ii) inadequate controls over accounting and financial reporting for the Business Combination; (iii) inadequate internal controls over the valuation of derivative financial instruments, including the warrant and tranche rights and obligations and liabilities resulting from the series B-2 preferred stock financing; and the Revenue Base Redemption liability associated with the Initial Commitment Amount; (iv) inadequate controls of the conversion of data from our legacy stock-based compensation management system to our new system and assumptions used to calculate fair value of certain equity awards; and (v) inadequate security management internal controls over certain IT applications supporting financial reporting, related to segregation of privileged IT user rights and to monitor elevated user activity; each described in more detail under the heading Part II — Item 9A. Controls and Procedures elsewhere in this Annual Report.

Our management developed a remediation plan, and we are taking steps to remediate each of the material weaknesses described above. The remediation plan included hiring four additional trained resources with requisite experience with complicated accounting issues, designing and enforcing processes that ensure adequate segregation of duties within the finance function and adequately reviewing the assumptions and inputs to accounting estimates and engaging outside expert consultants as needed. As of the date of this filing, we have hired all of the additional trained resources with such requisite experience. The material weaknesses will be considered remediated when our management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Our management will continue to monitor the effectiveness of the remediation plan and will make the changes it determines to be appropriate. Although our management intends to complete this remediation process as quickly as practicable, it cannot at this time estimate how long it will take, and initiatives may not prove to be successful in remediating the material weaknesses.

Furthermore, we cannot assure you that the remediation measures taken to date, and the actions we may take in the future, will be sufficient to remediate the control deficiencies that led to the material weaknesses in our internal controls over financial reporting described above or that we will prevent or avoid potential future material weaknesses. Further, additional weaknesses in our disclosure controls and internal controls over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in material errors in our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to the listing requirements of Nasdaq, investors may lose confidence in our financial reporting and our stock price may decline as a result. In addition, we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities as well as stockholder litigation which would require additional financial and management resources, and investors may lose confidence in our financial reporting and our stock price may decline as a result. As a result, our ability to obtain financing, or financing on favorable terms, could be materially and adversely affected, which in turn, could materially and adversely affect our business, financial condition and the market value of our securities and require us to incur additional costs to improve our internal control systems and procedures. In addition, perceptions of us among customers, partners, investors, securities analysts and others could also be adversely affected.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are required to comply with the requirements of the Sarbanes-Oxley Act, including, among other things, maintaining effective disclosure controls and procedures and internal control over financial reporting. We continue to develop and refine our disclosure controls and other procedures that are designed to ensure that the information we are required to disclose in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our management, including our principal executive and financial officers. We may, however, be unable to meet the time periods specified in the SEC rules and forms. For example, prior to the filing of the Annual Report on Form 10-K for the year ending December 31, 2023, we filed a Form 12b-25 (Notification of Late Filing) with the SEC to avail ourselves of a 15-day extension to file the Annual Report on Form 10-K. The need for the extension was primarily due to the calculation of non-cash stock compensation caused by data errors associated with a transition to a new service provider in 2023.

We must continue to improve our internal control over financial reporting. Our management will be required to make a formal assessment of the effectiveness of our internal control over financial reporting pursuant to Sarbanes-Oxley Act Section 404(a), and we may in the future be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with these requirements within the prescribed time period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

There is a risk that we will not be able to conclude, within the prescribed time period or at all, that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act.

Any failure to implement and maintain effective disclosure controls and procedures and internal control over financial reporting, including the identification of one or more material weaknesses, could cause investors to lose confidence in the accuracy and completeness of our financial statements and reports, which would likely adversely affect the market price of our Common Stock. In addition, we could be subject to sanctions or investigations by the stock exchange on which our Common Stock is listed, the SEC and other regulatory authorities.

The price of our securities has been and may continue to be volatile.

The price of our securities has been and may continue to be volatile. From August 11, 2023, the date following the Business Combination, through December 31, 2024, our common stock price has fluctuated from a low of $3.60 to a high of $12.00 per share, and the price of our publicly traded warrants have fluctuated from a low of $0.12 to a high of $2.18 per warrant. The price of our Common Stock and publicly traded warrants may continue to fluctuate in the future due to a variety of factors, including, without limitation:

- the volume and timing of sales of TriNav or other products;
- the introduction of new products or product enhancements by us or others in our industry;

- the timing and results of clinical trials of any of our product candidates;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- the success of existing or new competitive products or technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- establishment or termination of collaborations for our product candidates or development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries, including as a result of tariffs;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the level of expenses related to any of our product candidates or development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation or government investigations involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of (or inability to incur) additional debt;
- the volume of shares of Common Stock available for public sale;
- general economic and political conditions, such as recessions, interest rates, social, political and economic risks and acts of war or terrorism; and
- that the information we are required to disclose in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our management, including our principal executive and financial officers.

These market and industry factors may materially reduce the market price of our securities regardless of our operating performance. It is also possible that an active trading market will not be sustained. Any of these effects would make it difficult to sell our securities at an attractive price or at all.

We may be unable to maintain the listing of our securities on Nasdaq in the future.

We cannot guarantee that our securities will continue to be listed on Nasdaq. If we fail to meet the requirements of the applicable listing rules, such failure may result in a suspension of the trading of our shares or delisting in the future. This may further result in legal or regulatory proceedings, fines and other penalties, legal liability for us, the inability for our stockholders to trade their shares and negatively impact our share price, reputation, operations and financial position, as well as our ability to conduct future fundraising activities. If Nasdaq delists our securities and we are not able to list our securities on another national securities exchange, we expect that our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a limited amount of news and analyst coverage for the company; and

- a decreased ability to issue additional securities or obtain additional financing in the future.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, higher interest rates and uncertainty about economic stability, including as a result of actual or threatened tariffs. For example, the recent implementation and threat of tariffs have created extreme volatility in the global capital markets, disrupted global supply chains and may materially and adversely impact the cost of goods. As a further example, Russia's ongoing incursion of Ukraine has created extreme volatility in the global capital markets and disrupted global supply chain and energy markets; it is possible that wars in the Middle East may have similar effects. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of economic policies, political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates or tariffs can adversely affect us by increasing our costs. 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. These factors can individually or in the aggregate 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 equity holders, in the public market or otherwise, could cause the market price for our securities to decline.

The sale of our Common Stock in the public market or otherwise, or the perception that such sales could occur, could harm the prevailing market price of our Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of our Common Stock may cause the market price of our securities to drop significantly, even if our business is doing well. Specifically, we have filed a number of resale registration statements covering the resale of our Common Stock that is outstanding or that may be issued and become outstanding at the election of the holder of such security upon exercise or conversion thereof.

Our stockholders will be able to sell all of their securities held for so long as they remain registered for resale on an effective registration statement or if the sale is otherwise exempt from registration. This is more relevant now given all the conversion of the preferred stock. 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.

Following the closing of the offer and Consent Solicitation on July 1, 2024, there were approximately 1,751,825 Public Warrants to purchase an aggregate of 1,751,825 shares of Common Stock, 4,428,648 Private Placement Warrants to purchase an aggregate of 4,428,648 shares of Common Stock and 1,000,000 Conversion Warrants to purchase an aggregate of 1,000,000 shares of Common Stock. The Private Placement Warrants and Conversion Warrants became exercisable on September 10, 2023, in accordance with the terms of the Warrant Agreement. The Initial OrbiMed Warrant for 130,805 share of Common Stock became exercisable on April 30, 2024. The exercise price of the remaining SPAC Warrants is $11.50 per share, or approximately $82.6 million in the aggregate, assuming none of the SPAC Warrants are exercised through “cashless” exercise. The exercise price of the Initial OrbiMed Warrant was initially $9.5562 per share, or approximately $1.25 million in the aggregate, assuming none of the Initial OrbiMed Warrant is exercised through a "cashless" exercise. For the year ended December 31, 2024, the exercise price was adjusted pursuant to the terms of the Initial OrbiMed Warrant to $9.3722 per share, or approximately $1.23 million in the aggregate, assuming none of the Initial OrbiMed Warrant is exercised through a "cashless" exercise. We have the unilateral right to reduce the exercise price of the SPAC Warrants, and may do so as a means of raising capital. Additionally, pursuant to the Warrant Amendment, we have the unilateral right to force conversion of the remaining 1,751,825 Public Warrants in exchange for 0.27 shares of Common Stock per Public Warrant. There is no guaranty that the warrant holders will exercise their Warrants at the current exercise price or any reduced exercise price. We believe the likelihood that warrant holders will exercise their Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Common Stock. So long as the trading price for our Common Stock is less than $11.50 per share (or, if the exercise price is lowered, such lower exercise price), meaning the SPAC Warrants are “out of the money,” we believe holders of our SPAC Warrants that were issued will be unlikely to exercise their SPAC Warrants on a cash basis. Similarly, if the trading price of our Common Stock is below $9.3722, meaning the Initial OrbiMed Warrant would be “out of the money,” we believe OrbiMed would be unlikely to exercise the Initial OrbiMed Warrant on a cash basis. Additionally, the Initial OrbiMed Warrant, as shown above, is subject to customary price-based anti-dilution protections, such that, in certain circumstances, if we issue shares of our common stock below the current exercise price of the Initial OrbiMed Warrant, including through sales under the SEPA, the exercise price of the Initial OrbiMed Warrant will be adjusted downward based on such issuance. As a result, if there are any such adjustments, the amount of proceeds we receive from the exercise of the Initial OrbiMed Warrant will be less than $1.24 million in the aggregate. On December 31, 2024, the reported sales price of our Common Stock was $5.01 per share and the last reported sales price of our Public Warrants was $1.10 per warrant, both of which are lower than the exercise price of the Warrants.

To the extent such Warrants are exercised, or we force the conversion of the Public Warrants, additional Common Stock will be issued, which will result in dilution to the holders of Common Stock and will increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of Common Stock.

We are an emerging growth company as well as a smaller reporting company within the meaning of the Securities Act and, if we take advantage of certain exemptions from disclosure requirements available to “emerging growth companies,” our securities may be less attractive to investors and it may be more difficult to compare our performance with other public companies.

We qualify as an emerging growth company under SEC rules. As an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These provisions include: (1) presenting only two years of audited financial statements; (2) presenting only two years of related selected financial data and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure; (3) an exemption from compliance with the auditor attestation requirement in the assessment of internal control over financial reporting pursuant to Section 404 of Sarbanes-Oxley; (4) not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements; (5) reduced disclosure obligations regarding executive compensation

arrangements in periodic reports, registration statements, and proxy statements; and (6) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide will be different than the information that is available with respect to other public companies that are not emerging growth companies. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for the Common Stock, and its market price may be more volatile. We will remain an emerging growth company until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of MTAC's initial public offering (i.e., December 31, 2025), (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common equity that is held by non-affiliates exceeds $700.0 million as of the end of the prior fiscal year's second fiscal quarter; and (2) the date on which we will have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Additionally, we qualify as a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our Common Stock held by non-affiliates exceeds $250.0 million as of the end of that year's second fiscal quarter, or (2) our annual revenues exceeded $100.0 million during such completed fiscal year and the market value of Common Stock held by non-affiliates equals or exceeds $700.0 million as of the end of that year's second fiscal quarter. To the extent that we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Our Warrants may not be exercised at all or may be exercised on a cashless basis and we may not receive any cash proceeds from the exercise of the Warrants.

The exercise price of the Warrants may be higher than the prevailing market price of the underlying shares of Common Stock. The exercise price of the Warrants is subject to market conditions and may not be advantageous if the prevailing market price of the underlying shares of Common Stock is lower than the exercise price. The cash proceeds associated with the exercise of Warrants to purchase our Common Stock 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 March 31, 2025, the last reported sales price of our Common Stock was $5.38 per share. So long as the trading price of our Common Stock is less than $11.50, meaning the SPAC Warrants are "out of the money," meaning the exercise price is higher than the market price of our Common Stock, we believe that holders of the SPAC Warrants are unlikely to choose to exercise their SPAC Warrants. Similarly, so long as the trading price for our Common Stock is less than $9.3722, meaning the Initial OrbiMed Warrant is "out of the money," we believe OrbiMed would be unlikely to exercise the Initial OrbiMed Warrant. As a result, we may not receive any proceeds from the exercise of the Warrants.

Furthermore, to the extent that the Private Placement Warrants, Conversion Warrants, or Initial OrbiMed Warrants are exercised on a "cashless basis," we will not receive cash upon their exercise. A cashless exercise allows holders of such Warrants to convert the warrants into shares of our Common Stock without the need for a cash payment. Instead of paying cash upon exercise, the warrant holder would receive a reduced number of shares based on a predetermined formula. As a result, the number of shares issued through a cashless exercise will be lower than if the Private Placement Warrants, Conversion Warrants, or Initial OrbiMed Warrants were exercised on a cash basis.

The Public Warrants may only be exercised for cash provided there is then an effective registration statement registering the shares of Common Stock issuable upon the exercise of such warrants. If there is not a then-effective registration statement, then such Public Warrants may be exercised on a "cashless basis," pursuant to an available exemption from registration under the Securities Act.

Anti-takeover provisions contained in our Certificate of Incorporation and Bylaws, as well as provisions of Delaware law, could limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable.

Our Certificate of Incorporation and Bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the Board or taking other corporate actions, including effecting changes in our management. We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together these provisions may discourage transactions that otherwise could involve the payment of a premium over prevailing market prices for our securities. These provisions include:

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of the Board;
- the right of the Board to elect a director to fill a vacancy created by the expansion of the Board or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on the Board;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may only be called by a majority of the Board, the chairperson of the Board, or our chief executive officer which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the ability of the Board to issue shares of preferred stock, including "blank check" preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- limitation of the liability of, and the indemnification of, our directors and officers;
- the ability of the Board to amend our Bylaws, which may allow the Board to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the Bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to the Board or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in the Board, and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the potential acquirer's own slate of directors or otherwise attempting to obtain control of us.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control of us or changes in our Board and our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the General Corporation Law of the State of Delaware (the "DGCL"), which prevents some stockholders who hold more than 15% of our outstanding Common Stock from engaging in certain business combinations without approval of the holders of substantially all of our Common Stock. Any provision of our Certificate of Incorporation and Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for stockholders to receive a premium for their shares of Common Stock and could also affect the price that some investors are willing to pay for Common Stock.

Our Certificate of Incorporation designates the Delaware Court of Chancery or Delaware state or United States federal district courts as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit such stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, other employees or other stockholders.

Our Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for state law claims for (i) any derivative claim or cause of action brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, other employees or stockholders, us or our stockholder; (iii) any action against us or any of our current or former directors, officers or other employees asserting a claim arising pursuant to any provision of the DGCL, our Certificate of Incorporation or Bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or Bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction on the Delaware Court of Chancery; and (vi) any action asserting a claim against us or any of our current or former directors, officers or other employees governed by the internal affairs doctrine or otherwise related to our internal affairs. The foregoing provisions will not apply to any claims as to which the Delaware Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of such court, which is rested in the exclusive jurisdiction of a court or forum other than such court.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules or regulations promulgated thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such Securities Act claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

Any person or entity purchasing or otherwise acquiring, holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the forum provisions in our Certificate of Incorporation. Although we believe these exclusive forum provisions will benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. Furthermore, investors cannot waive compliance with the federal securities laws and rules and regulations promulgated thereunder.

Our Certificate of Incorporation, to the extent permitted by applicable law, contains provisions renouncing our interest and expectation to participate in certain corporate opportunities identified or presented to our non- employee directors or stockholders.

Our officers and directors and their respective affiliates may hold, and may, from time to time in the future, acquire interests in or provide advice to businesses that directly or indirectly compete with certain areas of our business. Our Certificate of Incorporation provides that we renounce, to the fullest extent permitted by Delaware or other applicable law, any expectancy that any of our non-employee directors, stockholders or the affiliates of such stockholders will offer any corporate opportunity of which such director or stockholder may become aware to us except with respect to a corporate opportunity that was offered to a director solely in his or her capacity as our director and (i) such opportunity is one we are legally and contractually permitted to undertake and (ii) the director is permitted to refer that opportunity to us without violating any legal obligation. As a result, these arrangements could adversely affect our business, results of operations, financial condition or prospects if attractive business opportunities are allocated to any of our non-employee directors, stockholders or the affiliates of such stockholders instead of to us.

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 importance of developing, implementing, and maintaining cybersecurity measures that are designed 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 in an effort 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 inform management and our Board of Directors of any significant cybersecurity risks and developments.

Our Senior 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 that help to identify, assess, and manage the Company's cybersecurity threats and risk. Our DO working knowledge of end-user best practices and regularly meets with our third-party IT support firm to discuss potential 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. Based on these meetings, our DO identifies additional end-user education and company security needs, which are supported through our IT support firm or other third-party IT experts.

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 us 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 ("Audit Committee") for certain cybersecurity incidents.

Governance

Cybersecurity risks are overseen by 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 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 importance 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 21.0 thousand square feet of office, manufacturing, and warehouse space pursuant to a lease that expires on December 31, 2031. The initial lease included two extension options, each for five years. On July 17, 2024, we exercised one of the two options to extend the current lease for the Westminster facility for an additional period of five years commencing on January 1, 2027, and ending on December 31, 2031 ("Second Extended Lease Term"). We lease office facilities in Bannockburn, Illinois and 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 March 31, 2025, there were 113 holders of record of our shares of Common Stock, 94 holders of record of our shares of Series A preferred stock, and 12 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.

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

None

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, 2024 and 2023, 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 dedicated to the research, development, and commercialization of an innovative drug delivery technology platform and an immuno-oncology therapeutic, aimed at improving outcomes for patients with difficult-to-treat liver and pancreatic cancers. Our advanced technology is designed for use by interventional radiologists to enhance the delivery of therapeutics and improve patient outcomes.

We market our cutting-edge Pressure Enabled Drug Delivery (PEDD™) infusion systems, which optimize therapeutic delivery for hepatocellular carcinoma, pancreatic cancer, and other solid liver tumors. Additionally, we are pursuing the development of nelitolimod to illustrate how an immunotherapeutic--when administered via PEDD in combination with systemic treatment--can enhance the effectiveness of other therapeutics, ultimately leading to better patient responses. The combination of our PEDD technology with nelitolimod is focused on solving the two main barriers in the tumor microenvironment 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 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. Effective April 1, 2025, TriNav received a second unique and permanent HCPCS code from CMS. This new code provides reimbursement clarity for mapping procedures conducted prior to TARE.

TriSalus recently expanded its portfolio of PEDD devices with the launch of the TriNav LV Infusion System and TriGuide Guiding Catheter to optimize therapeutic delivery for patients with larger vessels. The TriNav LV is suitable for patients with vessels sized between 3.5 and 5.0mm and is expected to allow us to meaningfully expand our addressable liver embolization market. The TriGuide Guiding Catheter has a larger inner diameter, lubricious inner lining, and reverse curve design to support femoral access for the TriNav LV, which we believe will enhance procedural efficiency. These new products are eligible for the same HCPCS reimbursement codes as existing TriNav products, enabling seamless integration into current billing structures.

TriSalus also initiated a registry study called PROTECT (Pressure Enabled Retrograde Occlusive Therapy with Embolization for Control of Thyroid Disease) and intends to enroll 100 patients across five leading academic sites. It is estimated that approximately 5% of adults have multinodular goiters, and the prevalence in adults over 50 is estimated to be up to 50%. We estimate that this could expand the addressable market by approximately 50,000 procedures, representing an incremental $400.0 million market opportunity. This new procedure utilizing the TriNav system is also eligible for the same Healthcare Common Procedure Coding System (HCPCS) reimbursement code allowing for seamless integration into current billing approaches.

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 We have initiated Phase 1 and Phase 1b clinical trials for nelitolimod, each of which are focused on a different target indication, specifically UMLM, ICC and HCC, and pancreatic cancer. Continued investigation for ICC and HCC may continue through IITs. Based on the changing landscape for second line treatment of uveal melanoma, we do not intend to proceed to Phase II trials for that indication on our own, but we are looking for potential partners to advance that indication. Our Phase I PERIO-03 clinical trial in pancreatic cancer is enrolled and we anticipate data from the study will be available in sometime in 2025, depending on when treatment is completed.

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 terms of 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 their equity holdings at an exchange ratio of 0.02471853 (the "Exchange Ratio") for an aggregate of 22,000,000 shares of our Common Stock. 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. All share and per share amounts of our common and preferred stock have been retrospectively adjusted for the exchange ratio in the following discussion. 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 increase 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 both mapping and therapeutic procedures involving TriNav. This code, HCPCS C9797, has been assigned to the Ambulatory Payment Classification (APC) 5194 - Level 4 Endovascular Procedures. The code became effective on January 1, 2024, and may be reported by hospital outpatient departments and ambulatory surgical centers, but there can be no assurance that continuing reimbursement will be available at similar reimbursement rates or at all. Effective April 1, 2025, TriNav received a second unique and permanent HCPCS code from CMS, C8004, which has been assigned to APC 5193 (Level 3 Endovascular Procedures). This new code provides reimbursement clarity for mapping procedures conducted prior to TARE. 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

SEPA Sales

For the year ended December 31, 2024, we sold 2,290,377 shares of common stock under the SEPA, raising $14.1 million.

Additional Fund Raising

During the year ended December 31, 2024, we also raised an additional $1.0 million, before expenses, through the sale of common stock outside of the SEPA.

OrbiMed Credit Agreement

In April 2024 (the "OrbiMed Closing Date"), we entered into a credit agreement (the "OrbiMed Credit Agreement") with OrbiMed Royalty & Credit Opportunities IV, LP ("OrbiMed"), a healthcare investment firm. The OrbiMed Credit Agreement provides for up to $50.0 million in senior secured term debt, of which (i) $25.0 million was made available to us on the Closing Date (the "Initial Commitment Amount") and (ii) up to $10.0 million will be made available to us on or prior to June 30, 2025, and up to $15.0 million will be made available to us on or prior to December 31, 2025, in each case,

subject to the satisfaction of certain revenue requirements (such additional commitment amounts, the "Delayed Draw Commitment Amount"). The term loan will mature on April 30, 2029. On April 30, 2024, we borrowed the Initial Commitment Amount, resulting in gross proceeds of $25.0 million.

In connection with the closing of the Initial Commitment Amount, we also issued OrbiMed a warrant to purchase 130,805 shares of our common stock, with the initial exercise price of $9.5562 per share, or approximately $1.25 million in the aggregate, assuming none of the Initial OrbiMed Warrant is exercised through a "cashless" exercise. For the year ended December 31, 2024, the exercise price was adjusted pursuant to the terms of the Initial OrbiMed Warrant to $9.3722 per share, or approximately $1.23 million in the aggregate. The Initial OrbiMed Warrant expires on April 30, 2031. On each of the closings of the Delayed Draw Commitment Amounts, if any, we agreed to issue additional warrants to purchase a number of shares of our common stock determined by dividing 5% of the applicable Delayed Draw Commitment Amount by the 10-day volume weighted average sale price of our common stock as of the issue date. The Subsequent Warrants will expire seven years from each applicable issuance date, if any. In connection with the Initial OrbiMed Warrants, we entered into a Registration Rights Agreement with OrbiMed, whereby OrbiMed will have certain customary registration rights with respect to the shares of common stock underlying the Initial OrbiMed Warrants.

Subsequent to December 31, 2024, we met the First Delayed Draw Term Loan Commitment and requested the additional $10.0 million term loan associated with the Second Tranche. On February 18, 2025, we received gross proceeds of $10.0 million. In connection with the closing of the First Delayed Draw, we issued OrbiMed 91,263 warrants on February 18, 2025. The Subsequent OrbiMed Warrants are held by the two of OrbiMed's operating entities associated with the Initial OrbiMed Warrants; one for 64,748 and the second for 26,515 common shares. The Subsequent OrbiMed Warrants expire seven years from the issuance date and contain an exercise price of $5.4787. Effective March 20, 2025, we executed the First Amendment To Credit Agreement and Registration Rights Agreement which required the registration of the Subsequent OrbiMed Warrants to be filed by May 15, 2025 and waived the prior default events related to the Series A Convertible Preferred Stock conversion in September 2024, February 2025, and March 2025.

Warrant Exchange Offering

On May 24, 2024, we announced the commencement of (i) our offer (the "Offer") to all holders of each class of certain outstanding warrants (the "Warrants"), consisting of (a) our publicly-traded Warrants (the "Public Warrants"), (b) certain Warrants we issued in a private placement transaction occurring simultaneously with the closing of the Business Combination (the "Private Placement Warrants") and (c) certain Warrants we issued for working capital requirements and payment of certain expenses ("Working Capital Warrants"), to receive 0.3 shares of our common stock in exchange for each Warrant tendered by the holder and exchanged pursuant to the Offer, and (ii) the solicitation of consents (the "Consent Solicitation") from holders of the Warrants to amend the Warrant Agreement, dated as of December 17, 2020 (the "Warrant Agreement" and such amendment, the "Warrant Amendment"), by and between the Company and Continental Stock Transfer & Trust Company, which governs all of the Warrants. Pursuant to the Offer, we offered up to an aggregate of 4,264,532 shares of our Common Stock in exchange for the Warrants.

Pursuant to the terms of the Warrant Agreement, certain amendments, including the Warrant Amendment, require the vote or written consent of holders of at least a majority of the then outstanding (a) Public Warrants (such threshold, the "Public Warrant Consent Threshold"), (b) Private Placement Warrants with respect to modifications or amendments that apply to the Private Placement Warrants (such threshold, the "Private Placement Warrant Consent Threshold") or any provision of the Warrant Agreement with respect to the Private Placement Warrants, including the Warrant Amendment, and (c) Working Capital Warrants with respect to modifications or amendments that apply to the Working Capital Warrants (such threshold, the "Working Capital Warrant Consent Threshold,") or any provision of the Warrant Agreement with respect to the Working Capital Warrants, including the Warrant Amendment.

The Offer and Consent Solicitation expired at one minute after 11:59 p.m., Eastern Standard Time, on June 25, 2024. The Warrants tendered were comprised of 6,529,954 Public Warrants and 504,685 Private Placement Warrants, which represented approximately 78.8% and 10.2% of the outstanding Warrants of each respective class. The Warrants were validly tendered and not validly withdrawn prior to the expiration of the Offer and Consent Solicitation. No Working Capital Warrants were tendered. On July 1, 2024, we issued 2,110,366 shares of Common Stock in exchange for the tendered Warrants.

Pursuant to the Consent Solicitation, the Company received the requisite approval to satisfy the Public Warrant Consent Threshold. The Company did not receive the approvals necessary to satisfy the Private Placement Warrant Consent Threshold or the Working Capital Warrant Consent Threshold. As a result, the Warrant Amendment was approved with respect to the Public Warrants but not the Private Placement Warrants or Working Capital Warrants.

Accordingly, on June 26, 2024, the Company and the Warrant Agent entered into the Warrant Amendment, which permits the Company to require that each Public Warrant that remains outstanding following the closing of the Offer be converted into 0.27 shares of Common Stock, which is a ratio 10% less than the exchange ratio applicable to the Offer. The Warrant Amendment has no effect on either the Private Placement Warrants or the Working Capital Warrants. Pursuant to the Warrant Amendment, the Company has the right to require the exchange of not less than all of the Public Warrants at any time while such Public Warrants are exercisable and prior to their expiration.

Convertible Preferred Stock

In 2023, we were authorized to issue up to 10,000,000 shares of preferred stock. On August 10, 2023 (the Business Combination "Closing Date"), we issued 4,015,002 shares of Series A Convertible Preferred Stock for $40.2 million. The original issue and initial conversion price per share 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, 2024, total undeclared cumulative dividends were $4.4 million. We have not recorded the undeclared dividends in our consolidated financial statements presented under "Undeclared dividends on Series A preferred stock" in our Consolidated Statement of Operations.

The Series A Convertible Preferred Stock contain a feature to automatically reset the Conversion Price 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 lower of:

(i) the then-current conversion price, and

(ii) the higher of 1) the Floor Price ($2.10 per share) or 2) the trailing ten-trading day volume weighted average price ("VWAP") of the Common Stock determined as of the date of such reset.

On February 10, 2025, the conversion price was reset to $5.277 based on the trailing ten-Trading Day VWAP of the Common Stock. As of March 31, 2025, approximately 365,000 shares of Series A Convertible Preferred Stock, including the applicable accrued dividends, have been converted for approximately 778,000 shares of Common Stock.

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, to which we sell directly.

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 $0.3 million of rebates in the 12 months ended December 31, 2024.

Cost of Goods Sold

Cost of goods sold primarily consists of raw materials, direct labor, manufacturing overhead and depreciation 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, including salaries, travel, materials purchased for R&D activities and patent expense. 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.

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 and Extinguishment of Tranche Liability

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 in a preferred stock financing and its subsequent tranche closings.

Change in Fair Value of SEPA, Warrant, and Revenue Base Redemption Liabilities

Change in fair value of SEPA, Warrant, and Revenue Base Redemption liabilities represents the change in fair value at each reporting period of the SEPA, the Series B-2 tranche liabilities (with accompanying warrants to purchase Series B-3 preferred stock) that were issued in October 2022, the change in fair value of the SPAC Warrants we assumed in the Business Combination, and the change in fair value of the Initial OrbiMed Warrant and Based Redemption Liability issued in connection with the Initial Term Loan under the OrbiMed Credit Agreement entered into in April 2024.

Change in Fair Value of Contingent Earnout Liability

Change in fair value of contingent earnout liability, which resulted from the issuance of the common stock with certain earnout triggered as part of the Merger Agreement, represents the remeasurement of the liability based on the likelihood of the unvested Common Stock becoming vesting based on reaching certain future common stock price thresholds.

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. During 2023, the Series B-2 Preferred Stock shares were converted.

Undeclared Dividends On Series A Convertible Preferred Stock

The undeclared dividends represents the value attributed to cumulative dividends associated with the Series A Convertible Preferred Stock. The cumulative dividends are calculated at the rate of 8.00% per annum on the original issue price of $10.00 per share. We have not recorded the undeclared dividends in our consolidated financial statements, other than under "Undeclared dividends on Series A Preferred Stock" in our Consolidated Statements of Operations.

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,		2024 Compared to 2023	
	2024	2023	$ Change	% Change
Revenue	$ 29,431	$ 18,511	$ 10,920	59.0%
Cost of goods sold	4,103	2,605	1,498	57.5
Gross profit	25,328	15,906	9,422	59.2
Operating expenses:				
Research and development	17,688	29,835	(12,147)	(40.7)
Sales and marketing	25,839	17,034	8,805	51.7
General and administrative	17,966	23,512	(5,546)	(23.6)
Loss from operations	(36,165)	(54,475)	18,310	33.6
Other income (expense)				
Interest income	404	431	(27)	(6.3)
Interest expense	(3,090)	(16)	(3,074)	n.m.
Loss on equity issuance	—	(5,874)	5,874	(100.0)
Extinguishment of tranche liability	—	1,520	(1,520)	(100.0)
Change in fair value of warrant, SEPA, and revenue base redemption liabilities	(2,107)	(10,855)	8,748	80.6
Change in fair value of contingent earnout liability	11,231	10,293	938	9.1
Other expenses, net	(312)	(378)	66	17.5
Loss before income taxes	(30,039)	(59,354)	29,315	49.4
Income tax expense	(6)	(9)	3	33.3
Net loss available to common stockholders	$ (30,045)	$ (59,363)	$ 29,318	49.4%
Deemed dividend related to Series B-2 preferred stock down round provision	$ —	$ (2,981)	$ 2,981.4	100.0%
Undeclared dividends on Series A preferred stock	$ (3,188)	$ (1,258)	$ (1,930)	(153.5)%
Net loss attributable to common stockholders	$ (33,233)	$ (63,602)	$ 30,369	47.7%

n.m.: not meaningful, represented by a percentage change greater than 1,000%, favorable or unfavorable.

Comparison of the Years Ended December 31, 2024, and 2023

Revenue

Revenue increased $10.9 million, or 59.0%, for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The increase in revenue was due to an increase of TriNav sales volumes.

Cost of Goods Sold and Gross Profit

Cost of goods sold increased by $1.5 million, or 57.5%, for the year ended December 31, 2024, as compared to the year ended December 31, 2023. 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 $9.4 million, or 59.2%, for the year ended December 31, 2024, as compared to the year ended December 31, 2023, and gross margin increased from 85.9% to 86.1%. 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 decreased by $12.1 million, or 40.7%, for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The decrease was primarily due to the completion of certain clinical studies related to nelitolimod in 2024.

Sales and Marketing

Sales and marketing expenses increased by $8.8 million, or 51.7%, for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The increase was primarily driven by approximately $6.9 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 $1.7 million of additional professional service expense as we increased our sales and marketing efforts in support of the expansion of the sales force.

General and Administrative Expenses

General and administrative expenses decreased by $5.5 million, or 23.6%, for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The decrease was due to a $2.5 million decrease in legal, $3.9 million decrease in accounting, and $1.1 million decrease for other professional services due to TriSalus incurring additional fees in 2023 following the Business Combination in the third quarter of 2023. These were offset by an increase of approximately $2.3 million in stock-based compensation expenses.

Interest Expense

Interest expense increased by $3.1 million for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The interest expense increase was driven by the addition of the OrbiMed loan in the second quarter of 2024.

Loss on Equity Issuance

There was no recorded loss on equity issuance for the year ended December 31, 2024, compared to a loss of $5.8 million in the year ended December 31, 2023, attributable primarily to the issuance of the Series B-2 preferred stock and the accompanying warrants to purchase Series B-3 preferred stock and related tranche obligations in 2023 with no comparable issuances in 2024.

Change in Extinguishment of Tranche Liability

The change of $1.5 million in extinguishment of the tranche liability was the result of the extinguishment of the Series B-2 tranche liabilities in the year ended December 31, 2023, compared to no extinguishments or other comparable equity activity during the year ended December 31, 2024.

Change in Fair Value of SEPA, Warrant. and Revenue Base Redemption Liabilities

The change in fair value of SEPA, warrant and Revenue Base Redemption liabilities resulted in a loss of $2.1 million in the year ended December 31, 2024, compared to a loss of $10.9 million in the year ended December 31, 2023, a difference of $8.7 million. The change was driven by the usage of the SEPA and the addition of the warrant and Revenue Base Redemption liability as part of the addition of the OrbiMed Credit Agreement in the second quarter of 2024, and the depreciation of the warrant liabilities, compared to the appreciation of the warrant liabilities in 2023.

Change in Fair Value of Contingent Earnout Liability

The change in fair value of earnout liability resulted in a gain of $11.2 million for the year ended December 31, 2024 compared to a gain of $10.3 million for the year ended December 31, 2023, due to slightly larger decreases of the TriSalus stock price and risk-free rate valuation inputs in 2024 compared to valuation inputs during the period ended 2023.

Other Income and Expense, Net

Other income and expense, net, decreased by $0.1 million, or 17.5%, for the year ended December 31, 2024, as compared to the year ended December 31, 2023, primarily due to receiving a federal refund identified in 2024 based on the completion and filing of the 2023 tax filings, offset by state increases in taxes due to the increase in 2024 sales.

Income Tax 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.

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

The change in the deemed divided related to the Series B-2 preferred stock was a result of the Business Combination on August 10, 2023, with the Series B-2 preferred stock no longer existing; therefore, we did not have a need to record a deemed dividend for the year ended December 31, 2024.

Undeclared dividend related to Series A convertible preferred stock

The change in the undeclared dividend related to Series A convertible preferred stock was a result of the Series A convertible preferred stock dividends calculated based on a full twelve-months for the year ended December 31, 2024 compared to a partial year for the year ended December 31, 2023.

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 $30.0 million and $59.4 million for the year ended December 31, 2024, and the year ended December 31, 2023, respectively. We had cash and cash equivalents of approximately $8.5 million and $11.8 million as of December 31, 2024 and 2023, 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 at all. If additional capital is not secured when required, we may need to delay or curtail our operations until such funding is received.

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 the rights of holders of our Common Stock. 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 2,290,377 shares of our Common Stock under the SEPA for gross proceeds of approximately $14.1 million. During the year ended December 31, 2024, we also raised an additional $1.0 million, before expenses, through the sale of Common Stock in a private placement. In addition, in April 30, 2024, we entered into the OrbiMed Credit Agreement providing for up to $50.0 million in senior secured term debt, of which we immediately drew $25.0 million, before expenses. Subsequent to December 31, 2024, we borrowed an additional $10.0 million term loan under the OrbiMed Credit Agreement.

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. If we are able to achieve certain targets specified in the Credit Agreement and are then able to draw the remainder of the funds available, and if market conditions allow us to sell additional shares under the SEPA, we believe we can fund our operations through the end of 2025. We have based these estimates on assumptions that may prove to be wrong and we could use our available capital resources sooner than we currently expect, and future capital requirements and the adequacy of available funds will depend on many factors, including those described in the section titled "*Risk Factors*" in this Annual Report. See also "Funding Requirements" below.

Cash Flows

Comparison of the Year Ended December 31, 2024 and December 31, 2023

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

	Year Ended	
	December 31, 2024	December 31, 2023
Net cash used in operating activities	(40,843)	$ (50,578)
Net cash used in investing activities	(345)	(1,588)
Net cash provided by financing activities	37,936	54,629
Net (decrease) / increase in cash, cash equivalents and restricted cash	$ (3,252)	$ 2,463

Cash Used in Operating Activities

For the year ended December 31, 2024, net cash used in operating activities was $40.8 million. The net cash used in operating activities consisted of net loss of $30.0 million, adjusted for non-cash activity totaling $1.2 million, primarily related to a gain on the adjustment of the fair value of the contingent earnout liability of $11.2 million, offset by share-based compensation of $5.4 million and a loss on the adjustment of the fair value of warrants to purchase common stock of $2.8 million. The increase in net operating assets of $9.5 million was primarily due to an increase in inventory and accounts receivable, offset by a decrease in trade payables and accrued liabilities.

For the year ended December 31, 2023, net cash used in operating activities was $50.6 million. The net cash used in operating activities consisted of net loss of $59.4 million adjusted for non-cash activity totaling $8.2 million, primarily related to a loss on equity issuance of $5.9 million and a $1.0 million adjustment related to a development milestone payment to Dynavax that is included as an investing cash outflow. The decrease in net operating assets of $0.5 million was primarily due to the increase of $2.8 million in trade payables and accrued liabilities, offset by the $2.0 million increase in accounts receivable.

Cash Used in Investing Activities

Net cash used in investing activities of $0.3 million for the year ended December 31, 2024 was primarily due to purchases of property and equipment of $0.3 million.

Net cash used in investing activities of $1.6 million for the year ended December 31, 2023 was primarily due to cash paid to Dynavax for a milestone payment under the Dynavax Agreement of $1.0 million and purchases of property and equipment of $0.6 million.

Cash Provided by Financing Activities

Net cash provided by financing activities of $37.9 million for the year ended December 31, 2024 was due to $22.4 million, net of expenses, from the initial draw down under the OrbiMed Credit Agreement, $14.1 million related to the sale of Common Stock under the SEPA, and $1.0 million, before expenses, through the sale of Common Stock in a private placement.

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

Funding Requirements

Our primary use of cash is to fund our operating expenses, which consist of sales and marketing expenses related to the growth of our sole commercial product TriNav, research, development and clinical expenses related to both TriNav and nelitolimod, as well as general and administrative expenses. If we obtain approval for our product candidates, we expect to incur commercialization expenses, which may be significant, related to establishing or expanding sales, marketing, manufacturing capabilities, distribution and other commercial infrastructure to commercialize such products. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Inflation and rising interest rates may result in an economic recession globally or in the U.S., which could lead to a reduction in product demand, a decrease in corporate capital expenditures, prolonged unemployment, labor shortages, reduction in consumer confidence, adverse geopolitical and macroeconomic events, or any similar negative economic condition. Economic conditions in some parts of the world have been worsening, with disruptions to, and volatility and uncertainty in, the credit and financial markets in the U.S. and worldwide resulting from the effects of inflation and rising interest rates. These conditions have been further exacerbated by recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, the war in Ukraine and conflicts in the Middle East. It is not possible at this time to estimate the long-term impact that these and related events could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. If these conditions persist and deepen, we could experience an inability to access additional capital, or our liquidity could otherwise be impacted. If we are unable to raise capital when needed and on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs and/or other efforts.

We also expect to continue to incur significant expenses in connection with our ongoing activities related to TriNav, including sales and marketing expenses 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; our ability to draw the remaining $15.0 million available under the OrbiMed Credit Agreement if and when needed; 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 the price of our securities. Additionally, we are subject to a number of affirmative and restrictive covenants pursuant to the OrbiMed Credit Agreement, which limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. As of March 31, 2025, we will also be required to maintain a minimum cash balance of $10.0 million under the OrbiMed Credit Agreement. A failure to comply with the terms of the OrbiMed Credit Agreement may result in an event of default, which could result in an acceleration of amounts due under the OrbiMed Credit Agreement. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and OrbiMed could seek to enforce security interests in the collateral securing such indebtedness, which would materially harm our business and our stock price.

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 capital 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, 2024, we had $8.5 million in cash and cash equivalents. As of December 31, 2024, we have the right but not the obligation to sell up to $15.9 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.

We will likely require additional capital in the near term in order to continue to fund our operations through one or a combination of securities offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements 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.

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 we may need to implement cost cutting measures, which may require us to reduce our marketing and commercialization expenditures for TriNav, discontinue or scale back the development of our product candidates or result in the delay of their development and commercialization, if approved, and other measures, which may materially and adversely impact our business. Further, we may need to pursue strategic alternatives, including mergers or other transactions, if we are unable to secure additional capital.

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 substantial doubt regarding our ability to continue as a going concern as of December 31, 2024 and the date of this Annual Report.

Contractual Obligations and Commitments

Our contractual obligations as of December 31, 2024, include lease obligations of $2.3 million, reflecting the minimum commitments for our principal administrative and production facility and other office spaces. See Note *(18) Leases* to our 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, 2024, 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 for nelitolimod. 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.

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.

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. Subsequent to a rebate being earned, the customer receives a credit to apply to future purchases.

Warrants 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 consolidated 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 liability of the underlying convertible preferred stock.

In connection with the Business Combination, we assumed warrants to purchase Common Stock. The warrants include the Public Warrants, Private Placement Warrants and Working Capital Warrants. We value the liability for all of the warrants based on the trading price of the publicly held warrants.

In connection with our borrowing under the Initial OrbiMed Credit Agreement, we issued the Initial OrbiMed Warrant, which we classified as a derivative liability because it did not meet the equity classification criteria under ASC 815-40. We calculated the fair value of the Initial OrbiMed Warrant based on the Black-Scholes-Merton option pricing model. This model considers several variables and assumptions in estimating the fair value of financial instruments, including the per-share fair value of the underlying common stock, exercise price, expected term, risk-free interest rate, expected stock price volatility over the expected term, and expected annual dividend yield. We calculated the expected terms as the contractual expiration period. The risk-free interest rate is estimated using the rate of return on U.S. treasury notes with a life that approximates the expected term. Our common stock does not have sufficient trading history and, therefore, we used the historical volatility of the stock prices of similar publicly traded peer companies. We utilized a dividend yield of zero, as we have no history or plan of declaring dividends on the Company's common stock.

Contingent Earnout Liability

In connection with the Business Combination, the sponsor of the public entity agreed that certain of the shares of Common Stock it held would 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 on the Common Stock.

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

Revenue Base Redemption Liability

In connection with the Initial OrbiMed Loan, a "Product Revenue Base" (i.e., with respect to any period, the net revenues for such period from sales of TriNav) on a trailing 12-month basis does not equal or exceed the specified amounts, we will start repaying the outstanding principal amount of the Term Loans. These required revenue thresholds are referred to as the "Revenue Base Redemption Liability." We determined that we should bifurcate and separately recognize the Revenue Base Redemption Liability. We determined the value of the Revenue Base Redemption Liability using a Monte Carlo simulation of future revenue and valuing the Initial Term Loan using the with and without method. The change in fair value of the liability is recorded in the Consolidated Statement of Operations. See Note *(14) Debt* for further detail.

Standby Equity Purchase Agreement

In October 2023, the Company entered into a SEPA with Yorkville. Pursuant to the SEPA, the Company has the right, but not the obligation, to sell to Yorkville up to $30.0 million 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, and is accounted for as a derivative pursuant to ASC 815-10, *Derivatives and Hedging* ("ASC 815-10"). The SEPA derivative is valued based on a scenario-based valuation model utilizing the expected draws, probability of the draws and risk-free rate inputs. The change in the fair value of the derivative is recorded in the Consolidated Statements of Operations. See Note *(13) Standby Equity Purchase Agreement* for further detail.

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.

Segment Reporting

In 2024, we adopted Accounting Standards Update 2023-07, *Improvements to Disclosures About Reportable Segments*. In connection with the adoption of this Update, we re-evaluated our segment and significant expenses utilized by our Chief Operating Decision Maker ("CODM"). Our CODM, our Chief Executive Officer ("CEO"), reviews our financial information on a consolidated basis for purposes of allocating resources and evaluating its financial performance. The CEO considers recommendations from the Chief Financial Officer ("CFO") and reviews the Monthly Financial Report ("MFR"), including financial information and the company's performance highlights, such as revenue, accounts receivable and inventory balances, cash flows and cash on-hand, operational expenditures and headcount. Based on the Company's consolidated financial information, the CEO makes the key operating decisions and determines how resources should be allocated. Once the CEO has decided, the CEO and CFO are responsible for carrying out the CEO's decisions. All of our customers and long-lived assets are located in the United States. Accordingly, we have determined we operate as a single reportable segment within a single geographic area. Since the Company operates as a single reporting segment, all required segment reporting disclosures can be found in the consolidated financial statements, as presented in Note *(2) Summary of Significant Accounting Policies.*

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 until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the 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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
TriSalus Life Sciences, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheet of TriSalus Life Sciences, Inc. and subsidiaries (the "Company") as of December 31, 2024, the related consolidated statements of operations, stockholders' deficit, and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as 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, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

We also have audited the adjustments to the 2023 consolidated financial statements to retrospectively apply the change in accounting (resulting from the adoption of Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures)*, as described in Note 2. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2023 consolidated financial statements of the Company other than with respect to such adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2023 consolidated financial statements taken as a whole.

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 incurred a loss of $33.2 million for the year ended December 31, 2024, and has an accumulated deficit of $279.5 million as of December 31, 2024. 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 the Company's consolidated financial statements based on our audit. 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 audit 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 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 audit 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 audit included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provide a reasonable basis for our opinion.

/s/ Grant Thornton LLP

We have served as the Company's auditor since 2024.

Chicago, Illinois
April 15, 2025

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited, before the effects to retrospectively apply the change in accounting described in paragraph (q) of Note 2, the consolidated balance sheet of TriSalus Life Sciences, Inc. and subsidiaries (the Company) as of December 31, 2023, the related consolidated statements of operations, stockholders' deficit, and cash flows for the year ended December 31, 2023, and the related notes (collectively, the consolidated financial statements). The consolidated financial statements before the effects described in paragraph (q) of Note 2 are not presented herein. In our opinion, the consolidated financial statements, before the effects to retrospectively apply the change in accounting described in paragraph (q) of Note 2, present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for the year then ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We were not engaged to audit, review, or apply any procedures to retrospectively apply the change in accounting described in paragraph (q) of Note 2 and, accordingly, we do not express an opinion or any other form of assurance about whether such retrospective application is appropriate and had been properly applied. The retrospective adoption was audited by other auditors.

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 audit. 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 audit 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. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor from 2022 to 2023.

Denver, Colorado

April 15, 2025

TRISALUS LIFE SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS
December 31, 2024 and 2023
(in thousands, except share and per share data)

	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 8,525	11,777
Accounts receivable, net	5,087	3,554
Inventory	4,048	2,545
Prepaid expenses	3,009	2,986
Total current assets	20,669	20,862
Property and equipment, net	1,669	2,091
Right-of-use assets	1,210	1,179
Other assets	423	466
Total assets	$ 23,971	$ 24,598
Liabilities and Stockholders' Deficit		
Current liabilities:		
Trade payables	$ 2,274	$ 3,391
Accrued liabilities	7,355	10,556
Short-term lease liabilities	216	351
Other current liabilities	383	389
Total current liabilities	10,228	14,687
Long-term debt, net of unamortized discount and debt issuance costs	22,084	—
Revenue base redemption liability	507	—
Long-term lease liabilities	1,329	1,244
Contingent earnout liability	7,401	18,632
Warrant and SEPA liabilities	8,316	17,100
Total liabilities	49,865	51,663
Commitments and contingencies		
Stockholders' deficit:		
Preferred Stock, Convertible Series A, $0.0001 par value per share, $10.00 liquidation value per share. Authorized 10,000,000 shares at December 31, 2024 and 2023, respectively; issued and outstanding, 3,985,002 and 4,015,002 shares at December 31, 2024 and 2023, respectively	—	—
Common stock, $0.0001 par value per share. Authorized 400,000,000 shares at December 31, 2024 and 2023, respectively; issued and outstanding 31,279,264 shares and 26,413,213 shares at December 31, 2024 and 2023, respectively	3	2
Additional paid-in capital	253,652	222,437
Accumulated deficit	(279,549)	(249,504)
Total stockholders' deficit	(25,894)	(27,065)
Total liabilities and stockholders' deficit	$ 23,971	$ 24,598

See accompanying notes to consolidated financial statements.

TRISALUS LIFE SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended December 31, 2024 and 2023
(in thousands, except share and per share data)

	2024	2023
Revenue	$ 29,431	18,511
Cost of goods sold	4,103	2,605
Gross profit	25,328	15,906
Operating expenses:		
Research and development	17,688	29,835
Sales and marketing	25,839	17,034
General and administrative	17,966	23,512
Loss from operations	(36,165)	(54,475)
Other income (expense)		
Interest income	404	431
Interest expense	(3,090)	(16)
Loss on equity issuance	—	(5,874)
Extinguishment of tranche liability	—	1,520
Change in fair value of warrant, SEPA, and revenue base redemption liabilities	(2,107)	(10,855)
Change in fair value of contingent earnout liability	11,231	10,293
Other expenses, net	(312)	(378)
Loss before income taxes	(30,039)	(59,354)
Income tax expense	(6)	(9)
Net loss available to common stockholders	$ (30,045)	$ (59,363)
Deemed dividend related to Series B-2 preferred stock down round provision	$ —	$ (2,981)
Undeclared dividends on Series A preferred stock	$ (3,188)	$ (1,258)
Net loss attributable to common stockholders	$ (33,233)	$ (63,602)
Net loss per share, basic and diluted	$ (1.31)	$ (6.77)
Weighted average common shares outstanding, basic and diluted	25,331,753	9,395,748

See accompanying notes to consolidated financial statements.

TRISALUS LIFE SCIENCES, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
Years ended December 31, 2024 and 2023
(in thousands, except share data)

	Preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total
	Shares	Amount	Shares	Amount			
At December 31, 2022	—	$ —	347,926	$ —	$ 10,028	$ (187,160)	$ (177,132)
Exercise of options	—	—	247,612	—	180	—	180
Stock-based compensation	—	—	—	—	1,402	—	1,402
Deemed dividend	—	—	—	—	2,981	(2,981)	—
Impact of Business							
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	—	—	—	—	—	(59,363)	(59,363)
At December 31, 2023	4,015,002	$ —	26,413,213	$ 2	$ 222,437	$ (249,504)	$ (27,065)
Exercise of options	—	—	180,778	—	76	—	76
Stock-based compensation	—	—	—	—	5,441	—	5,441
Proceeds from sale of common stock	—	—	2,542,262	1	15,474	—	15,475
Record exchange warrants	—	—	—	—	11,924	—	11,924
Record issuance costs	—	—	—	—	(1,700)	—	(1,700)
Issuance of common stock for exchange warrants	—	—	2,110,366	—	—	—	—
Preferred stock conversion	(30,000)	—	32,645	—	—	—	—
Net loss	—	—	—	—	—	(30,045)	(30,045)
At December 31, 2024	**3,985,002**	**$ —**	**31,279,264**	**$ 3**	**$ 253,652**	**$ (279,549)**	**$ (25,894)**

See accompanying notes to consolidated financial statements.

TRISALUS LIFE SCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2024 and 2023
(in thousands)

	2024	2023
Cash flows from operating activities:		
Net loss available to common stockholders	$ (30,045)	$ (59,363)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	744	684
Reduction in the carrying amount of right-of-use assets	264	202
Change in fair value of warrants and SEPA liability	2,777	10,855
Change in fair value of contingent earnout liabilities	(11,231)	(10,293)
Change in fair value of Initial OrbiMed Warrant and revenue base redemption	(670)	—
Non-cash interest expense	604	—
Loss on equity issuance	—	5,874
Extinguishment of tranche liability	—	(1,520)
Stock-based compensation expense	5,441	1,402
Allowance for credit losses	187	—
Loss on disposal of fixed assets	23	44
Amortization of debt issuance costs	612	—
Milestone payment to Dynavax	—	1,000
Changes in operating assets and liabilities:		
Accounts receivable	(1,719)	(1,979)
Inventory	(1,503)	(1,073)
Prepaid expenses	(1,708)	1,032
Deposits	43	—
Operating lease liabilities	(278)	(281)
Trade payables and accrued liabilities	(4,384)	2,838
Net cash used in operating activities	(40,843)	(50,578)
Cash flows from investing activities:		
Purchases of property and equipment	(345)	(588)
Milestone payment to Dynavax	—	(1,000)
Net cash used in investing activities	(345)	(1,588)
Cash flows from financing activities:		
Proceeds from the issuance of preferred stock	—	9,189
Proceeds from the issuance of common stock	15,537	—
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)
Debt issuance costs	(2,593)	—
Proceeds from the issuance of debt	25,000	—
Payments on finance lease liabilities	(84)	(87)
Proceeds from the exercise of stock options for common stock	76	179
Net cash provided by financing activities	37,936	54,629
(Decrease) increase in cash, cash equivalents and restricted cash	(3,252)	2,463
Cash, cash equivalents and restricted cash, beginning of period	12,127	9,664
Cash, cash equivalents and restricted cash, end of period	$ 8,875	$ 12,127
Supplemental disclosures of cash flow information:		
Interest paid	1,750	18
Income taxes	18	14
Supplemental disclosure of noncash items:		
Right-of-use assets obtained in exchange for new operating lease liabilities	294	—

See accompanying notes to consolidated financial statements.

Fixed asset purchases included in trade payables and accrued expenses	—	19
Prepaid warrant issuance costs	1,700	—
Fair value of initial warrants issued with OrbiMed debt	362	—
Fair value of revenue base redemption liability related to OrbiMed debt	507	—
Non-cash interest expense	604	—
Transfer of warrant liability to common stock upon exercise of warrant	11,924	—
Transfer of warrant liability to preferred stock upon exercise of warrants	—	25,409

See accompanying notes to consolidated financial statements.

(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.

We are a growing, oncology focused medical technology business seeking to transform outcomes for patients with solid tumors by integrating our innovative delivery technology with standard-of-care therapies, and with our investigational immunotherapeutic, nelitolimod, a class C Toll-like receptor 9 ("TLR9") agonist, for a range of different therapeutic and technology applications. Our ultimate goal is to transform the treatment paradigm for patients battling solid tumors. We have developed an innovative technology 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) off target delivery. Nelitolimod, specifically, combined with our technology, aims to address the immunosuppressive properties of tumor immune cells in liver, pancreas and other solid tumors. By systematically addressing these barriers, we aim to improve response to therapies and to enable improved patient outcomes.

We market our cutting-edge Pressure Enabled Drug Delivery (PEDD™) infusion systems, which optimize therapeutic delivery for hepatocellular carcinoma, pancreatic carcinoma, and other solid liver tumors. 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. Additionally, we are studying a drug product candidate, nelitolimod (a TLR9 agonist), which has demonstrated a potential to enhance immune system response, when delivered via PEDD, in the treatment of 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 microenvironment that inhibits the success of systemic therapies. 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. 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. 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 Ambulatory Payment Classification ("APC") code with CMS. In December 2023, CMS granted a New Technology Healthcare Common Procedure Coding System ("HCPCS") code for both mapping and therapeutic procedures involving TriNav. This code, HCPCS C9797, has been assigned to the APC code 5194 - Level 4 Endovascular procedures. The code became effective on January 1, 2024, and may be reported by hospital outpatient departments and ambulatory surgical centers. Effective April 1, 2025, TriNav received a second unique and permanent HCPCS code from CMS, C8004, which

has been assigned to APC 5193 (Level 3 Endovascular Procedures). This new code provides reimbursement clarity for mapping procedures conducted prior to TARE.

Liquidity

As of December 31, 2024, we had cash, cash equivalents and restricted cash of $8.9 million. 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 an accumulated deficit of $279.5 million as of December 31, 2024. 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 that 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 debt. We have funded operations resulting in the cumulative net losses of $279.5 million, as of December 31, 2024, principally with proceeds from the sale of preferred stock, from the issuance of debt and convertible debt, and the closing of the Business Combination.

For the year ended December 31, 2024, we issued $15.6 million of common stock for cash, which included $76 from the exercise of stock options. As described in Note *(13) Standby Equity Purchase Agreement*, we have the right but not the obligation, to sell up to $30.0 million of our Common Stock at our request under the Standby Equity Purchase Agreement, which we entered into with YA II PN, Ltd. ("Yorkville") on October 2, 2023 (the "SEPA"), subject to terms and conditions specified in the agreement. For the year ended December 31, 2024, we sold 2,290,377 shares of common stock under the SEPA, raising $14.1 million. During the year ended December 31, 2024, we also raised an additional $1.0 million, before expenses, through the sale of common stock in a private placement.

On April 30, 2024 (the "OrbiMed Closing Date"), we entered into the OrbiMed Credit Agreement (the "Credit Agreement") with OrbiMed Royalty & Credit Opportunities IV, LP ("OrbiMed"), a healthcare investment firm. Under the terms of the OrbiMed Credit Agreement, we may borrow up to $50.0 million, of which we immediately drew $25.0 million, before expenses. The remaining debt is available in two increments of $10.0 million and $15.0 million, subject to the achievement of certain revenue targets. Subsequent to December 31, 2024, we drew the $10.0 million increment before expenses. As part of the First Amendment To Credit Agreement and Registration Rights Agreement, effective March 20, 2025, we received a waiver for the prior default events related to the Series A Convertible Preferred Stock conversions and the Agreement was amended to allow for these conversions going forward. In addition, we received a waiver on March 31, 2025 to extend the timing for the required audited financial statements to occur on or before April 15, 2025. Upon receiving the waivers, we were in compliance with all financial covenants under the OrbiMed Credit Agreement. In addition, we received See Note *(14) Debt* for further discussion.

Outside of these agreements, 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 nelitolimod, 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 nelitolimod, 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

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, 2024 and 2023, 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.

We have modified the presentation of certain warrants within our financial statements and corresponding footnotes. In previous filings, we reported the Working Capital Warrants in combination with the Private Warrants, calling them collectively the Private Warrants. For the current Annual Report on Form 10-K, we have separated the Working Capital Warrants from the Private Placement Warrants. We have modified the presentation through the separation of the activity related to the extinguishment of certain pre-merger equity and the associated tranche liability. We have also modified the presentation of the Long-Lived Assets footnote to conform with the current year presentation and provide comparative information.

(a) Revision of Previously Issued Financial Statements

In connection with the preparation of the consolidated financial statements for the period ended December 31, 2024, we identified errors in our previously filed consolidated financial statements and unaudited quarterly consolidated financial statements relating to incorrectly capitalizing the costs of obtaining and maintaining patents.

In accordance with Staff Accounting Bulletins ("SAB") No. 99, Materiality and SAB No. 108, *Considering the Effects of Misstatements when Quantifying Misstatements in the Current Year Financial Statements*, we assessed the materiality of these errors to our previously issued and current year consolidated financial statements. Based upon our evaluation of both quantitative and qualitative factors, we concluded the errors were not material to our previously issued annual or interim consolidated financial statements.

The following table summarize the effects and modification of the revision on our previously issued consolidated financial statements for prior year ended December 31, 2023 and the first quarter of 2024 (in thousands, except net loss per share) for associated activity all of which occurred through March 31, 2024:

Consolidated Balance Sheet	As Previously Stated 12/31/23	Adjustments 12/31/23	As Revised 12/31/23
Intangible assets, net	$ 1,127	$ (1,127)	$ —
Total assets	25,725	(1,127)	24,598
Accumulated deficit	(248,377)	(1,127)	(249,504)
Total Stockholders' deficit	(25,938)	(1,127)	(27,065)

Consolidated Statement of Operations	As Previously Stated	Adjustments	As Revised
Twelve Months Ended December 31, 2023			
Research and development expenses	29,510	325	29,835
Loss from operations	(54,150)	(325)	$ (54,475)
Net loss available to common stockholders	(59,038)	(325)	(59,363)
Net loss attributable to common stockholders	(63,277)	(325)	(63,602)
Net loss per share, basic and diluted	(6.73)	(0.04)	(6.77)
Three Months Ended March 31, 2024			
Research and development expenses	$ 5,857	$ (13)	$ 5,844
Loss from operations	(11,685)	13	$ (11,672)
Net loss available to common stockholders	(13,219)	13	$ (13,206)
Net loss attributable to common stockholders	(14,020)	13	$ (14,007)
Net loss per share, basic and diluted	(0.60)	—	(0.60)

Consolidated Statement of Cash Flows	As Previously Stated	Adjustments	As Revised
Year Ended December 31, 2023			
Net loss available to common stockholders	$ (59,038)	$ (325)	$ (59,363)
Depreciation and amortization	702	(18)	684
Loss on impairment of intangible assets	190	(190)	—
Net cash used in operating activities	(50,045)	(533)	(50,578)
Cash paid for intellectual property and licenses	(533)	533	—
Net cash used in investing activities	(2,121)	533	(1,588)
Three Months Ended March 31, 2024			
Net loss available to common stockholders	$ (13,219)	$ 13	$ (13,206)
Depreciation and amortization	188	(13)	175
Net cash used in operating activities	(10,867)	—	$ (10,867)

(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 Federal Deposit Insurance Corporation ("FDIC") insured financial institutions. At times, the deposits in these institutions may exceed the amount of insurance provided on such deposits. Although we have not experienced any losses in such accounts and believe that we are not exposed to any significant risk on these balances, bank failures, events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to liquidity constraints.

(d) Accounts Receivable and Customer Concentrations

Accounts receivable are recorded at the invoiced amount and do not bear interest. Our payment terms are typically on net 30 day terms. Our accounts receivables balances were 5.1 million and 3.6 million as of December 31, 2024 and 2023 and $1.6 million as of January 1, 2023, respectively. In accordance with ASC Topic 326, *Financial Instruments-Credit Losses*, the allowance for credit losses is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review our allowance for credit losses 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 incur any credit losses for the year ended December 31, 2023.

The following table summarizes the allowance for credit losses accounts activity:

	December 31, 2024
Beginning Balance	$ —
Amount charged (reversed) to costs and expenses	187
Write-off of uncollectible receivables	—
Ending Balance	$ 187

(e) Inventory

Inventory is carried at the lower of cost or net realizable value. The balances are recorded on the first-in first-out method. Raw materials consist of purchase material, completed sub-assemblies, and parts for general production use. Finished goods consist of completed products, including direct labor and manufacturing overhead. 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 the Initial OrbiMed warrant liability, the contingent earnout liability, the Revenue Base Redemption 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) Warrants 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 consolidated 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 liability of the underlying convertible preferred stock.

In connection with the Business Combination, we assumed warrants to purchase Common Stock. The warrants include the Public Warrants, Private Placement Warrants and Working Capital Warrants. We value the liability for all of the warrants based on the trading price of the publicly held warrants. See Note *(10) Warrants* and *(4) Financial Instruments* for further discussion.

In connection with our borrowing under the Initial OrbiMed Credit Agreement, we issued the Initial OrbiMed Warrant, which we classified as a derivative liability because it did not meet the equity classification criteria under ASC 815-40. We calculated the fair value of the Initial OrbiMed Warrant based on the Black-Scholes-Merton option valuation model (“Black-Scholes”). This model considers several variables and assumptions in estimating the fair value of financial instruments, including the per-share fair value of the underlying common stock, exercise price, expected term, risk-free interest rate, expected stock price volatility over the expected term, and expected annual dividend yield. We calculated the expected terms as the contractual expiration period. The risk-free interest rate is estimated using the rate of return on U.S. treasury notes with a life that approximates the expected term. Our Common Stock does not have sufficient trading history and, therefore, we used the historical volatility of the stock prices of similar publicly traded peer companies. We utilized a dividend yield of zero, as we have no history or plan of declaring dividends on the Company's Common Stock.

(j) Revenue Base Redemption Liability

In connection with our the Initial OrbiMed Loan, a “Product Revenue Base” (i.e., with respect to any period, the net revenues for such period from sales of TriNav) on a trailing 12-month basis does not equal or exceed the specified amounts, we will start repaying the outstanding principal amount of the loans under the OrbiMed Credit Agreement. These required revenue thresholds are referred to as the “Revenue Base Redemption Liability." We determined that we should bifurcate and separately recognize the Revenue Base Redemption Liability. We determined the value of the Revenue Base Redemption Liability using a Monte Carlo simulation of future revenue and valuing the Initial Term Loan using the with and without method. The change in fair value of the liability is recorded in the Consolidated Statement of Operations. See Note (14) Debt for further detail.

(k) 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 using a Monte Carlo simulation of our future stock price 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.

(l) Standby Equity Purchase Agreement

In October 2023, the Company entered into a SEPA with Yorkville. Pursuant to the SEPA, the Company has the right, but not the obligation, to sell to Yorkville up to $30.0 million 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, and is accounted for as a derivative pursuant to ASC 815-10, *Derivatives and Hedging* ("ASC 815-10"). The SEPA derivative is valued based on a scenario-based valuation model utilizing the expected draws, probability of the draws and risk-free rate inputs. The change in the fair value of the derivative is recorded in the Consolidated Statements of Operations. See Note *(13) Standby Equity Purchase Agreement* for further detail.

(m) Impairment and Disposal of Long-Lived Assets

We review long-lived assets 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.

(n) 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 for stock options and price of our common stock on the grant date for restricted stock units ("RSUs") and performance stock units ("PSUs"). 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, RSUs and PSUs granted are recognized as compensation expense on a straight-line basis over the expected life for each separately vesting portion of the awards. All shares issued upon the exercise of stock options and vesting of RSUs and PSUs are from our reserved authorized common stock.

(o) 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 and only offer our customers an assurance-type warranty, which provides assurance the product will work as intended.
3. Determine the transaction price — We maintain a single sales price for each of our products, which is generally fixed. For customers with rebate agreements, the rebates are accounted for within a contra-revenue account at the time the rebate milestone is achieved. 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. Refunds, allowances or other concessions are accounted for as a reduction of revenue.
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; therefore, 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. Our sale team is able to make in-person sales. When this occurs, the revenue in not recognized until we receive a Purchase Order ("P.O.") from the customers, with the inventory treated as consignment until the time receiving the P.O. Shipping and handling activities are not considered to be a separate performance obligation; therefore, the costs are considered to be a fulfillment cost and the expenses are accounted for within cost of goods sold.

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. Subsequent to a rebate being earned, the customer receives a credit to apply to future purchases. We recognized $0.3 million and $0.2 million of rebates in the 12 months ended December 31, 2024 and 2023, respectively.

(p) 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. The costs are related to internal headcount and external services we purchase, such as pre-clinical supplies and materials, clinical study management and supplies, and consulting related to our R&D. There were no development milestone payments to Dynavax for nelitolimod in for the year ended December 31, 2024 as compared to $1.0 million for the year ended December 31, 2023. 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.

(q) Segment Reporting

Our Chief Operating Decision Maker ("CODM"), the Chief Executive Officer ("CEO"), reviews our financial information on a consolidated basis for purposes of allocating resources and evaluating its financial performance. The CEO considers recommendations from the Chief Financial Officer ("CFO") and reviews the Monthly Financial Report ("MFR"), including financial information and the Company's performance highlights, such as revenue, accounts receivable and inventory balances, cash flows and cash on-hand, operational expenditures and headcount. Based on the Company's consolidated financial information, the CEO makes the key operating decisions and determines how resources should be allocated. Once the CEO has decided, the CEO and CFO are responsible for carrying out the CEO's decisions. All of our customers and long-lived assets are located in the United States. Since the Company operates as a single reporting segment, all required segment reporting disclosures can be found in the consolidated financial statements. Accordingly, we have determined we operate as a single reportable segment within a single geographic area.

(r) Advertising

Advertising expense, which is included in sales and marketing costs, is expensed as incurred, and expense for the years ended December 31, 2024 and 2023, was $0.5 million and $1.3 million, respectively.

(s) 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 statement 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 2024, 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.

(t) 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*, *(15) Convertible Preferred Stock*, and *(16) 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, 2024 and 2023, all potentially dilutive shares were excluded from net loss per share in both years. See Note *(17) Net Loss Per Share* for further details.

(u) Recent Accounting Pronouncements

Recently issued and Adopted Accounting pronouncements

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 adopted ASU 2022-03 on January 1, 2024. The effect of the adoption had no 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 15, 2024. We adopted ASU 2023-07 on January 1, 2024. The effect of the adoption did not have an impact on our consolidated financial statements. Refer to the "*Segment Reporting" section of Note (2) Summary of Significant Accounting Policies* of our consolidated financial statements for further discussion of our segment.

Accounting Pronouncements Not Yet Adopted

In October 2023, the FASB issued ASU No. 2023-06, Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative. The amendments in ASU 2023-06 update requirements in various disclosure areas, including the statement of cash flows, earnings per share, debt, and equity. The amendments in ASU 2023-06 will be effective on the date the related disclosures are removed from Regulation S-X or Regulation S-K by the SEC and will no longer be effective if the SEC has not removed the applicable disclosure requirement by June 30, 2027. Early adoption is prohibited. We are currently evaluating the impact the adoption of this ASU will have 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.

In March 2024, the FASB issued ASU 2024-01, *Compensation - Stock Compensation (Topic 718): Scope Application of Profits Interest and Similar Awards,* which clarifies the guidance on ASC Topic 718 by illustrating how to apply the scope guidance to determine whether a profit interest award should be accounted for as a shared-based payment arrangement under ASC 718 or another accounting standard (e.g., employee profit-sharing arrangement under ASC 710). The ASU aims to reduce the complexity diversity in practice by adding an example to ASC 718 that describes four fact patterns and illustrates how an entity evaluates common terms and characteristics of profit interests and similar awards to reach a conclusion about whether an award meets the scope conditions in ASC 718-10-15-3. The ASU is effective for all public entities for fiscal years beginning after December 15, 2024 and interim periods within those fiscal years. We are currently evaluating the impact the adoption of this ASU will have on our consolidated financial statements.

In March 2024, the FASB issued ASU 2024-02, *Codification Improvements — Amendments to Remove References to the Concept Statements,* which removes references to the Board's concepts statement from the FASB Accounting Standards Codification (the "Codification" or ASC). The ASU is part of the Board's standing project to make "Codification updates for technical corrections such as conforming amendments, clarifications to guidance, simplifications to wording or the structure of guidance, and other minor improvements." Before establishing the Codification in 2009, the FASB used or referred to the concepts statements as part of its standard setting. However, the Board is now removing those references since "references to the Concepts Statements in the Codification could imply that the Concepts Statements are authoritative." The amendment is effective for all public entities for fiscal years beginning after December 15, 2024. Those who adopt the amendments in an interim period would have to adopt them as of the beginning of the fiscal year that includes that interim period. We are currently evaluating the impact the adoption of this ASU will have on our consolidated financial statements.

In November 2024, the FASB issues ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires additional disclosure of the nature of expenses included in the income statement in response to longstanding requests from investors for more information about an entity's expenses. The new standard requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. The amendment applies to all public business entities and is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. The requirements will be applied prospectively with the option for retrospective application. Early adoption is permitted. We are currently evaluating the impact the adoption of this ASU will have on our consolidated financial statements.

In November 2024, the FASB issues ASU 2024-04, *Debt - Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments*, which amends ASC 470-20, Debt: Debt With Conversion and Other Options, to clarify the requirements related to accounting for the settlement of a debt instrument as an induced conversion. Based primarily on the consensus-for-exposure reached on Issue 23-A, Induced Conversion of Convertible Debt Instruments, by the Emerging Issues Task Force on September 14, 2023. The ASU is intended to "improve the relevance and consistency in application of the induced conversion guidance in Subtopic 470-20 for (a) convertible debt instruments with cash conversion features and (b) debt instruments that are not currently convertible." The amendments are effective for all entities for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. Early adoption is permitted as of the beginning of the annual reporting period for all entities that have adopted the amendments in Update 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): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* 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.

Proceeds from this transaction totaled $42.9 million. These proceeds were comprised of $2.7 million from the MTAC trust account, and $40.2 million received from a concurrent private investment in public equity financing ("PIPE Financing"). Pursuant to the terms of the Merger Agreement, $6.0 million of the proceeds were used to pay expenses incurred by MTAC related to the merger, resulting in net cash proceeds of $36.9 million. The Company incurred $6,069 in transaction costs relating to the merger with MTAC, of which $1.7 million was recorded as a reduction of equity and the balance of $4.3 million was recorded in general and administrative expense.

Pursuant to the terms of the Merger Agreement, the existing stockholders of Legacy TriSalus exchanged their equity holdings at an exchange ratio of 0.02471853 (the "Exchange Ratio") for an aggregate of 21,999,886 shares of our Common Stock. 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. See Note *(10) Warrants* for additional discussion of the warrants.

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.

On the Closing Date, the Company recorded a liability related to the MTAC Warrants of $2.6 million. During the period from August 10, 2023 to December 31, 2023, the fair value of the MTAC Warrants increased to $16.9 million, resulting in a loss on the change in fair value of $14.3 million in the Consolidated Statements of Operations for the period ended December 31, 2023.

For December 31, 2024, the fair value of the MTAC Warrants decreased to $7.9 million. The fair value decreased as a result of the exchange of 7,034,639 warrants for common stock, valued at $11.9 million, offset by a loss on the change in fair value of $2.9 million in the Consolidated Statements of Operations for the year ended December 31, 2024.

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 $40.2 million, pursuant to separate subscription agreements dated June 7, 2023, and July 4, 2023 (collectively, the "Subscription Agreements"). See Note *(15) Convertible Preferred Stock* for further discussion.

During the year ended December 31, 2024, certain investors agreed to purchase an additional $1.0 million of common stock, before expenses, in a private placement.

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 and cash equivalents, accounts receivable, trade accounts payable, tranche and warrant liabilities to purchase preferred stock, the contingent earnout liability and the warrant liability and revenue based redemption liability related to the Initial OrbiMed Credit Agreement. The carrying values of these financial instruments (other than the contingent earnout liability, tranche liabilities, revenue based redemption liability, and warrant liabilities, which are held at fair value) approximate fair value through the use of publicly available market prices for the years ended December 31, 2024 and 2023. 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, earnout liabilities, SEPA, and Revenue Base Redemption liability are measured at fair value on a recurring basis.

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 were traded publicly (the "Public Warrants"), 5,933,333 were privately held (the 4,933,333 "Private Placement Warrants" and 1,000,000 "Working Capital Warrants" and together with the Public Warrants, the "SPAC Warrants"). At the Closing Date, we determined the fair value of all the SPAC Warrants to be $2.6 million based on the closing price of $0.18 for the Public Warrants (Level 1).

At the Closing Date, we determined the fair value of the earnout liability to be $28.9 million based on a Monte Carlo simulation of future trading prices for our common stock. See Note *(9) Contingent Earnout Liability* for further discussion.

The carrying amount of our outstanding SPAC Warrants liabilities was $7.9 million and $16.9 million, respectively, at December 31, 2024 and 2023. The carrying amount of outstanding earnout liability was $7.4 million and $18.6 million, respectively, at December 31, 2024 and 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 Warrants and Working Capital 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.

On October 2, 2023, we entered into the SEPA with Yorkville. Upon execution of the SEPA, we determined the fair value of the SEPA derivative liability to be $0.2 million 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 $0.1 million at December 2024; we recorded the change in fair value in other income (expense).

In connection with the closing of our closing of our initial $25.0 million borrowing under the OrbiMed Credit Agreement on April 30, 2024, we also issued OrbiMed a warrant to purchase 130,805 shares of our common stock, with the initial exercise price of $9.5562 (the "Initial OrbiMed Warrant") per share, or approximately $1.25 million in the aggregate, assuming none of the Initial OrbiMed Warrant is exercised through a "cashless" exercise. For the year ended December 31, 2024, the exercise price was adjusted pursuant to the terms of the Initial OrbiMed Warrant to $9.3722 per share, or approximately $1.23 million in the aggregate. The Initial OrbiMed Warrant expires on April 30, 2031 (see Notes *(10) Warrants* and *(14) Debt* for more information on the OrbiMed Credit Agreement). The Initial OrbiMed Warrant is accounted for as a liability under ASC 815, *Derivatives and Hedging, Contracts in Equity's Own Equity* ("ASC 815-40"), as it provides settled provision that does not meet the requirements of the indexation guidance under ASC 815-40. On August 15, 2024, at OrbiMed's request, the Initial OrbiMed Warrant was split into two separate warrants ("Substitute Warrant Certificate #1" and "Substitute Warrant Certificate #2" and, together, the "OrbiMed Warrants") held by two of OrbiMed's operating entities; one for 92,801 and the second for 38,004 common shares, with no change to the related terms and conditions.

We use a Black-Scholes option pricing model to estimate the fair value of the Initial OrbiMed Warrant, as warrants give the holders the right, but not the obligation, to purchase the underlying securities at a contractual exercise price. This method utilizes certain unobservable inputs, including the determination of the expected volatility, and is therefore considered a Level 3 fair value measurement. Certain inputs used in this Black-Scholes pricing model may fluctuate in future periods based upon factors that are outside of our control, including potential change in control. A significant change in one or more of these inputs used in the calculation of the fair value may cause a significant change to the fair value of the warrant liabilities, which could also result in material non-cash gains or losses being reported in the statement of operations. The expected volatility was implied from a blend of the Company's own common shares and the average historical share volatilities of several unrelated public companies within the Company's industry that the Company considers to be comparable to its own business. We determined the fair value of the Initial OrbiMed Warrant to be $0.4 million at December 31, 2024 and recorded the adjustment to the change in fair value of SEPA, warrant, and Revenue Base Redemption liabilities.

If the “Product Revenue Base” (i.e., with respect to any period, the net revenues for such period from sales of TriNav) on a trailing 12-month basis does not equal or exceed the specified amount as stipulated (see table in Note *(14) Debt)*, we will start repaying the outstanding principal amount in equal monthly installments through April 30, 2029 (the "Maturity Date"). Such repayments will commence in the calendar month immediately following the applicable Test Date per the OrbiMed Credit Agreement (see table in Note *(14) Debt*) and occur on the last day of each calendar month ("Amortization Payment Date"). The repayments are calculated from the first Amortization Payment Date through the Maturity Date and the balance of the principal amount of the loans under the OrbiMed Credit Agreement shall be repaid on the Maturity Date. The repayments include the applicable Repayment Premium and the Exit Fee (see Note *(14) Debt*). The repayment of the loans under the OrbiMed Credit Agreement as aforementioned, is referred to as the “Revenue Base Redemption Liability.” Furthermore, if on the subsequent test date, the revenue-based condition is met, we will stop repaying the outstanding principal amount in equal installments and directly repay the balance amount on the Maturity Date. We determined the fair value of the Revenue Base Redemption liability to be $0.5 million at December 31, 2024 and recorded the adjustment to the change in fair value of SEPA, warrant, and Revenue Base Redemption liabilities.

On May 24, 2024, we commenced an offer (the “Offer”) to all holders of Public Warrants, Private Placement Warrants and Working Capital Warrants (collectively, the "Exchange Warrants") to receive 0.30 shares of common stock of the Company in exchange for each Exchange Warrant tendered by the holder and exchanged pursuant to the Offer. The Offer expired at one minute after 11:59 p.m., Eastern Standard Time, on June 25, 2024. The Exchange Warrants tendered were comprised of 6,529,954 Public Warrants and 504,685 Private Placement Warrants. We determined the Exchange Warrants

met the criteria to be equity classified at June 26, 2024, and that their fair value was $11.9 million. Adjusting for issuance costs of $1.7 million, the net fair value of the Exchange Warrants was $10.2 million. Accordingly, we recorded that amount as a reduction of the warrant liability and a charge to additional paid-in capital ("APIC").

The following tables summarize the changes in fair value of our outstanding warrant liabilities, contingent earnout liability, SEPA derivative liability, and Revenue Base Redemption liability for the year ended December 31, 2024:

SPAC Warrant Liabilities	Fair Value at December 31, 2023	Change in Unrealized (Gains) Losses	Issuances (Settlements)	Fair Value at December 31, 2024
Public Warrants - Level 1	$ 9,855	$ 3,140	$ (11,068)	$ 1,927
Private Placement Warrants - Level 2	$ 5,871	$ (144)	$ (855)	$ 4,872
Working Capital Warrants - Level 2	$ 1,190	$ (90)	$ —	$ 1,100

Level 3 Liabilities	Fair Value at December 31, 2023	Change in Unrealized (Gains) Losses	Issuances (Settlements)	Fair Value at December 31, 2024
Contingent earnout liability	$ 18,632	$ (11,231)	$ —	$ 7,401
SEPA derivative liability	$ 185	$ (130)	$ —	$ 55
Initial OrbiMed Warrant liability	$ —	$ (449)	$ 811	$ 362
Revenue base redemption liability	$ —	$ (222)	$ 729	$ 507

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:

SPAC Warrant Liabilities	Fair Value at December 31, 2022	Change in Unrealized (Gains) Losses	Issuances (Settlements)	Fair Value at December 31, 2023
Public Warrants - Level 1	$ —	$ 8,367	$ 1,488	$ 9,855
Private Placement Warrants - Level 2	$ —	$ 4,990	$ 881	$ 5,871
Working Capital Warrants - Level 2	$ —	$ 1,011	$ 179	$ 1,190

Level 3 Liabilities	Fair Value at December 31, 2022	Change in Unrealized (Gains) Losses	Issuances (Settlements)	Fair Value at December 31, 2023
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, 2024	December 31, 2023
Cash and cash equivalents	$ 8,525	$ 11,777
Restricted cash (included in Other assets)	350	350
Total cash, cash equivalents and restricted cash shown in the Consolidated Statements of Cash Flows	$ 8,875	$ 12,127

Restricted cash is $0.4 million held by our bank to support our corporate credit card program.

(6) Inventory

The components of inventory at are summarized as follows:

	December 31, 2024	December 31, 2023
Raw materials	$ 1,338	$ 607
Finished goods	2,720	2,055
Reserve for obsolete inventory	(10)	(117)
Total Inventory	$ 4,048	$ 2,545

(7) Long-Lived Assets

Property and Equipment

Property and equipment consists of the following:

	Useful Life (Years)	December 31, 2024	December 31, 2023
Machinery and equipment	5 – 7	$ 2,636	$ 2,357
Computers and software	2	1,279	970
Furniture	5	425	474
Leasehold improvements	5	772	772
Other property	7	13	13
Construction in progress		331	598
Gross property and equipment		5,456	5,184
Less accumulated depreciation		(3,787)	(3,093)
Net property and equipment		$ 1,669	$ 2,091

Depreciation expense for property and equipment for the years ended December 31, 2024 and 2023, was $0.7 million and $0.7 million, respectively. The Company did not recognize any impairment losses for the years ended December 31, 2024 and 2023, other than losses on disposal of $0.02 million and $0.04 million in 2024 and 2023, respectively.

(8) Accrued Liabilities

Accrued liabilities consists of the following:

	December 31,	
	2024	2023
Accrued liabilities - clinical trials	$ 2,297	$ 3,115
Accrued incentives	2,094	3,736
Accrued liabilities - general	1,850	2,790
Accrued vacation	362	327
Accrued payroll	718	557
Accrued taxes	34	31
Total Accrued Liabilities	$ 7,355	$ 10,556

Accrued liabilities - general includes accruals from our services providers and other miscellaneous operating accruals.

(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 $28.9 million based on a Monte Carlo simulation valuation model. The liability was remeasured to its fair value of $7.4 million and $18.6 million as of December 31, 2024 and 2023, respectively. This remeasurement resulted in recording gains of $11.2 million and $10.3 million for the years ended December 31, 2024 and 2023, respectively, classified as changes in fair value of contingent earnout liability in the Consolidated Statements of Operations. Assumptions used in the valuation are described below:

	December 31, 2024	December 31, 2023
Current stock price	$ 5.01	$ 8.45
Expected share price volatility	70.0 %	65.0 %
Risk-free interest rate	4.3 %	3.9 %
Expected term (years)	3.61	4.60
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 on the common stock of the Company.

The inputs utilized by management to value the warrant liabilities are subjective. The assumptions used in calculating the fair value of the warrant liabilities represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, the fair value of the warrant liabilities may be materially different in the future.

(10) Warrants

Warrants outstanding are as follows:

	December 31, 2024	December 31, 2023
Public Warrants	1,751,825	8,281,779
Private Placement Warrants	4,428,648	4,933,333
Working Capital Warrants	1,000,000	1,000,000
Initial OrbiMed Warrant	130,805	—
Total warrants	7,311,278	14,215,112

Public, Private Placement and Working Capital 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. As of December 31, 2024 and 2023, there were 1,751,825 and 8,281,779, respectively, Public Warrants outstanding. The Public Warrants expire on August 10, 2028 or earlier upon redemption or liquidation.

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. The Company will use its best efforts to maintain the effectiveness of such registration statement and 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 SPAC Warrants become redeemable, 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 we call the Public 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, the warrants will not be adjusted for issuances of common stock at a price below its exercise price. Additionally, in no event will we be required to net cash settle the warrants. Accordingly, the warrants may expire worthless.

In addition to the Public Warrants, we assumed the warrant liabilities associated with 4,933,333 Private Placement Warrants and 1,000,000 Working Capital Warrants. The Private Placement Warrants and Working Capital Warrants are identical to the Public Warrants, except that the Private Placement Warrants and Working Capital Warrants, and the common stock issuable upon the exercise of the Private Placement Warrants and Working Capital Warrants, were not transferable, assignable or saleable until 30 days after the completion of the Business Combination, subject to certain limited exceptions. Additionally, the Private Placement Warrants and Working Capital Warrants are exercisable on a cashless basis and are non-redeemable so long as they are held by the initial purchasers or their permitted transferees. If the Private Placement Warrants and Working Capital Warrants are held by someone other than the initial purchasers or their permitted transferees, they will be redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants. As of December 31, 2024 and 2023, there were 4,428,648 and 4,933,333, respectively, Private Placement Warrants and 1,000,000 Working Capital Warrants outstanding.

We determined that the Public Warrants, Private Placement Warrants, and Working Capital 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 our control, and such event may not result in a change in control of the Company. As a result, the Public Warrants, Private Placement Warrants, and Working Capital Warrants do not meet the criteria for equity classification.

At the close of the Business Combination, the fair values of the Public Warrants, Private Placement Warrants and Working Capital Warrants were $1.5 million, $0.9 million and $0.2 million , respectively. As of December 31, 2024, the fair values of the Public Warrants, Private Placement Warrants and Working Capital Warrants were $1.9 million, $4.9 million, and $1.1 million, respectively. As of December 31, 2023, the fair values of the Public Warrants, Private Placement Warrants and Working Capital Warrants were $9.9 million, $5.9 million, and $1.2 million, 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 or Working Capital Warrants to anyone outside of a small group of individuals who are permitted transferees would result in the Private Placement Warrants and Working Capital Warrants having substantially the same terms as the Public Warrants. Therefore, we determined that the fair value of each Private Warrant and Working Capital Warrants is equivalent to that of each Public Warrant.

On May 24, 2024, we commenced (i) the Offer and (ii) the solicitation of consent (the "Consent Solicitation") from holders of the Exchange Warrants to amend the Warrant Agreement, dated as of December 17, 2020 (the "Warrant Agreement" and such amendment, the "Warrant Amendment"), by and between the Company and Continental Stock Transfer & Trust Company, which governs all of the Exchange Warrants.

The Offer and Consent Solicitation expired at one minute after 11:59 p.m., Eastern Standard Time, on June 25, 2024. The Exchange Warrants tendered were comprised of 6,529,954 Public Warrants and 504,685 Private Placement Warrants, which represents approximately 78.8% and 10.2% of the outstanding warrants of each respective class. The Warrants were validly tendered and not validly withdrawn prior to the expiration of the Offer and Consent Solicitation. No Working Capital Warrants were tendered. We determined the Exchange Warrants met the criteria to be equity classified at June 26, 2024, and that their fair value was $11.9 million. Accordingly, we recorded that amount as a reduction of the warrant

liability and a charge to APIC, partially offset by issuance costs of $1.7 million. On July 1, 2024, we issued 2,110,366 shares of common stock in exchange for the Exchange Warrants.

In addition, the Warrant Amendment was entered into with respect to the Public Warrants. As a result all (and not less than all) of the outstanding Public Warrants may be exchanged, at our option, at any time while they are exercisable and prior to their expiration, at the office of the warrant agent, upon notice to the holders of the then outstanding Public Warrants, at the exchange rate of 0.27 shares of Common Stock per Public Warrant (subject to equitable adjustment by us in the event of any stock splits, stock dividends, recapitalizations or similar transaction with respect to the Common Stock).

For the year ended December 31, 2024, we issued 2,110,366 shares of common stock in exchange for 6,529,954 (or approximately 78.8%) of the Public Warrants and 504,685 (or approximately 10.2%) of the Private Placement Warrants.

The following table summarizes activity in the Public Warrants, Private Placement Warrants and Working Capital Warrants for the year ended December 31, 2024 . There was no activity for the year ended December 31, 2023.

Series	Balance at December 31, 2023	Exchanges	Issuances	Retirements / Conversions	Balance at December 31, 2024
Public Warrants	8,281,779	—	—	(6,529,954)	1,751,825
Private Placement Warrants	4,933,333	—	—	(504,685)	4,428,648
Working Capital Warrants	1,000,000	—	—	—	1,000,000

Initial OrbiMed Warrant

In connection with the closing of our initial $25.0 million borrowing under the OrbiMed Credit Agreement, we also issued OrbiMed a warrant to purchase 130,805 shares of our common stock (the "Warrant Shares"), with the initial exercise price of $9.5562, (as adjusted from time to time the "Exercise Price") per share, or approximately $1.25 million in the aggregate, assuming none of the Initial OrbiMed Warrant is exercised through a "cashless" exercise. For the year ended December 31, 2024, the exercise price was adjusted pursuant to the terms of the Initial OrbiMed Warrant to $9.3722 per share, or approximately $1.23 million in the aggregate. The Initial OrbiMed Warrant expires on April 30, 2031 (the "Expiration Date"). On each of the closings of our borrowings of the delayed draw commitment amounts of $10.0 million and $15.0 million under the OrbiMed Credit Agreement, if any, we agreed to issue additional warrants to purchase a number of shares of our common stock determined by dividing 5.0% of the applicable borrowed amount by the 10-day volume weighted average sale price of our common stock as of the issue date (the “Subsequent OrbiMed Warrants” and collectively, with the Initial OrbiMed Warrant, the “OrbiMed Warrants” and together with the SPAC Warrants, the “Warrants”). The Subsequent Warrants will expire seven years from each applicable issuance date, if any. In connection with the OrbiMed Warrants, we entered into a Registration Rights Agreement with OrbiMed (the “OrbiMed Registration Rights Agreement”), whereby OrbiMed will have certain customary registration rights with respect to the shares of common stock underlying the OrbiMed Warrants.

The Initial OrbiMed Warrant may be exercised in whole or in part, at any time prior to the Expiration Date (the "Exercise Period"), by either:

a. making a payment to the Company, in an amount in immediately available funds equal to the aggregate Exercise Price to be paid upon the exercise of the Initial OrbiMed Warrant; or

b. instructing the Company to withhold a number of Warrant Shares then issuable upon exercise of the Initial OrbiMed Warrant with an aggregate fair market value as of the exercise date equal to such aggregate Exercise Price to be paid upon the exercise of the Initial OrbiMed Warrant (the “Cashless Exercise”); or

c. any combination of the foregoing.

If either upon (i) the occurrence of the Expiration Date, or (ii) the date on which a Sale of the Company (defined in the Initial OrbiMed Warrant) is consummated pursuant to which the sole consideration payable to the Company or its stockholders in respect of such sale transaction consists of cash, marketable securities or a combination thereof, and the per share fair market value of a Warrant Share is greater than the exercise price, any portion of the Initial OrbiMed Warrant that remains unexercised on such date shall be deemed to have been exercised automatically pursuant to a Cashless Exercise (the “Automatic Cashless Exercise”).

Ownership Cap

The holder in any circumstance cannot exercise the Initial OrbiMed Warrant if such exercise would result in the holder and its affiliates to own more than 9.99% of the Company's common stock (the “Ownership Cap”).

Adjustments

The Exercise Price and the number of Warrant Shares underlying the Initial OrbiMed Warrant are subject to certain anti-dilutive adjustments. These are triggered by events such as stock splits, reclassification of shares, recapitalizations, combinations, substitutions or the like. Additionally, the Initial OrbiMed Warrant is subject to customary price-based anti-dilution protections, such that, in certain circumstances, if we issue shares of our common stock below the current Exercise Price of the Initial OrbiMed Warrant, the Exercise Price of the Initial OrbiMed Warrant will be adjusted downward based on such issuance. As a result of any adjustments, the amount of proceeds we receive from the exercise of the Initial OrbiMed Warrant would be less than the amount we would receive immediately prior to such adjustment. For the year ended December 31, 2024, the Exercise Price of the Initial OrbiMed Warrant was adjusted down from $9.5562 to $9.3722 per share in accordance with the above described adjustment mechanics.

If we declare or pay a dividend or distribution on our outstanding common shares payable in cash, capital securities or other property, the holder shall be entitled to receive, at the time such dividend or distribution is paid, without additional cost to the holder, the total number and kind of cash, capital securities or other property which the holder would have received had the holder owned the Warrant Shares of record as of the date such dividend or distribution was paid (the "Pro-Rata Distribution").

Transfers of Initial OrbiMed Warrant

The Initial OrbiMed Warrant may be transferred or assigned in whole or in part, subject to compliance with applicable federal and state securities laws.

Allocation of Proceeds and Issuance Costs

The agreement explicitly permits the settlement of the Initial OrbiMed Warrant in a cashless manner (i.e., net share settlement) and not indexed to the Company's own stock, therefore, it is considered as a derivative instrument and will be classified as a liability and is subsequently measured at fair value with changes reported to earnings following the proceeds from the issuance of the initial $25.0 million borrowing under the OrbiMed Credit Agreement.

The fair value of the Initial OrbiMed Warrant was measured using the Black-Scholes option pricing model. The key inputs used in the valuations were as follows:

	December 31, 2024	April 30, 2024
Expected term (years)	6.3	7.0
Risk free interest rate	4.5%	4.7%
Expected volatility	70.0%	65.0%
Dividend yield	0	0
Exercise price	$9.3722	$9.5562
Stock price	$5.01	$9.31

The inputs utilized by management to value the warrant liabilities are subjective. The assumptions used in calculating the fair value of the warrant liabilities represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, the fair value of the warrant liabilities may be materially different in the future.

(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 are summarized as follows:

	December 31, 2024	December 31, 2023
Federal:		
Current	$ (15)	$ —
Deferred	—	—
	(15)	—
State:		
Current	21	9
Deferred	—	—
	21	9
Total	$ 6	$ 9

The provision for income taxes differs from income taxes computed at the federal statutory tax rates are due to the following items:

	December 31, 2024	December 31, 2023
Statutory rate	21.0%	21.0%
State and local taxes	5.1	3.4
Change in valuation allowance	(33.1)	(22.0)
Disallowed interest expense on convertible debt	—	—
Prior year true-up	1.7	1.0
Permanent differences	5.3	(3.4)
	—%	—%

The income tax effects of temporary differences that give rise to significant portions of the deferred income tax assets and liabilities are presented below:

	December 31, 2024	December 31, 2023
Deferred tax assets:		
NOL carryforwards	$ 44,336	$ 37,322
Fixed assets	2,664	2,565
Accrued liabilities	140	1,115
Inventory	652	222
Interest limitation	674	—
Charitable contributions	33	37
Lease accounting	52	46
Capitalized R&D expenses	11,919	10,176
Stock-based compensation expense	1,264	305
Total deferred income tax assets	61,734	51,788
Deferred tax liabilities:		
Prepaid expenses	(407)	(470)
Total deferred income tax assets and liabilities	61,327	51,318
Less: Valuation allowance	(61,327)	(51,318)
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, 2024 and 2023 was $10.0 million and $13.2 million, respectively.

As of December 31, 2024, 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, 2024	
	Federal	State
NOLs expiring between 2029 and 2037	$ 43,912	$ 106,320
NOLs which do not expire	135,875	37,045
Total NOLs	$ 179,787	$ 143,365

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, 2024 and 2023, 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, 2024 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 $9.0 million that was split into two payments ($5.0 million and $4.0 million, paid in July and December 2022, 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 development milestone payments range from $1.0 million to $10.0 million, triggered by development achievements for each of up to four indications. The development milestone payments cannot exceed $170.0 million. We made a milestone payment of $1.0 million 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 $80.0 million. We will also pay annual royalties at the rate of 10% for aggregate annual net sales less than or equal to $1,000.0 million and 12% for aggregate annual net sales above that amount. For 2024 and 2023, no annual royalties payments were made.

We record the milestone payments in R&D expense when they are incurred. 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 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. We intend to utilize the SEPA to access capital to fund our operations. We did not issue any Advances during the year ended December 31, 2023.

The estimated fair value of the SEPA derivative liability on December 31, 2023 was $0.2 million, which was determined using a scenario-based valuation model. The liability was remeasured to its fair value of $55 as of December 31, 2024, and is classified within other long-term liabilities in the Consolidated Balance Sheets. This remeasurement resulted in the recognition of a gain of $0.1 million for the year ended December 31, 2024, 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, 2024	December 31, 2023
Expected draws	$ 2,000	$ 5,000
Expected probability of draws	90%	90%
Risk-free interest rate	4.4%	5.4%

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 $2.0 million and $5.0 million, at December 31, 2024, and December 31, 2023, respectively, through the issuance of multiple separate advances under the Option 2 Pricing Period at December 31, 2024, and Option 1 Pricing Period at December 31, 2023;

(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, 2024, we had sold 2,290,377 shares of common stock under the SEPA, raising approximately $14.1 million.

(14) Debt

On April 30, 2024 (the "OrbiMed Closing Date"), we entered into the Credit Agreement with OrbiMed, a healthcare investment firm, and certain of its affiliates to support the execution of strategic expansion plans, fuel continued growth, and provide financial flexibility.

Pursuant to the to the OrbiMed Credit Agreement, OrbiMed agreed to provide a term loan facility to the borrower, in an aggregate principal amount of $50.0 million, as follows:

a. $25.0 million funded on the OrbiMed Closing Date (the “Initial Term Loan”).

b. $10.0 million term loan available at the election of the borrower (the "Second Tranche"), provided that Product Revenue Base (defined below) for the trailing 12-months ending on the last day of the month immediately prior to the funding of such loan was at least $30.0 million (the “First Delayed Draw Term Loan Commitment”). The First Delayed Draw Term Loan Commitment expires on June 30, 2025.

c. An additional $15.0 million term loan available at the election of the borrower (the "Third, provided that Product Revenue Base (defined below) for the trailing 12-months ending on the last day of the month immediately prior to the funding of such loan was at least $50.0 million (the “Second Delayed Draw Term Loan Commitment” and together with the First Delayed Draw Term Loan Commitment the “DDTL Commitments”). The Second Delayed Draw Term Loan Commitment expires on December 31, 2025.

The loans under the OrbiMed Credit Agreement will mature on April 30, 2029. On April 30, 2024, we borrowed the Initial Term Loan, resulting in gross proceeds of $25.0 million.

The OrbiMed Credit Agreement includes a subjective acceleration clause whereby an event of default, including a material adverse change in the business, operations, or conditions (financial or otherwise), could result in the acceleration of the obligations under the OrbiMed Credit Agreement. Under certain circumstances, a default interest rate of an additional 4.0% per annum will apply, at the election of OrbiMed, on all outstanding obligations during the occurrence and continuance of an event of default. OrbiMed can also declare all or a portion of the outstanding principal amount of the loan due and payable, and cancel any unmade draws. OrbiMed has not exercised its right under this clause, as there have been no such events.

Subsequent to December 31, 2024, we met the conditions for borrowing of the First Delayed Draw Term Loan Commitment and requested the additional $10.0 million term loan associated with the Second Tranche. On February 18, 2025, we borrowed the Second Tranche and received gross proceeds of $10.0 million.

Repayment

If the “Product Revenue Base” (i.e., with respect to any period, the net revenues for such period from sales of TriNav) on a trailing 12-month basis does not equal or exceed the specified amount as stipulated in table below, the borrower will start repaying the outstanding principal amount of the loans under the OrbiMed Credit Agreement. Such repayments will commence in the calendar month immediately following the applicable Test Date (stipulated in the table below) and occur on the last day of each calendar month ("Amortization Payment Date"). The repayments are made in equal monthly installments, calculated from the first Amortization Payment Date through the Maturity Date and the balance of the principal amount of the loans under the OrbiMed Credit Agreement shall be repaid on the Maturity Date. The repayments include the applicable Repayment Premium and the Exit Fee (each as defined below). The repayment of the of the loans under the OrbiMed Credit Agreement as aforementioned, is referred to as the “Revenue Base Redemption Liability.”

Test Dates (fiscal Quarter Ending)	Product Revenue Base for 12 months Period	
December 31, 2024	$	26,200
March 31, 2025	$	29,600
June 30, 2025	$	33,400
September 30, 2025	$	37,800
December 31, 2025	$	42,700
March 31, 2026	$	46,400
June 30, 2026 and each Fiscal Quarter ending thereafter	$	50,000

As of December 31, 2024, we were in compliance with the Product Revenue Base requirement and no repayments were required.

Repayment Premium

All repayments and prepayments of the loans under the OrbiMed Credit Agreement (other than on Maturity Date) shall be accompanied by the payment of the premium, which shall be determined based on the timing of the repayment as follows (the "Repayment Premium"):

Time of Repayment	Premium Rate
Within the first 12 months from the funding date of each respective loan.	3.0% plus the Make-Whole Amount (defined below) [(1)]
After the first 12 months but before the 24-month anniversary of the funding date of each respective loan.	3.0%
After the 24-month anniversary but before the 36-month anniversary of the funding date of each respective loan.	2.0%
After the 36-month anniversary but before the 48-month anniversary of the funding date of each respective loan.	1.0%
After the 48-month anniversary of the funding date of each respective loan.	0.0%

[(1)] *"Make-Whole Amount" is equal to the sum of the remaining scheduled interest payments through the 12-month anniversary of the closing date of each respective loa*n.

Interest Rate and Payment

The interest rate is calculated as Secured Overnight Financing Rate for the interest period (which shall not be less than 4.0% (the "Floor")) plus 8.5% (the "Interest Rate"). Until the first full interest period after the 15 month anniversary of the OrbiMed Closing Date, 3.5% of the Interest Rate shall be designated as paid-in-kind interest, which is added to the outstanding principal amount of the loans under the OrbiMed Credit Agreement (the "PIK Interest"). However, the borrower upon written notice can elect to pay all interest in cash, or to pay a percentage less than 3.5% as PIK Interest.

On and after occurrence of any event of default, until such event of default is cured, the borrower is obligated to pay 4.0% in addition to the otherwise applicable Interest Rate (the "Default Rate").

Interest payments are due on the last day of the month (except PIK Interest, which is added to the outstanding principal amount of the loans under the OrbiMed Credit Agreement on the last day of each month). Whenever a prepayment is made on the principal of the loans under the OrbiMed Credit Agreement, the accrued interest and any applicable Repayment Premium on the amount prepaid is also due on such date.

Debt Related Fees

(1) Exit Fee

The borrower on the repayment of the loans under the OrbiMed Credit Agreement is obligated to pay an additional fee equal to 4.0% of the of the principal amount being repaid. This applies whether the repayment is made on the Maturity Date, or under any other conditions specified in the Agreement (the "Exit Fee").

(2) Commitment Fee

The borrower on the funding date of the loans under the OrbiMed Credit Agreement, shall pay a commitment fee to the Lender, equal to 2.0% of the principal amount drawn (the "Commitment Fee").

(3) Undrawn Fee

Every month, the borrower is obligated to remit a fee to the lender, calculated as 0.25% per annum of the total undrawn amount under the DDTL Commitments.

(4) Administrative Fee

The borrower will pay to the agent under the OrbiMed Credit Agreement for its own account a quarterly loan administration fee of $0.01 million, payable in advance, with the first payment due and payable upon the OrbiMed Closing Date.

Increased Costs

If, at any time, any lender incurs additional cost, reductions in any sum receivable by the lender under the OrbiMed Agreement or reduction in the rate of return with respect to the loans under the OrbiMed Credit Agreement because of any change in applicable law or government rule including laws regarding capital adequacy, reserve requirements, taxes, or similar requirements, etc., (collectively, "Yield Adjustment Events"), the borrower will pay the lenders an additional amount to compensate the lender for such increased costs or reduction in rate of return (the "Yield Protection Adjustment Feature").

Taxes

Unless otherwise required by applicable law, any and all payments shall be made free and clear of and without deduction for any taxes; provided, that if any taxes shall be deducted (as required by law or otherwise) from such payments, then the borrower or the withholding agent shall be entitled to make such deductions and shall timely pay the full amount deducted to the relevant government authority in accordance with applicable law.

If such taxes are Non-Excluded Taxes (as defined in the OrbiMed Credit Agreement), then the sum payable by the borrower shall be increased as necessary so that after all required deductions have been made, the Lenders receive an amount equal to the sum it would have received had no such deduction been made (the "Tax Gross-Up Feature").

Warrant

In connection with the closing of the OrbiMed Credit Agreement, we issued OrbiMed the Initial OrbiMed Warrant. See Note *(10) Warrants* for further discussion. In addition to issuing the Initial OrbiMed Warrant, on each of the closings of the Delayed Draw Commitment Amounts, if any, we agreed to issue additional warrants to purchase a number of shares of our common stock determined by dividing 5.0% of the applicable Delayed Draw Commitment Amount by the 10-day volume weighted average sale price of our common stock as of the issue date (the "Subsequent OrbiMed Warrants" and collectively, with the Initial OrbiMed Warrant, the "OrbiMed Warrants" and together with the SPAC Warrants, the "Warrants"). The Subsequent Warrants will expire seven years from each applicable issuance date, if any. In connection with the OrbiMed Warrants, we entered into a Registration Rights Agreement with OrbiMed (the "OrbiMed Registration Rights Agreement"), whereby OrbiMed will have certain customary registration rights with respect to the shares of common stock underlying the OrbiMed Warrants. If we fail to comply with certain of our obligations under the OrbiMed Registration Rights Agreement with respect to maintaining an effective registration statement covering shares of Common Stock underlying the OrbiMed Warrants, then the expiration date of an OrbiMed Warrant may be extended.

Additionally, the Initial OrbiMed Warrant is subject to customary price-based anti-dilution protections, such that, in certain circumstances, if we issue shares of our common stock below the current exercise price of the Initial OrbiMed Warrant, the exercise price of the Initial OrbiMed Warrant will be adjusted downward based on such issuance.

In connection with the closing of the First Delayed Draw, we issued OrbiMed 91,263 warrants on February 18, 2025. The Subsequent OrbiMed Warrants are held by the two of OrbiMed's operating entities associated with the Initial OrbiMed Warrants; one for 64,748 and the second for 26,515 common shares. The Subsequent OrbiMed Warrants expire seven years from the issuance date and contain an exercise price of $5.4787. Effective March 20, 2025, we executed the First Amendment To Credit Agreement and Registration Rights Agreement which required the registration of the Subsequent OrbiMed Warrants to be filed by May 15, 2025 and waived the prior default events related to the Series A Convertible Preferred Stock conversions in September 2024, February 2025, and March 2025.

Accounting Treatment

In accordance with ASC 470, *Debt*, we recorded the Initial Term Loan as long term debt, and recorded the costs incurred to obtain the loan as contra-debt. We incurred $2.6 million in legal, origination and other fees to acquire the OrbiMed Credit Agreement. In addition, we determined that the Initial OrbiMed Warrant met the definition of a derivative under ASC 815, *Derivatives and Hedging*, and should be recorded as a liability, and that we should bifurcate and separately recognize the Revenue Base Redemption Liability. At April 30, 2024, we determined the initial value of the Initial OrbiMed Warrant was $0.8 million using the Black-Scholes pricing model (see Note *(10) Warrants* for further discussion.). We determined the initial value of the Revenue Base Redemption Liability to be $0.7 million using a Monte Carlo simulation of future revenue and valuing the Initial Term Loan using the with and without method.

The proceeds related to the OrbiMed Credit Agreement of with OrbiMed of $25.0 million will be allocated first to the Initial OrbiMed Warrants and to the Revenue Base Redemption Liability, in an amount equal to their respective fair value at the OrbiMed Closing Date. The Initial OrbiMed Warrant and the Revenue Base Redemption liability will be remeasured subsequently, with changes recorded to expense at each remeasurement date. Any residual proceeds should be allocated to the Initial Term Loan, whereas the issuances should be allocated in proportion to the proceeds between the Initial OrbiMed Term Loan and the Initial Warrant. Assumptions used in the valuation are described below:

	December 31, 2024	April 30, 2024
Expected term (years)	6.3	7.0
Risk free interest rate	4.5 %	4.7%
Expected volatility	70.0%	65.0%
Dividend yield	0	0
Exercise price	$9.3740	$9.5562
Stock price	$5.01	$9.31

The estimated fair value of the liabilities were 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 term, based on the Initial Term Loan maturity date;

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

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

(d) expected dividend yield, which we estimate to be zero based on the fact that we have never paid or declared dividends on the Company's common stock;

(e) exercise price, which we calculate as prescribed by the OrbiMed Credit Agreement; and

(f) our stock price, as of the closing price per the Nasdaq on the last day of the reporting period.

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

For the year ended December 31, 2024, we recognized interest of $2.3 million related to the Initial Term Loan, of which $0.6 million was recorded as PIK interest. The remaining $1.7 million was paid in cash to OrbiMed. We also expensed $0.5 million of the capitalized debt issuance costs, which was charged to non-cash interest, and we accreted $0.1 million of the Exit Fee which will be due at the termination of the Initial Term Loan.

The following table summarizes activity within the Initial Term Loan for the year ended December 31, 2024. There was no activity for year ended December 31, 2023.

OrbiMed Debt		
Initial draw	$	25,000
Debt issuance costs		
Cash issuance costs		(2,593)
Noncash issuance costs:		
Revenue base redemption liability		(729)
Warrant liability		(811)
Balance at April 30, 2024	$	20,867
Amortization of debt issuance costs		486
PIK interest		604
Accretion of exit fee liability		127
Balance at December 31, 2024	**$**	**22,084**

As part of the First Amendment To Credit Agreement and Registration Rights Agreement, effective March 20, 2025, we received a waiver for the prior default events related to the Series A Convertible Preferred Stock conversions. In addition, we received a waiver on March 31, 2025 to extend the timing for the required audited financial statements to occur on or before April 15, 2025. Upon receiving the waivers, we were in compliance with all financial covenants under the OrbiMed Credit Agreement.

(15) 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 $40.2 million. 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, 2024, total undeclared cumulative dividends were $4.4 million. We have not recorded the undeclared dividends in our consolidated financial statements, other than under "Undeclared dividends on Series A Preferred Stock" in the Consolidated Statement of Operations.

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

(iii) 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.

(iv) 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.

(v) 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.

(vi) 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 lower of:

(i) the then-current Conversion Price, and

(ii) the higher of 1) the Floor Price ($2.10 per share) or 2) the trailing ten-trading day VWAP of the Company's common stock determined as of the date of such reset.

On February 10, 2025, the Conversion Price was reset to $5.277 based on the trailing ten-trading day VWAP of the Company's common stock. As of March 31, 2025, approximately 365,000 shares of Series A Convertible Preferred Stock, including the accrued dividends thereon, have been converted for approximately 778,000 shares of the Company's common stock.

(vii) 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, 2024. 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.

The following table summarizes activity in the Series A Convertible Preferred Stock for the years ended December 31, 2024. There was no activity for the year ended December 31, 2023.

Series	Balance at December 31, 2023	Issuances	Retirements / Conversions	Balance at December 31, 2024
Series A Convertible Preferred Stock (assuming maximum conversion)	25,237,155	—	(188,571)	25,048,584
Total convertible preferred stock	25,237,155	—	(188,571)	25,048,584

On September 16, 2024, a holder of Series A Convertible Preferred Stock elected to convert 30,000 shares of preferred stock. In accordance with the subscription agreement, these shares were converted to 32,645 shares of common stock (including common shares issued as consideration for a total of $0.03 million in undeclared accumulated dividends,

calculated at the rate of 8.00% per annum from the date of original issuance of the Series A Convertible Preferred Stock on the original issue price).

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 $9.6 million. In addition, $25.4 million 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 $0.1 million 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 $2.9 million, 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 $0.3 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 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 $3.7 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 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 was 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 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 per share, as of August 10, 2023, which is based upon the enterprise value stated in the Merger Agreement of $220.0 million allocated to all outstanding shares of preferred stock, warrants to purchase preferred stock, and common stock on an as-if converted basis. The Business Combination scenario as of August 10, 2023 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 $14.7 million. 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 $1.4 million for the year ended December 31, 2023.

(16) Stockholders' Equity

(a) Common Stock

As of December 31, 2024 and 2023, the Company's authorized shares of common stock were 400,000,000. As of December 31, 2024, the Company had reserved the following shares of common stock for future issuance in connection with the conversion of shares of Series A Convertible Preferred Stock, at the applicable conversion rates (see Note *(15) Convertible Preferred Stock*) and upon the exercise of certain options and warrants:

	December 31, 2024	December 31, 2023
Preferred stock:		
Series A convertible preferred stock (assuming maximum conversion)	25,048,584	25,237,155
Warrants:		
Public Warrants	1,751,825	8,333,333
Private Placement Warrants	4,428,648	4,933,333
Working Capital Warrants	1,000,000	1,000,000
Initial OrbiMed Warrant	130,805	—
Total Warrants	7,311,278	14,266,666
Employee Stock Purchase Plan	2,253,197	1,396,252
Equity Awards:		
Stock options and restricted stock units outstanding	5,050,896	3,666,234
Shares available for future grant	4,190,566	3,515,303
Total Equity Awards	9,241,462	7,181,537
Grand Total	**43,854,521**	**48,081,610**

(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 primarily 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 CEO and CFO, 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, 2024, the balances under the two plans are below.

	December 31, 2024		
	Authorized	Outstanding	Available for Issue
2009 Plan	1,274,985	1,274,985	—
2023 Plan	7,966,477	3,775,911	4,190,566
Total	9,241,462	5,050,896	4,190,566

2009 Equity Incentive Plan

As of December 31, 2024 and 2023, there were in total 1,240,985 and 1,532,356, 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.

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, 2023	1,671,076	$ 1.62	8.4
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
Granted	—	—	—
Exercised	(121,335)	0.51	—
Forfeiture	(170,036)	3.40	—
Options outstanding at December 31, 2024	1,240,985	$ 2.92	6.1

The following table summarizes certain information about all options outstanding under the 2009 Plan as of December 31, 2024.

	Options outstanding		Options Exercisable
Exercise Price	Number outstanding at December 31, 2024	Weighted average remaining contractual life	Number exercisable at December 31, 2024
$0.41	197,244	5.97	194,256
$1.22	200,832	2.95	200,832
$2.03	7,415	2.55	7,415
$2.43	673,807	6.80	453,451
$3.65	3,657	0.32	3,657
$10.30	158,030	7.56	73,531
Total	1,240,985	6.10	933,142

2009 Plan	December 31, 2024	December 31, 2023
Valuation assumptions:		
Expected dividend yield	—%	—%
Expected volatility	53%	53%
Expected term (years)[(1)]	6.0 – 6.2	6.0 – 6.2
Risk-free interest rate	4.2%	4.18%

(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.

Recognized compensation expense under the 2009 Plan for employees and nonemployees in 2024 was $0.3 million, which was predominately included in general and administrative expense in the accompanying Consolidated Statements of Operations. As of December 31, 2024, there was $0.5 million of unrecognized compensation expense related to unvested share-based compensation arrangements granted under the 2009 Plan. The December 31, 2024, balance will be recognized over a weighted average period of 1.1 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. The share reserve increased to 7,966,477 authorized shares in 2024 due to the automatic feature of the 2023 Plan. 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, 2024.

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Options outstanding at January 1, 2023	—	$ —	—
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
Granted	1,962,406	8.07	—
Exercised	(4,225)	4.83	—
Forfeiture	(677,332)	7.40	—
Options outstanding at December 31, 2024	3,350,554	$ 7.77	8.6

We granted 141,000 options to members of the Board of Directors and other non-employees during the year ended December 31, 2024

The following table summarizes certain information about all options outstanding under the 2023 Plan as of December 31, 2024.

	Options outstanding		Options Exercisable
Exercise Price	**Number outstanding at December 31, 2024**	**Weighted average remaining contractual life**	**Number exercisable at December 31, 2024**
$4.60	381,229	8.86	23,712
$4.78	679,753	7.92	208,231
$6.70	500,416	8.77	119,393
$9.28	205,000	9.05	10,000
$9.40	288,750	9.12	—
$9.50	653,843	8.87	—
$9.62	35,000	9.34	—
$11.34	233,334	7.83	93,336
$11.51	172,500	8.62	57,500
$12.00	200,729	7.84	79,061
Total	**3,350,554**	**8.55**	**591,233**

2023 Plan	**December 31, 2024**	**December 31, 2023**
Valuation assumptions:		
Expected dividend yield	—%	—%
Expected volatility	54 %	53 %
Expected term (years)[(1)]	5.5 - 6.3	6.0 - 6.2
Risk-free interest rate	4.2%	4.2%

Recognized compensation expense under the 2023 Plan for employees and nonemployees in 2024 was $3.6 million, which was predominantly included in general and administrative expense in the accompanying Consolidated Statements of Operations. As of December 31, 2024, there was $10.1 million of unrecognized compensation expense related to unvested share-based compensation arrangements granted under the 2023 Plan. The December 31, 2024, balance will be recognized over a weighted average period of 2.8 years.

Restricted and Performance Stock

Pursuant to both the 2009 and 2023 Plans, we issue restricted stock unit awards ("RSUs") and performance stock unit awards ("PSUs"). The estimated fair value of the awards at the time of grant was determined using the price of our common stock on the grant date for the RSUs and PSUs. All such grants are satisfied 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. PSUs are share awards that vest upon meeting the stated performance metric(s) during the stated performance period(s). We granted one PSU award in 2024.

The following table summarize activity for RSUs and PSUs issued to employees and directors under the 2009 and 2023 Plan. As of December 31, 2024:

Restricted Stock and Performance Stock:	Net Stock Units	Weighted-Average Grant-Date Fair Value per Share	Weighted average remaining contractual life
Stock Units Outstanding at December 31, 2022	—	$ —	—
Awarded	184,018	10.30	—
Released	(25,091)	10.30	—
Forfeited	(94,754)	10.30	—
Stock Units outstanding at December 31, 2023	64,173	10.30	1.8
Awarded	498,255	9.46	—
Released	(21,325)	10.30	—
Forfeited	(81,746)	9.59	—
Stock Units outstanding at December 31, 2024	459,357	9.51	1.5

Recognized compensation expense for RSUs and PSUs for employees and nonemployees in 2024 was $0.2 million and $1.1 million for awards under the 2009 and 2023 Plans, respectively, which was predominantly included in general and administrative expense in the accompanying Consolidated Statements of Operations. As of December 31, 2024, there was $0.3 million and $2.9 million of unrecognized compensation expense for awards under the 2009 and 2023 Plans, respectively, related to unvested RSUs and PSUs. The December 31, 2024, balance will be recognized over a weighted average period of 2.5 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 became active in 2024. There were 2,253,197 shares of Common Stock initially 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. As of December 31, 2024, there were 97,333 shares purchased through the ESPP, which we recognized compensation expense of $0.2 million in 2024.

(17) 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, RSUs, PSUs 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, 2024 and 2023, 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,	
	2024	2023
Preferred stock	25,048,584	25,237,155
Common stock warrants	7,311,278	14,215,112
Restricted stock units	459,357	64,173
Options to purchase common stock	4,591,539	3,602,061
Shares issuable under the SEPA	3,468,998	—
Total	40,879,756	43,118,501

(18) Leases

We have three property leases in effect as of December 31, 2024, 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, 2031. This lease includes one option to extend the lease by five years from the end of the then current term.
- A lease for office space at 2275 Half Day Road, Bannockburn, Illinois, which expires in January 2028. This lease includes an option to extend the lease by three 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 July 31, 2025.

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

On July 17, 2024, we exercised one of the two options to extend the current lease for the Westminster facility for an additional period of five years commencing on January 1, 2027, and ending on December 31, 2031 ("Second Extended Lease Term"). All terms and conditions of the lease shall continue to apply during the Second Extended Lease Term. We will pay approximately $1.5 million in rent during the Second Extended Lease Term.

The components of right-of-use assets, short-term lease liabilities and long-term lease liabilities as of December 31, 2024, is as follows:

	Operating Leases	Finance Leases	
Right-of-use assets	$ 1,210	$ 128	(1)
Short-term lease liabilities	$ 136	$ 78	
Long-term lease liabilities	$ 1,311	$ 18	

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

The components of lease expense for the year ended December 31, 2024 and 2023, were as follows:

	December 31,	
	2024	2023
Operating lease expense	$ 409	$ 473
Finance lease expense:		
Amortization of ROU assets	115	13
Interest on lease liabilities	11	3
Total finance lease expense	126	16
Total lease expense	$ 535	$ 489

Maturities of lease liabilities under noncancellable leases as of December 31, 2024, are as follows:

	Operating Leases	Finance Leases
2025	$ 322	$ 83
2026	298	9
2027	371	9
2028	300	1
2029	304	—
Thereafter	645	—
Total undiscounted lease payments	2,240	102
Less imputed interest	(793)	(6)
Total lease liabilities	$ 1,447	$ 96

As of December 31, 2024, the weighted average life of our operating and finance leases is six and two years, respectively. The weighted average discount rate for operating and finance leases are 13.8% and 8.1%, respectively, which is based on interest rates we paid for our most recent term loan and convertible notes.

(19) 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 $0.7 million and $0.6 million to the plan for the years ended December 31, 2024 and 2023, 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.

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.

Other

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.

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

On April 12, 2024, the Audit Committee (the "Audit Committee") of the Board of Directors of the Company approved the dismissal of KPMG LLP ("KPMG") as the Company's independent registered public accounting firm. On April 12, 2024, KPMG was informed that they were dismissed.

KPMG's audit reports on the Company's consolidated financial statements as of and for the years ended December 31, 2023 and 2022, did not contain any adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles, except as follows: KPMG's report on the consolidated financial statements of the Company as of and for the years ended December 31, 2023 and 2022 contained a separate paragraph stating that "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 *(1) Nature of Business*. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty."

During the Company's two fiscal years ended December 31, 2023, and the subsequent interim period through April 12, 2024, there were no: (1) "disagreements" (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304) with KPMG on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of KPMG, would have caused KPMG to make reference in connection with their opinion to the subject matter of such disagreement or (2) "reportable events" (as defined in Item 304(a)(1)(v) of Regulation S-K), except for the following material weaknesses in the Company's internal control over financial reporting, as disclosed in Part II, Item 9A of the Company's Annual Report on Form 10-K for the year ended December 31, 2023, with respect to the following:

(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 Standby Equity Purchase Agreement dated October 2, 2023, by and between the Company and YA II PN, Ltd.,

3. patent costs, and

4. certain research and development accruals;

(ii) inadequate controls over the accounting and financial reporting for the business combination (the "Business Combination") pursuant to that certain Agreement and Plan of Merger, dated as of November 11, 2022, as amended, by and among the Company (f/k/a MedTech Acquisition Corporation), MTAC Merger Sub, Inc. and TriSalus Operating Life Sciences, Inc. (f/k/a TriSalus Life Sciences, Inc.);

(iii) inadequate internal controls over the valuation of the warrant and tranche rights and obligations and liabilities resulting from the TriSalus Operating Life Sciences, Inc.'s 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.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) and 15d-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 ("CEO") and Chief Financial Officer ("CFO") have concluded that our disclosure controls and procedures were not effective at the reasonable assurance

level as of the end of the period covered by this Annual Report, 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, 2024, as discussed below.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined by Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Our management, including our CEO and CFO, assessed the effectiveness of our internal control over financial reporting as of December 31, 2024, based upon the framework presented in "Internal Control-Integrated Framework" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based upon our assessment, our management concluded that our internal control over financial reporting was not effective as of December 31, 2024, due to the material weaknesses discussed below.

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 year ended December 31, 2024 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. patent costs,
3. certain R&D accruals,
4. certain general accruals,
5. accounting for leases under ASC 842,
6. accounting for revenue, and
7. accounting for significant transactions, including costs associated with the SEPA, the Exchange Warrants, and accounting for the OrbiMed Credit Agreement, including the Initial OrbiMed Commitment amount and the related derivative financial instruments;

(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 the revenue base redemption liability associated with the Initial OrbiMed Commitment Amount;

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

(v) inadequate security management internal controls over certain IT applications supporting financial reporting, related to segregation of privileged IT user rights and to monitor elevated user activity.

Our management developed a remediation plan, and we have continued to take steps to remediate each of the material weaknesses described above. The remediation plan included hiring 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, 2024, we have hired additional trained resources with such requisite experience or selected outside expert consultants. We will continue to evaluate the existing finance function experience and expertise to identify additional resource needs to aid in the remediation of the material weaknesses. 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

During the year ended December 31, 2024, it was determined that no change to our internal control over financial reporting occurred during the last fiscal quarter ended December 31, 2024, 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

The information required by this item and not set forth below will be set forth below will be set forth in the proposal headed *Election of Directors* and section headed *Executive Officers* contained in our definitive proxy statement for our 2025 annual meeting of shareholders to be filed with the Securities and Exchange Commission on or before April 30, 2025 ("the Proxy Statement"), pursuant to General Instructions G(3) of Form 10-K and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on the Governance section of our website at investors.trisaluslifesci.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation

The information required by this item will be set forth in the sections headed *Executive Compensation* and *Non-Employee Director Compensation* contained in the Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owner and Management and Related Stockholder Matters

The information required by this item will be set forth in the sections headed *Security Ownership of Certain Beneficial Owners* and *Management and Executive Compensation* contained in the Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be set forth in the sections headed *Certain Related-Person Transactions and Information Regarding the Board of Directors and Corporate Governance* contained in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

Our independent registered public accounting firm is Grant Thornton, Chicago, IL, Auditor Firm ID: 248.
The information required by this item will be set forth in the proposal headed *Ratification of Selection of Independent Registered Public Accounting Firm* contained in the Proxy Statement and is incorporated herein by reference.

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 audited Consolidated Financial Statements are listed in the "Financial Statements and Supplementary Data" under Part II. Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules:

None.

(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	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	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	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,	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 8-K	001-39813	3.2	August 16, 2023
3.3	Form of Certificate of Designations, Preferences, and Rights of Series A Convertible Preferred Stock of TriSalus Life Sciences, Inc.	Form 8-K	001-39813	3.3	August 16, 2023
4.1	Specimen Common Stock Certificate	Form 8-K	001-39813	4.1	August 16, 2023
4.2	Specimen Warrant Certificate	Form 8-K	001-39813	4.2	August 16, 2023
4.3	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
4.4	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

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
4.5	Registration Rights Agreement, dated April 30, 2024, by and between TriSalus Life Sciences, Inc., and OrbiMed Royalty & Credit Opportunities IV, LP.	Form 10-Q	001-39813	4.4	May 15, 2024
4.6	Amendment No. 1 to Warrant Agreement, dated June 26, 2024, by and between the Company and Continental Stock Transfer & Trust Company.	Form 8-K	001-39813	10.1	June 27, 2024
4.7	Description of Securities	Form 10-Q	001-39813	4.7	August 14, 2024
4.8	Substitute Warrant Certificate, dated August 15, 2024, by and between TriSalus Life Sciences, Inc, and OrbiMed Royalty & Credit Opportunities IV, LP.	Form S-3	001-39813	4.1	October 29, 2024
4.9	Substitute Warrant Certificate, dated August 15, 2024, by and between TriSalus Life Sciences, Inc, and OrbiMed Royalty & Credit Opportunities IV Offshore, LP.	Form S-3	001-39813	4.1	October 29, 2024
4.10	Warrant Certificate, dated February 18, 2025, by and between TriSalus Life Sciences, Inc., and OrbiMed Royalty & Credit Opportunities IV, L.P.				
4.11	Warrant Certificate, dated February 18, 2025, by and between TriSalus Life Sciences, Inc., and OrbiMed Royalty & Credit Opportunities IV Offshore, L.P.				
10.1*	TriSalus Life Sciences, Inc. 2023 Equity Incentive Plan	Form 8-K	001-39813	10.21	August 16, 2023
10.2*	TriSalus Life Sciences, Inc. 2023 Employee Stock Purchase Plan	Form 8-K	001-39813	10.24	August 16, 2023
10.3*	Letter Agreement, dated December 17, 2020, by and among MedTech Acquisition Corporation, its officers and directors and MedTech Acquisition Sponsor LLC.	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	001-39813	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

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
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
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*	Amended and Restated Non-Employee Director Compensation Policy.				
10.1	Standby Equity Purchase Agreement, by and between TriSalus Life Sciences, Inc. and YA II PN, LTD.	Form 8-K	001-39813	99.1	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*##	Executive Employment Agreement, by and between the Company and James Young, dated January 6, 2025.	Form 8-K	001-39813	10.1	January 4, 2025
10.18*##	Amended and Restated Executive Employment Agreement, by and between the Company and Sean Murphy, dated	Form 8-K	001-39813	10.2	January 4, 2025
10.19*##	Amended and Restated Executive Employment Agreement, dated March 2, 2023, 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

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
10.22*##	Amended and Restated Executive Employment Agreement, Dated January 6, 2025, by and between TriSalus Life Sciences, Inc. and Jodi Devlin.				
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. Anderson Cancer Center.	Form S-4/A	333-269138	10.2	April 21, 2023
10.24*##	Office/Warehouse Lease, dated February 4, 2014 between Colorado Industrial Portfolio LLC and Surefire Medical, Inc., as amended.	Form S-4/A	333-269138	10.3	July 6, 2023
10.25##	Credit Agreement, dated April 30, 2024, by and between TriSalus Operating Life Sciences, Inc., TriSalus Life Sciences, Inc., and OrbiMed Royalty & Credit Opportunities IV, LP.	Form 10-Q	001-39813	10.1	May 15, 2024
10.26##	First Amendment to Credit Agreement and Registration Rights Agreement by and between TriSalus Operating Life Sciences, Inc., TriSalus Life Sciences, Inc., OrbiMed Royalty & Credit Opportunities IV, LP., and OrbiMed Royalty & Credit Opportunities IV Offshore, LP.				
10.27##	Second Amendment to Lease of Space dated July 17, 2024, by and between TriSalus Life Sciences, Inc. and BPAZ Holdings 14, LLC.	Form 10-Q	001-39813	10.2	August 14, 2024
10.28#	Form of Dealer Manager and Solicitation Agent Agreement.	Form S-4	333-279691	10.28	May 24, 2024
10.29	Form of Tender and Support Agreement, by and between the Company and Supporting Stockholders.	Form S-4	333-279691	10.29	May 24, 2024
10.30*	Amendment No. 1 to Amended and Restated Executive Employment Agreement, dated January 24, 2024, by and between TriSalus Life Sciences, Inc. and Richard Marshak.				
10.31*	Amendment No. 2 to Amended and Restated Executive Employment Agreement, dated January 6, 2025, by and between TriSalus Life Sciences, Inc. and Richard Marshak.				
19.1	TriSalus Life Sciences, Inc. Insider Trading Policy				
21.1	List of Subsidiaries				

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
23.1	Consent of Grant Thornton LLP, independent registered public accounting firm of TriSalus.				
23.2	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.	Form 10-K	001-39813	97.1	April 11, 2024
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.				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents.				
101.DEF	Inline XBRL Taxonomy Extension Schema Document.				
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.				

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
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 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.

\+ Certain of the exhibit 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.

^ 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 Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on the 15th day of April, 2025.

TriSalus Life Sciences, 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 James Young, 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 Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and 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 15, 2025
/s/ James Young James Young	Chief Financial Officer *(Principal Financial and Accounting Officer)*	April 15, 2025
/s/ Mats Wahlström Mats Wahlström	Director and Chairman of the Board	April 15, 2025
/s/ Arjun "JJ" Desai Arjun "JJ" Desai	Director	April 15, 2025
/s/ Andrew von Eschenbach Andrew von Eschenbach	Director	April 15, 2025
/s/ Gary Gordon Gary Gordon	Director	April 15, 2025
/s/ Kerry Hicks Kerry Hicks	Director	April 15, 2025
/s/ Liselotte Hyveled Liselotte Hyveled	Director	April 15, 2025
/s/ George Kelly Martin George Kelly Martin	Director	April 15, 2025
/s/ David J. Matlin David J. Matlin	Director	April 15, 2025
/s/ Sean Murphy Sean Murphy	Director	April 15, 2025
/s/ William Valle William Valle	Director	April 15, 2025

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