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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, 2025

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 every Interactive Data File required to be submitted 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 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 $111.5 million as of June 30, 2025 (the last trading day of the registrant's most recently completed second quarter), based on the closing price of $5.45 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 61,306,437 outstanding shares of common stock as of March 2, 2026.

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 within 120 days after the end of the fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ending December 31, 2025, ("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. Except as otherwise required by applicable law, we disclaim any duty to update any forward-looking statements, all of which are expressly qualified by the statements in this section, to reflect events or circumstances after the date of this Annual Report.

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

- our ability to raise financing in the future;
- our ability to service our indebtedness and to access additional delayed draws that may in the future become available to us;
- changes in applicable laws or regulations;
- our ability to retain or recruit, or changes required in, our officers, key employees or directors;
- our ability to successfully commercialize any product candidates that we successfully develop and that are approved by applicable regulatory authorities;
- our expectations for the timing and results of data from clinical trials and regulatory approval applications;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our business, operations and financial performance including:
    - our history of operating losses and expectations of significant expenses and continuing losses for the foreseeable future;
    - our ability to execute our business strategy, including the growth potential of the markets for our products and our ability to serve those markets;
    - our ability to grow market share in our existing markets or any new markets we may enter;
    - our ability to develop and maintain our brand and reputation;
    - our ability to partner with other companies;
    - the size of the addressable markets for our product candidates;
    - our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
    - our ability to manage our growth effectively;
    - our ability to maintain the listing of our securities in the Nasdaq Global Market, and the potential liquidity and trading of such securities;
    - the outcome of any legal proceedings that may be instituted against us; and

- unfavorable conditions in our industry, the global economy or global supply chain, including financial and credit market fluctuations, international trade relations, pandemics, political turmoil, natural catastrophes, warfare and terrorist attacks.

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

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

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"), liver tumors and various other tumor types 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 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"), 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 device, the TriNav Infusion System ("TriNav") using PEDD technology is currently being used for 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 device with a novel (PEDD) delivery method. At the core of the TriNav system is SmartValve technology, a self-expanding mechanism that:

- Modulates pressure and flow of the vasculature feeding the tumor to physiologically open collapsed blood vessels,
- Creates consistent turbulent flow to promote more uniform and repeatable distribution of particles or drugs,
- Self-centers the catheter tip within the vessel for precise delivery.

This design represents a meaningful departure from traditional end-hole catheter designs by actively controlling flow dynamics and positioning to improve therapeutic outcomes.

It is U.S. Food and Drug Administration ("FDA")-cleared and has undergone peer-reviewed studies at multiple clinical sites. The PEDD method has now been used in over 31,000 procedures, primarily TACE and TARE. TriNav achieved $45.2 million in revenue in 2025 representing growth of 53.4% vs. the previous year.

Additionally, our PEDD technology has proven to demonstrate improved drug delivery in a range of other non-malignant tumor embolizations such as Thyroid Artery embolization for treatment of Multi-nodular goiters, uterine artery embolization ("UAE") for treatment of fibroid tumors, prostate embolization for treatment of prostate cancer and an emerging new application for treatment of osteoarthritis and genicular artery embolization.

These tumor types share common procedural and drug delivery challenges as oncologic embolization such as tortuosity and small caliber target vessels, variable floor and collateral circulation, risk of off target embolization and the need for deeper penetration of embolic particles into the abnormal tissues. TriSalus is currently marketing our PEDD technology and generating clinical data in thyroid embolization, uterine artery embolization, and genicular artery embolization.

We also have developed a separate 510(k) cleared device for infusions into the pancreas, Pancreatic Retrograde Venous Infusion device, ("PRVI") 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 with its use of PEDD, is designed to address many of the limitations inherent to arterial infusions in the pancreas. The PRVI device is currently being studied in a Phase I dose escalation trial for nelitolimod delivery into pancreatic tumors that has completed enrollment. 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 solid tumor indications, including those 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, but also will prove to be beneficial when co-administered with currently approved chemotherapeutics and radiation, based on published clinical and preclinical data.

We are in the early stages of our development and have completed Phase I nelitolimod dose escalation (Uveal Melanoma with Liver Metastases ("UMLM") and LA-PDAC) and Phase Ib (Intrahepatic Cholangiocarcinoma ("ICC")/ Hepatocellular Carcinoma ("HCC")) clinical trials. Due to physician and investigator interest, we are supporting two Investigator Initiated Trials of nelitolimod, one in patients with advanced HCC in combination with cryoablation, durvalumab and tremelimumab and another in patients with resectable colorectal liver metastases. TriSalus may seek to partner nelitolimod in recognition of the significant opportunity within the med-tech platform, while strategically leveraging a partner’s established drug development infrastructure. Following the completion of data analysis from the the studies mentioned above, we will explore potential partners to advance nelitolimod development to Phase II trials in one or more chosen indications. Results of these early trials will be available in 2026 and we will begin discussions with potential partners on further clinical development.

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 solid 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 ("Y90") 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. This treatment is used commonly when the tumor can't be surgically removed, the patient's disease is liver dominant and their liver function is still reasonably preserved.

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 Tumor /Normal (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 and patient complications.

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. 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 Y90 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 Y90 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 studies summarized below:
    - A prospective company sponsored study included nine 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 Y90 radioembolization. All patients in the study underwent an MAA planning procedure delivered via a standard endhole ("EH") catheter. 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.

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

- TriSalus is collaborating with leading academic sites to expand the clinical evidence for PEDD in TACE and TARE procedures. The studies include: (1) a prospective, randomized study to compare PEDD versus standard microcatheter and T/N ratios in hypovascular and hypervascular liver tumors, (2) a study to measure concordance of MAA mapping and Y90 radioembolization using PEDD, (3) a prospective, randomized study to compare PEDD versus standard microcatheter to deliver TACE neuroendocrine tumors, (4) a prospective, randomized study to compare PEDD versus standard microcatheter for delivery of Y90 embolization in liver metastases, and (5) a prospective, randomized study to compare PEDD versus standard microcatheter for delivery of Y90 radioembolization for large liver tumors.

Real-world Evidence

TriSalus recently presented a Health Economic and Outcomes Research ("HEOR") study looking at real-world data capturing both safety and clinical complications for TriNav as compared to conventional catheters over the 2020-2023 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 in propensity matched cohort analysis:

- TriNav patients showed reduced rates of post-procedure fatigue compared to non-TriNav patients ($p < 0.05$)

- 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 ($p<0.05$)

- TriNav patients with had fewer clinical complications post-procedure vs. non-TriNav patients in matched cohort comparison ($p = 0.07$)

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 neuroendocrine 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 portfolio of devices, representing a potential market opportunity of approximately 62 thousand units, or approximately $494 million, based on our current unit price of $7,983.

TriSalus has expanded its portfolio of PEDD devices with multiple product launches in 2025 providing interventional radiologists ("IR") a choice of TriNav devices customized to specific patient anatomy and expanding the use in additional applications. These include the launch of TriNav FLX, a device with a more flexible distal tip for easier navigation of tortuous vascular anatomy and the launch of TriNav XP, a device with the more flexible distal tip and an increased internal diameter ensuring compatibility with the larger embolic beads commonly used in certain procedures such as uterine artery embolization. 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.

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 two thousand patients annually adding an additional market expansion of $400 million.

In addition to the use of our technology for treatment of liver and pancreatic tumors, Interventional Radiologists have initiated its use in a range of other non-malignant tumor applications which include uterine artery embolization, thyroid artery embolization, prostate artery embolization and an emerging treatment for osteoarthritis, genicular artery embolization. All represent significant market opportunities for the use of the PEDD technology.

In regards to UAE, roughly 10% of women aged 18-65 lives with uterine fibroid today and current treatment approaches include hysterectomy, endometrial ablation and uterine artery embolizations. We estimate TriNav XP is applicable for 20 thousand UAEs 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 is enrolling up to 100 patients across several 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%. This new procedure for thyroid goiters utilizing the TriNav system is eligible for the same HCPCS reimbursement code allowing for seamless integration into current billing approaches.

Another potential application of TriNav is for the use in prostate embolizations. 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 embolizations 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.

An emerging new application of TriNav is for the use of our PEDD technology is for genicular artery embolization. This procedure aims to treat the chronic knee pain from osteoarthritis, especially for patients who aren't ready for or want to avoid knee replacement surgery. This procedure offers significant pain reduction for many patients, improved function and mobility and offers an alternative to other treatments. We estimate that TriSalus has the potential in 100,000 patients of the 33 million people who suffer from this disease.

The estimated total addressable market for TriSalus PEDD technology in the U.S. is project to exceed >$2.3 billion annually. The market is divided into a current market valued at $1B million and an additional market opportunity estimated at $1.3 Billion. 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, uterine artery embolization, genicular artery embolization and prostate artery embolization.

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 transitional pass-through payments ("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.

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, TARE and other embolization procedures.

Our sales representatives, clinical specialists and sales leaders have substantial medical device sales experience and market our products directly to interventional radiologists who perform embolization procedures. We are focused on developing strong relationships with physicians and hospital 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 43 professionals as of December 31, 2025.

The use of TriNav is consistent with the current steps an interventional radiologist utilizes to conduct TACE and TARE and other embolization 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 Ratio), and we are focused on enhancing this capability.

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

We are advancing our PRVI device, 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 PRVI device has not been commercialized and commercial sales are not anticipated before 2027.

Pre-clinical pancreatic cancer model experiments indicated that using our 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.

We believe our pancreatic infusion technology with PEDD offers a potential platform opportunity due to its ability to enable targeted controlled delivery of a broad range of therapeutics directly to the tumor microenvironment. By overcoming the vascular and stromal barriers that have historically limited effective drug penetration in pancreatic cancer, the system has the potential to enhance local drug concentration while minimizing systemic exposure. This approach is modality-agnostic supporting administration of small molecules, biologics, viral vectors, immunotherapies and combination regimens and can be adapted across multiple treatment paradigms. As a result, our goal is to scale this platform across a wide array of therapeutic delivery to improve patient outcomes.

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 tumor microenvironment ("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 Note 10 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") 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).

Results of our three Phase 1 nelitolimod studies will be available in 2026 and we will begin discussions for a pharmaceutical partner for further clinical development in the most promising indication(s). Investigation for HCC is continuing through an IIT.

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.

Market Opportunity for Investigational Therapeutic Nelitolimod

Nelitolimod Market Opportunities

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 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.

Both PDAC and liver cancers are areas of very high unmet medical need and represent large market opportunities for nelitolimod, and for our TriNav device portfolio.

We have initially focused 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. 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.

Clinical Site Partnership

MD Anderson Cancer Center

In 2021, we entered into a five-year Alliance Program (the "MDACC Agreement") with the University of Texas MD Anderson Cancer Center ("MDACC") to serve as the lead investigators for the PERIO-01, PERIO-02, and PERIO-03 studies. We agreed to pay MDACC $10 million in collaboration funding for MDACC to conduct preclinical and clinical studies as mutually agreed to by the parties. To date, we have paid an aggregate $9.4 million towards these studies. The term of the agreement was 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. Effective February 25, 2025, we modified our payment terms and extended the MDACC Agreement for an additional year.

Nelitolimod Competition

We expect nelitolimod to compete primarily with a number of therapeutics that are now, or will soon be, approved for use in liver metastases, liver cancers and locally advanced PDAC. These therapeutics include a range of immunotherapies and chemotherapeutics, some already approved and some of which are currently in development.

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, 2025 and 2024, we have made three milestone payments of $1.0 million each, totaling $3.0 million. No payments were made in the years ended December 31, 2025 and 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 $1.0 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

We manufacture TriNav at our facility in Westminster, Colorado, and through a recent expansion of our clean room we 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, 2025, we owned at least 82 registered patents expiring between 2030 and 2040, with at least an additional 11 pending patent applications.

For our TriNav device, we are the sole owner of eight granted U.S. patents, three pending U.S. patent applications, 13 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 eight 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, 14 granted foreign patents (counting national validations in Europe) and two pending foreign patent applications in Europe and Hong Kong relating to atraumatic occlusive system with compartment for measurement of vascular pressure change The six granted U.S. patents expire between 2034 to 2039. The 14 granted foreign patents expire between 2035 and 2040. Any patents issuing from the pending patent applications (or in the case of priority applications, if issued from future non-provisional applications that we file) are expected to expire between 2035 and 2041, without accounting for potential terminal disclaimers or potentially available patent term adjustments or extensions. Some patents and applications relating to the TriSalus Infusion System overlap with those identified for the TriNav device.

For nelitolimod, we are the sole owner of five pending U.S. patent applications, two pending Patent Cooperation Treaty ("PCT") patent applications, and 34 pending foreign patent applications relating to methods of using immunostimulatory sequence oligonucleotides and specifically nelitolimod. However, we jointly own with Merck Sharp & Dohme LLC two granted US and 12 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.

Successful approval of nelitolimod in the U.S., would provide an opportunity for five years of regulatory exclusivity in the U.S. We are studying nelitolimod in orphan indications and 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 and 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.

TriSalus has Class II devices that 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. 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. A PMA supplement 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.

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.

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 (or BLA, for biologics) 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, some of which may require 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. TriSalus opened an IND in 2021, under which it launched three (3) Phase 1 studies. TriSalus also obtained three additional INDs when it licensed nelitolimod from Dynavax.

Clinical Trials. Clinical trials must be conducted by qualified investigators, and are 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 the well-being of study participants. Clinical trials are subject to the FDA's Bioresearch Monitoring ("BIMO") program, a comprehensive program of on-site inspections, data audits, and remote regulatory assessments. 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 are conducted under protocols reviewed by the FDA, that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated., Each clinical trial must be reviewed and approved by , an Institutional Review Board ("IRB") for each clinical site. Companies sponsors, investigators, and IRBs 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 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 company or study sponsor is required to publicly post specified details about certain clinical trials and l 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 to primarily establish safety before proceeding to additional phase of drug development.
- 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 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.

Success in early-stage clinical trials does not ensure 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. An NDA is submitted under Section 505(b) of the FD&C Act, and includes, among other things, preclinical and clinical study data sufficient 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 complete 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. A 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 submission of an 505(b)(1) NDA 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. Approval will require us to produce data to confirm nelitolimod's or any other therapeutic contribution improves the efficacy of the therapeutic regimen. FDA precedent indicates that these data may 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. We expect that the FDA's Center for Drug Evaluation and Research ("CDER") will have primary jurisdiction for review of the NDA, and that FDA's Center for Devices and Radiological Health will be consulted during the NDA review process. As part of a combination product, we may be required to produce data supporting TriNav or PEDD's contribution to the efficacy of the regimen in the targeted indications beyond the original data used in support of 510(k) clearance. The same is true for our PRVI device currently being studied in combination with nelitolimod in the PERIO-03 trial. 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 the regimen in the targeted indications beyond the original data used in support of 510(k) clearance of the PRVI device.

An NDA submission to the FDA generally requires payment of a substantial user fee, 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, a small business submitting its first human drug application to the Agency without another approved human drug application introduced or delivered into interstate commerce is eligible for a waiver. 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. The FDA may occasionally 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 when making decisions.

FDA accepts (or rejects) an NDA submission — which occurs within 60 days after submission of the NDA — with a non-priority review goal of ten months. FDA's goal for the review of an application granted priority review is six months after the 60-day acceptance period.

The review process can be somewhat or significantly extended, however, by FDA requests for additional information, studies, or clarification. Upon completion of its review and manufacturing inspection, , the FDA either issues an approval letter or a complete response letter ("CRL") outlining the deficiencies in the submission. A CRL may require additional information or additional clinical data. Even with submission of additional information and data, FDA may interpret the data differently from the sponsor and decide that the NDA still does not meet the standards for approval.

Drug development and 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 of the candidate as demonstrated in clinical trials. Even upon approval, the FDA may 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 which could affect the commercial success of a drug.

Post-Approval Regulation

Drug and medical device products are subject to continuing regulation following approval. Failure to meet ongoing regulatory requirements or safety or manufacturing problems may cause the FDA to to take actions that would limit or suspend marketing. Post-approval changes in indications, labeling, manufacturing processes or facilities may require a sponsor to develop additional data or conduct additional preclinical or clinical studies and the submission of a supplemental NDA. Changes to the product's approved labeling could include the addition of new warnings and contraindications, or the implementation of other risk management measures, if new safety information develops.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable current Good Manufacturing Practices ("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 and may conduct periodic visits post-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.

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.

FDA also has manufacturing and safety regulations for devices that apply to the Company. In addition to cGMP, the FDA requires that devices or drug-device combination products comply with the QSR, which sets forth manufacturing quality standards for medical devices. The FDA also requires that we comply with certain device safety reporting requirements for our devices.

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. A manufacturer may not promote a drug or device for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding its drugs or devices. In addition to FDA restrictions on marketing of pharmaceutical or device products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices. 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.

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 any ANDA or 505(b)(2) application for a drug with the same active moiety.

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 until three years after approval of the RLD. The exclusivity is limited to the conditions of approval that required submission of the clinical data.

A Paragraph IV certification filing triggers certain notice requirements for the applicant to notify the NDA or patent holder. 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.

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 does 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 exclusivity 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. These designations do not affect the standards for approval, however, the FDA will attempt to facilitate early and frequent meetings with a sponsor and generally seek to expedite the NDA for a promising drug. 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. Additionally, in April 2025, an executive order was signed directing the Secretary of HHS to take appropriate steps to, among other things, modify certain provisions of the Medicare Drug Price Negotiation Program, develop and implement a payment model to reduce the price of high-cost prescription drugs and biological products covered by Medicare, accelerate approval of generic and biosimilar products, and facilitate the ability of states to import pharmaceuticals from other countries, and in May 2025, an executive order was signed, among other things, directing the Secretary of HHS to propose rules that impose "most-favored-nation" pricing and take other measures to reduce the cost of prescription drugs. It is currently unclear whether and to what extent these measures will be implemented and what impact any such implementation would have on our business. Further, there can be no assurance that the current administration or future administrations will not pursue different or additional measures, such as those intended to more closely align U.S. drug prices with international drug prices (often referred to as "reference" or "international price index" drug pricing). Future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs could restrict the amount that we are able to charge for our product candidates, which could render our product candidates, if approved, commercially unviable and materially adversely affect our ability to raise additional capital on acceptable terms.

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.

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

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 prohibiting, 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. Medical device manufacturers are generally not considered covered entities under HIPAA, but may become subject to HIPAA regulations as business associates with they handle protected health information.

- 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. The regulations differ by state but may require the reporting of certain marketing costs or the reporting of gifts and payments to individual health care providers. Other states require the Company to be licensed or registered where it or its sales representatives conduct sales. In addition, several states require pharmaceutical or device 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 or 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.

Because federal and state health care laws and regulations related to compliance are broad and available statutory exceptions and regulatory safe harbors are narrow, 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

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. During 2025, we terminated our lease for the 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, 2025, we had approximately 102 full-time employees,

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 for the year ended December 31, 2025.

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.

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.
- Until we are able to generate significant revenues or achieve profitability through product sales, we may 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.
- We may not be able to generate sufficient cash to service our indebtedness or borrow additional funds pursuant to our Loan Facility.
- 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.
- 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.
- Any change to TriNav's reimbursement status that reduces our level of reimbursement could cause TriNav sales to materially decline and impede market adoption.
- We 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.
- 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.
- 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 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.
- Our management has identified material weaknesses in its internal control over financial reporting in prior years and we may identify additional material weaknesses in the future. If we 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.

Item 1A. Risk Factors

Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Cautionary 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 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 $39.2 million and $30.0 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $330.6 million. We anticipate incurring increased sales and general and administrative expenses related to our operations 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.

Until we are able to generate significant revenues or achieve profitability through product sales, we may 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.

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. Until we can generate a sufficient amount of revenue, we may need to finance our operations through strategic alliance and licensing arrangements and/or public or private debt and equity financings. The amount of capital we may 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 partners 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 U.S. 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.

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 and borrowed $35.0 million 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. 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. 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.

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, 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 U.S., 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.

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 completed nelitolimod dosing in Phase 1 and Phase 1b clinical trials for UMLM, ICC and HCC, and locally- advanced pancreatic cancer. Based on physician and investigator interest, we are supporting two Investigator Initiated Trials with nelitolimod, one in patients with advanced HCC in combination with cryoablation, durvalumab and tremelimumab another in patients with resectable colorectal liver metastases. Due to the excessive costs of capital, we are looking for potential partners for funding to advance nelitolimod development in Phase II trials in one or more chosen indications based on the results of these early studies. Results will be available in 2026, and we will begin discussions on further clinical development. Phase II studies will require FDA authorization prior to initiation. 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 nelitolimod, 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.

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 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. 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*" within the Item 1. Business.

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.

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 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, 2025, we had approximately 102 full-time employees. 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.

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 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 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 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S., 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 U.S. on a timely basis, if at all. Approvals or clearances by the FDA do not ensure approval or clearance by regulatory authorities in other countries or jurisdictions, and approval or clearance by one regulatory authority outside the U.S. 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 good clinical practices ("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 U.S. 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 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 U.S., 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 FLX, TriNav XP 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 U.S. 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 U.S., 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the U.S., 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 U.S. 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.

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 U.S. 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 U.S. 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 U.S. 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 U.S., are also uncertain. Changes in either the patent laws or their interpretation in the U.S. 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 U.S. 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 U.S. 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 U.S.

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 any 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 and we 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 U.S. 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 U.S. 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, 2025, we owned at least 82 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 exclusivity 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, 2025, we have at least 111 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 U.S. 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 U.S. and, if available, in other countries where we are prosecuting patents, to extent permitted by applicable law in each jurisdiction.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. 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 (and no longer than fourteen years from the date of approval of the approved product) 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, and is subject to the statutory and regulatory requirements of patent term extension in the U.S. and other jurisdictions. 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 U.S., 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 U.S. can be less extensive than those in the U.S. 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 U.S. 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 U.S., or from selling or importing products made using our inventions in and into the U.S. 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 U.S. 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 we intend 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 U.S. 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 U.S.

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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 as a matter of law with underlying facts, in light of the claim language itself, b the written disclosure in a patent (e.g. the specification), the patent's prosecution history and/or other scientific references provided that they are not inconsistent with the patent specification. 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 U.S. 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.

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 U.S. 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 regulatory exclusivity within the U.S. 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, as defined by applicable statue and regulation 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 ("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 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, and which may apply to 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.

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 PEDD are our trademarks and, in the U.S., 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 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 as 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 Global Market ("Nasdaq"), 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 hired 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 a non-accelerated filer as defined by Rule 12b-2 of the Exchange Act, 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 unremediated material weakness 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 consolidated financial statements for the year ended December 31, 2024, management identified material weaknesses in its internal control over financial reporting with respect to (i) financial reporting, (ii) lease accounting (iii) maintenance and accuracy of our outstanding equity information and accounting for stock-based compensation, (iv) accounting for revenue, (v) accounting for accrued liabilities, including patent costs, (vi) accounting for the previous Business Combination, (vii) accounting for significant transactions, (vii) oversight and accounting of the valuation of financial instruments, and (ix) IT general controls. The status of our material weaknesses and remediation efforts are described in Part II — Item 9A. *Controls and Procedures* elsewhere in this Annual Report.

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, 2024, 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.

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, 2025, 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 $2.93 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 U.S. 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 the 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.

We are a smaller reporting company within the meaning of the Securities Act and, if we take advantage of certain exemptions from disclosure requirements available to smaller reporting 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 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 (i) 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 (ii) 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.

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 U.S. 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 U.S. 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 (the "Board") of any significant cybersecurity risks and developments.

Our Vice President of Operations (“VPO”), 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 VPO has 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 VPO 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 VPO 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 VPO 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 VPO. Our VPO 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 VPO, 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's 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 VPO 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 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. We exited our laboratory space at Rhode Island Hospital in Providence, Rhode Island during the first half of 2025. 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 2, 2026, there were 114 active holders of record of our shares of Common Stock and 12 active 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' consolidated financial statements as of and for the fiscal years ended December 31, 2025 and 2024*, 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 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. 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.

In 2025, TriSalus expanded its portfolio of PEDD devices with the commercial launch of the TriNav® FLX Infusion System and the TriNav XP Infusion System, further broadening the TriNav product family. These systems complement the Company’s existing TriNav Infusion System, TriNav LV Infusion System and TriGuide Guiding Catheter and are designed to support therapeutic delivery across a broader range anatomical complexity. The TriNav FLX Infusion System incorporates a more flexible distal tip, intended to improve trackability and navigation in tortuous vasculature. While the TriNav XP Infusion System also includes the more flexible distal tip, it is also designed to support delivery of larger embolic particles, expanding procedural versatility across embolization applications. Together with TriNav LV, which is suitable for vessels 3.5 mm to 5.0 mm in diameter, these products are intended to increase the addressable embolization market. TriNav FLX and TriNav XP are eligible for the same HCPCS reimbursement codes as previously commercialized TriNav products, allowing for integration into existing reimbursement framework.

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 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.

We are a high growth, high margin company approaching a level of revenues that can generate sufficient cash flow to sustain our operations. Beginning in 2020, our mission was to improve the delivery of therapeutics to solid tumors across a range of different diseases and tumor types. Additionally, we acquired an immune-oncology drug, nelitolimod, in July 2020, and conducted several Phase I clinical trials to study the ability and value of our PEDD technology. We have completed Phase I dose escalation (UMLM and LA-PDAC) and Phase Ib (ICC/HCC) clinical trials for nelitolimod. Due to physician and investigator interest, we are supporting two Investigator Initiated Trials of nelitolimod, one in patients with advanced HCC in combination with cryoablation, durvalumab and tremelimumab and another in patients with resectable colorectal liver metastases. Due to the excessive cost of capital, 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 PERIO-03 Phase I dose escalation in LA-PDAC has completed enrollment and we anticipate data from the study will be available in early 2026 and will begin discussions for a pharmaceutical partner for further clinical development.

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 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

On February 19, 2026, we entered into an underwriting agreement (the "Underwriting Agreement") with Lake Street Capital Markets, LLC ("LSCM"), as representative of the underwriters named therein (the "Underwriters"), relating to the public offering (the "Offering") of 9,756,100 shares (the "Shares") of common stock of the Company, par value $0.0001 per share (the "Common Stock"), at a price to the public of $4.10 per Share (the "Offering Price"). Pursuant to the terms of the Underwriting Agreement, the Company also granted the Underwriters a 30-day option to purchase up to an additional 1,463,415 shares of Common Stock (the "Option Shares" and together with the Shares, the "Securities") to cover over-allotments, if any, at the Offering Price less the underwriting discounts and commissions.

On February 23, 2026, the Offering closed, which resulted in the issuance of the Shares for net proceeds of approximately $37.0 million. Subsequent to the closing of the Offering, the Underwriters purchased the Option Shares which resulted in additional net proceeds of approximately $5.6 million.

Components of Results of Operations

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

Revenue

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

The primary end-user customers for our products are hospitals and clinics, 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.

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 and materials purchased for R&D activities. We expense R&D costs as incurred. We recognize expenses for certain development activities, such as preclinical studies and manufacturing, based on an evaluation of the progress to completion of specific tasks using data or other information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of expenses incurred. Non-refundable advance payments for goods or services to be received in the future for use in R&D activities are recorded as prepaid expenses. These amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered.

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 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.

Interest Income

Interest income is for interest earned on our cash, cash equivalents and restricted cash.

Interest Expense

Interest expense includes mainly the interest incurred on our outstanding indebtedness, as well as amortization of deferred financing costs, mainly exit and commitment fees.

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 change in fair value of the Public Warrants, Private Placement Warrants, and Working Capital Warrants (the "Exchange Warrants"), the change in fair value of the OrbiMed Warrants and the change in the revenue base redemption liability.

Change in Fair Value of Contingent Earnout Liability

Change in fair value of contingent earnout liability represents the remeasurement of the fair value.

Other Expense, Net

Other expense, net represents miscellaneous expenses that historically have been immaterial.

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.

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,			
	2025	2024	$ Change	% Change
Revenue	$ 45,151	$ 29,431	$ 15,720	53.4%
Cost of goods sold	6,965	4,103	2,862	69.8%
Gross profit	38,186	25,328	12,858	50.8%
Operating expenses:				
Research and development	14,965	17,688	(2,723)	(15.4)%
Sales and marketing	28,709	25,839	2,870	11.1%
General and administrative	21,458	17,966	3,492	19.4%
Loss from operations	(26,946)	(36,165)	9,219	25.5%
Other income (expense)				
Interest income	555	404	151	37.4%
Interest expense	(5,544)	(3,090)	(2,454)	79.4%
Change in fair value of SEPA, warrant and revenue base redemption liabilities	(4,086)	(2,107)	(1,979)	(93.9)%
Change in fair value of contingent earnout liability	(2,743)	11,231	(13,974)	n.m.
Other expense, net	(456)	(312)	(144)	(46.2)%
Loss before income taxes	(39,220)	(30,039)	(9,181)	(30.6)%
Income tax expense	(7)	(6)	(1)	(16.7)%
Net loss	$ (39,227)	$ (30,045)	$ (9,182)	(30.6)%

n.m: not meaningful, represented by a percentage change equal to or greater than 100%, favorable or unfavorable.

Comparison of the Years Ended December 31, 2025, and 2024

Revenue

Revenue increased $15.7 million, or 53.4%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The increase in revenue was primarily due to an increase of TriNav units sold.

Cost of Goods Sold and Gross Profit

Cost of goods sold increased by $2.9 million, or 69.8%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The increase in cost of goods sold was due to more TriNav units sold.

Gross profit increased by $12.9 million, or 50.8%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024, while gross margin decreased from 86.1% to 84.6% year over year. The increase in gross profit was due primarily to the increase in TriNav units sold, while the year-over-year decline in gross margin was primarily driven by lower manufacturing efficiency associated with newly launched products, which is a dynamic we expect to improve as production scales and processes mature.

Research and Development

R&D expenses decreased by $2.7 million, or 15.4%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The decrease was primarily due to the close-out of clinical trial expenses related to nelitolimod of approximately $2.1 million.

Sales and Marketing

Sales and marketing expenses increased by $2.9 million, or 11.1%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The increase was primarily due to an increase in performance related compensation driven by the increase in sales during the year ended December 31, 2025 compared to prior year.

General and Administrative Expenses

General and administrative expenses increased by $3.5 million, or 19.4%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The increase was primarily due to the acceleration of a non-cash stock-based compensation award of approximately $1.8 million, the revision of certain patent-related expenses from research and development to general and administrative expenses of approximately $0.7 million, and professional services as a result of the timing of various filing and audit related expenses.

Interest Income

Interest income was relatively consistent for the year ended December 31, 2025 compared to the year ended December 31, 2024, as the increase was only $0.2 million or 37.4%, due to the increase in interest earned on a higher cash and cash equivalents balance during the year.

Interest Expense

Interest expense increased by $2.5 million or 79.4% for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The increase was due to interest on the additional funds borrowed under the First Delayed Draw Term Loan in 2025 that was not present in the prior year.

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 $4.1 million in the year ended December 31, 2025, compared to a loss of $2.1 million in the year ended December 31, 2024, a difference of $2.0 million. The change was primarily due to changes in the Company's stock price and the addition of the Subsequent OrbiMed Warrant as a result of the First Delayed Draw during the first quarter of 2025.

Change in Fair Value of Contingent Earnout Liability

The change in fair value of contingent earnout liability resulted in a loss of $2.7 million for the year ended December 31, 2025 compared to a gain of $11.2 million for the year ended December 31, 2024. The change in the fair value of the contingent earnout liability during the period is primarily driven by a change of the following inputs into the valuation of the liability: the increase in stock price, the shortened achievement time frame for the vesting thresholds and the slight decrease in the risk-free rate.

Other Expense, Net

Other expense, net, increased by $0.1 million, or 46.2%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The expense is relatively flat year over year.

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 $39.2 million and $30.0 million for the years ended December 31, 2025 and December 31, 2024, respectively. We had cash and cash equivalents of approximately $20.4 million and $8.5 million as of December 31, 2025 and 2024, respectively. Since inception, we have financed operations primarily through the issuance of and sales of common and preferred stock, convertible notes, 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.

During the year ended December 31, 2025, we achieved the trailing 12-month Product Revenue Base of $30.0 million in January 2025 and were able to borrow the First Delayed Draw Term Loan Commitment resulting in gross proceeds of $10.0 million. On November 10, 2025, we entered into the OrbiMed Third Amendment, which lowered the the minimum cash requirement for the liquidity covenant from $10.0 million to $5.0 million. On April 30, 2025, we raised gross proceeds of approximately $22.0 million through a Private Placement. On February 23, 2026, we raised net proceeds of $42.6 million through a public offering of shares of our Common Stock, including the purchase of optional shares as per the Underwriting Agreement.

Cash Flows

Comparison of the Year Ended December 31, 2025 and December 31, 2024

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

	Year Ended	
	December 31, 2025	December 31, 2024
Net cash used in operating activities	$ (18,012)	$ (40,843)
Net cash used in investing activities	(838)	(345)
Net cash provided by financing activities	30,764	37,936
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 11,914	$ (3,252)

Cash Used in Operating Activities

For the year ended December 31, 2025, net cash used in operating activities was $18.0 million. The net cash used in operating activities consisted of net loss of $39.2 million, adjusted for non-cash activity totaling $19.1 million, primarily related to a loss on the adjustment of the fair value of the contingent earnout liability and the fair value of the SEPA, warrant and revenue base redemption liabilities of $2.7 million and $4.1 million, respectively, stock-based compensation of $9.1 million, depreciation of $0.6 million and amortization of debt issuance costs of $1.0 million. Net operating assets decreased $2.1 million was primarily due to an decrease in inventory, net and prepaid expenses, offset by an increase in trade payables and accrued liabilities and accounts receivable.

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.

Cash Used in Investing Activities

Net cash used in investing activities of $0.8 million for the year ended December 31, 2025 was primarily due to purchases of property and equipment of $0.9 million.

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.

Cash Provided by Financing Activities

Net cash provided by financing activities of $30.8 million for the year ended December 31, 2025, consisted primarily of $20.5 million, net of expenses, from the April 30, 2025 Private Placement and $9.5 million, net of expenses, from the First Delayed draw under the OrbiMed Credit Agreement.

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.

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 may 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. 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; 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.

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

We may require additional capital 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.

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, strategic alliances and/or licensing arrangements 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. There can be no assurances that we will be successful in any of these respects, or that we will be able to continue to obtain outside capital in the future or do so on terms that are acceptable to us.

Contractual Obligations and Commitments

Our contractual obligations as of December 31, 2025, include lease obligations of $2.0 million, reflecting the minimum commitments for our principal administrative and production facility and other office spaces.

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, 2025, and may be required to pay Dynavax up to an additional $170.0 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

During the periods presented and currently, we do not 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:

The preparation of financial statements in conformity with GAAP requires us to make certain estimates and assumptions. These estimates and assumptions affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the balance sheet date, as well as reported amounts of revenue and expenses during the reporting period. Our most significant estimates and judgments involve difficult, subjective or complex judgments made by management. Actual results may differ from these estimates. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations, and cash flows will be affected. We believe that the accounting policies described below involve a greater degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our financial condition and results of operations. For further information, see Note 2 to our consolidated financial statements included in this Annual Report.

Revenue Recognition

Our revenue is derived from shipments of our TriNav infusion devices to our customers which are generally comprised of hospitals and clinics, 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. Freight on Board ("FOB") Shipping 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.

Warrant 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, *Derivatives and Hedging*. 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, 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.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included elsewhere in this Annual Report for 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 sheets of TriSalus Life Sciences, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

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

Our audits included performing procedures to assess the risks of material misstatement of the 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 audits 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 audits provide a reasonable basis for our opinion.

Critical audit matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Grant Thornton LLP

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

Chicago, Illinois
March 5, 2026

TriSalus Life Sciences, Inc.

Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 20,439	$ 8,525
Accounts receivable, net	6,558	5,087
Inventory, net	3,077	4,048
Prepaid expenses	2,170	3,009
Total current assets	32,244	20,669
Property and equipment, net	1,808	1,669
Right-of-use assets	861	1,210
Other assets	418	423
Total assets	$ 35,331	$ 23,971
Liabilities and Stockholders' Deficit		
Current liabilities		
Trade payables	$ 3,002	$ 2,274
Accrued liabilities	8,096	7,355
Short-term lease liabilities	167	216
Other current liabilities	234	383
Total current liabilities	11,499	10,228
Long-term debt	33,046	22,084
Revenue base redemption liability	383	507
Long-term lease liabilities	1,228	1,329
Contingent earnout liability	10,144	7,401
Warrant and SEPA liabilities	12,892	8,316
Total liabilities	69,192	49,865
Commitments and contingencies		
Stockholders' deficit		
Preferred Stock, $0.0001 par value, 10,000,000 shares authorized at December 31, 2025 and 2024, respectively; 0 and 3,985,002 shares issued and outstanding at December 31, 2025 and 2024, respectively	—	—
Common stock, $0.0001 par value, 400,000,000 shares authorized at December 31, 2025 and 2024, respectively; 49,997,836 shares and 31,279,264 shares issued and outstanding at December 31, 2025 and 2024, respectively	4	3
Additional paid-in capital	296,718	253,652
Accumulated deficit	(330,583)	(279,549)
Total stockholders' deficit	(33,861)	(25,894)
Total liabilities and stockholders' deficit	$ 35,331	$ 23,971

See accompanying notes to consolidated financial statements.

TriSalus Life Sciences, Inc.

Consolidated Statements of Operations
(in thousands, except share and per share data)

	Years Ended	
	December 31, 2025	December 31, 2024
Revenue	$ 45,151	$ 29,431
Cost of goods sold	6,965	4,103
Gross profit	38,186	25,328
Operating expenses:		
Research and development	14,965	17,688
Sales and marketing	28,709	25,839
General and administrative	21,458	17,966
Loss from operations	(26,946)	(36,165)
Other income (expense)		
Interest income	555	404
Interest expense	(5,544)	(3,090)
Change in fair value of SEPA, warrant and revenue base redemption liabilities	(4,086)	(2,107)
Change in fair value of contingent earnout liability	(2,743)	11,231
Other expense, net	(456)	(312)
Loss before income taxes	(39,220)	(30,039)
Income tax expense	(7)	(6)
Net loss	$ (39,227)	$ (30,045)
Series A Preferred Stock conversion inducement	$ (18,516)	$ —
Deemed dividend related to Series A Preferred Stock conversion	(11,947)	—
Undeclared dividends on Series A Preferred Stock	—	(3,188)
Net loss attributable to common stockholders	$ (69,690)	$ (33,233)
Net loss per common share, basic and diluted	$ (1.84)	$ (1.31)
Weighted average common shares outstanding, basic and diluted	37,897,785	25,331,753

See accompanying notes to consolidated financial statements.

TriSalus Life Sciences, Inc.

Consolidated Statements of Stockholders' Deficit
(in thousands, except share data)

	Preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2023	4,015,002	$ —	26,413,213	$ 2	$ 222,437	$ (249,504)	$ (27,065)
Net loss	—	—	—	—	—	(30,045)	(30,045)
Exercise of options and vesting of restricted stock units [1]	—	—	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	—	—	—	—
Balance as of December 31, 2024	3,985,002	$ —	31,279,264	$ 3	$ 253,652	$ (279,549)	$ (25,894)
Net loss	—	—	—	—	—	(39,227)	(39,227)
Exercise of options and vesting of restricted stock units [1]	—	—	466,329	—	510	—	510
Issuance of common stock through employee stock purchase plan [1]	—	—	105,609	—	404	—	404
Stock-based compensation [2]	—	—	—	—	9,755	—	9,755
Proceeds from sale of common stock	—	—	5,500,000	—	20,451	—	20,451
Preferred stock conversion	(3,985,002)	—	12,646,634	1	11,946	(11,947)	—
Prior period adjustment	—	—	—	—	—	140	140
Balance as of December 31, 2025	—	$ —	49,997,836	$ 4	$ 296,718	$ (330,583)	$ (33,861)

(1) The Company records the issuance of the shares when they are recorded by the transfer agent and as such, there could be timing differences between when the expense is recorded and shares are transferred.

(2) Amount includes $0.6 million related to 2024 bonus paid in 2025 in the form of stock-based compensation.

See accompanying notes to consolidated financial statements.

TriSalus Life Sciences, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Years Ended	
	December 31, 2025	December 31, 2024
Cash flows from operating activities		
Net loss	$ (39,227)	$ (30,045)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	626	744
Non-cash lease expense	429	264
Change in fair value of SEPA, warrant and revenue base redemption liabilities	4,086	2,107
Change in fair value of contingent earnout liability	2,743	(11,231)
Paid-in-kind interest	800	604
Stock-based compensation expense	9,131	5,441
Allowance for credit losses	163	187
Loss on disposal of property and equipment	120	23
Amortization of debt issuance costs	1,049	612
Changes in operating assets and liabilities:		
Accounts receivable	(1,634)	(1,719)
Inventory, net	971	(1,503)
Prepaid expenses and other assets	840	(1,708)
Deposits	5	43
Operating lease liabilities	(134)	(278)
Trade payables and accrued liabilities	2,020	(4,384)
Net cash used in operating activities	(18,012)	(40,843)
Cash flows from investing activities		
Purchases of property and equipment	(918)	(345)
Proceeds from disposal of property and equipment	80	—
Net cash used in investing activities	(838)	(345)
Cash flows from financing activities		
Proceeds from the issuance of common stock	22,000	15,104
Common stock issuance costs	(1,549)	—
Proceeds from the exercise of stock options for common stock	510	76
Proceeds from the issuance of common stock through employee stock purchase plan	404	433
Debt issuance costs	(520)	(2,593)
Proceeds from the issuance of debt	10,000	25,000
Payments on finance lease liabilities	(81)	(84)
Net cash provided by financing activities	30,764	37,936
Increase (decrease) in cash, cash equivalents and restricted cash	11,914	(3,252)
Cash, cash equivalents and restricted cash, beginning of period	8,875	12,127
Cash, cash equivalents and restricted cash, end of period	$ 20,789	$ 8,875
Supplemental disclosures of cash flow information		
Cash paid for interest	3,697	1,750
Cash paid for income taxes	16	18
Supplemental disclosure of noncash items		
Right-of-use assets obtained in exchange for new operating lease liabilities	—	294
Right-of-use assets obtained in exchange for new finance lease liabilities	66	—
Non-cash capital expenditures included in trade payables	68	—
Fixed asset purchase through exchange of finance lease right-of-use asset	85	—
Derecognition of finance lease right-of-use asset	(85)	—
Prepaid warrant issuance costs	—	1,700
Fair value of warrants issued with OrbiMed debt	366	362

Fair value of revenue base redemption liability related to OrbiMed debt	—	507
Transfer of warrant liability to common stock upon exercise of warrant	—	11,924

See accompanying notes to consolidated financial statements.

TriSalus Life Sciences, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except percentages, share and per share data)

(1) Nature Of Business

On August 10, 2023 (the "Closing Date"), TriSalus Life Sciences, Inc., a Delaware corporation (the "Company," "TriSalus," "we," "us"), formerly known as MedTech Acquisition Corporation ("MTAC"), consummated the previously announced merger pursuant to the Agreement and Plan of Merger 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"). In connection with the consummation of the Business Combination, 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. 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 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.

(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"). In management's opinion, the accompanying consolidated financial statements include all adjustments, including normal recurring items, considered necessary for fair presentation. All intercompany accounts and transactions have been eliminated. Certain reclassifications have been made to the 2024 consolidated statements of stockholders' deficit to conform to the presentation as of December 31, 2025. The accounts of the Company and its wholly owned subsidiaries as of December 31, 2025 and 2024, 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.

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 of $0.4 million is held in a separate account at our bank to support our corporate credit card program and is recorded in other assets on our consolidated balance sheets.

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.

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 $6.6 million and $5.1 million as of December 31, 2025 and 2024 and $3.6 million as of January 1, 2024, 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.

The following table summarizes the allowance for credit losses accounts activity for the year ended December 31, 2025:

	December 31, 2025
Beginning Balance	$ 187
Amount charged (reversed) to costs and expenses	(103)
Write-off of uncollectible receivables	(60)
Ending Balance	$ 24

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.

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 OrbiMed warrant liabilities (see Note 8), the contingent earnout liability (see Note 7), the revenue base redemption liability (see Note 12) and the valuation allowance on deferred tax assets (see Note 9).

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. The approximate useful life of each class of property and equipment is as follows:

	Useful Life (Years)
Machinery and equipment	5 – 7
Computers and software	2 – 3
Furniture	5
Leasehold improvements	Lesser of estimated useful lives of the assets or the lease term
Other property	7

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 rate, 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. To determine the expected lease term, we excluded all options as it is not reasonably certain we would exercise these options. 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. The Company has made an accounting policy election applicable to all asset classes not to record leases with an initial term of twelve months or less on the balance sheet as allowed within ASC 842.

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.

Warrant 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 consolidated balance sheets at their estimated fair values. Changes in fair value of the liability are calculated each reporting period and any change in value is recognized in the consolidated statements of operations.

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 (the "Exchange Warrants"). We value the liability for all of the warrants based on the trading price of the publicly held warrants. See Notes 3 and 8 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. See Notes 3 and 8 for further discussion.

Revenue Base Redemption Liability

In connection with our the Initial OrbiMed Loan, if 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 12 for further detail.

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 fifth 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 3 and 7 for further detail.

Standby Equity Purchase Agreement

In October 2023, the Company entered into a SEPA with Yorkville, which expired November 1, 2025. Pursuant to the SEPA, the Company had 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, was not classified as a liability pursuant to ASC 480, and was accounted for as a derivative pursuant to ASC 815-10, *Derivatives and Hedging* ("ASC 815-10"). The SEPA was 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 was recorded in the consolidated statements of operations. See Note 11 for further detail.

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 undiscounted 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.

Stock-Based Compensation

We account for all employee stock-based compensation awards by recording expense based on the estimated fair value of the awards at the time of grant using the Black-Scholes option pricing model 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 term of the awards, expected volatility of the underlying stock over the term of the awards, and risk-free interest rates. We have elected to not include an estimated forfeiture rate in our stock-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. We record the issuance of shares when they are recorded by the transfer agent and, as such, there could be timing differences between when the expense is recorded and shares are transferred.

Revenue Recognition

Our revenue is derived from the shipments of our PEDD infusion systems to our customers. Our customers are generally comprised of hospitals and clinics. 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 or discount agreements, the rebates and discounts are accounted for within a contra-revenue account at the time the rebate milestone is achieved or discount is given. 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 Freight on Board (FOB) Shipping Point. Therefore, we recognize revenue when the shipment leaves our premises. In certain cases, the purchase order specifies alternate shipping terms, usually FOB destination. 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 $1.0 million and $0.3 million of rebates for the years ended December 31, 2025 and 2024, respectively.

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 during the years ended December 31, 2025 and 2024 (see Note 10).

In 2021, we entered into a 5-year Alliance Program (the “MDACC Agreement”) with the University of Texas MD Anderson Cancer Center (“MDACC”) to serve as the lead investigators for the PERIO-01, PERIO-02, and PERIO-03 studies. The term of the agreement was 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. Effective February 25, 2025, we modified our payment terms and extended the MDACC Agreement for an additional year.

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. With the close out of some of our clinical studies related to nelitolimod, we recorded a charge of approximately $2.1 million during the year ended December 31, 2025.

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.

Advertising

Advertising expense, which is included in sales and marketing costs, is expensed as incurred. Expense for the years ended December 31, 2025 and 2024, was $1.4 million and $0.5 million, respectively.

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 2025, 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.

Recently Adopted Accounting Pronouncements

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. The Company adopted this guidance during the most recent fiscal year (see Note 9).

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 adopted ASU 2024-01 on January 1, 2025. The effect of the adoption had no impact 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 adopted ASU 2024-02 on January 1, 2025. The effect of the adoption had no impact on our consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

In October 2023, the FASB issued ASU No. 2023-06, D*isclosure 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 November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, and in January 2025, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date.* ASU 2024-03 requires additional disclosure of the nature of expenses included in the income statement as well as disclosures about specific types of expenses included in the expense captions presented in the income statement. ASU 2024-03, as clarified by ASU 2025-01. 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 issued 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.

In May 2025, the FASB issued ASU 2025-04, *Compensation - Stock Compensation and Revenue from Contracts with Customers*, which clarifies the guidance for accounting for stock-based payments to customers, including the treatment of vesting conditions tied to customer purchases and the requirement to estimate forfeitures. ASU 2025-04 will become effective for us for annual periods beginning after December 15, 2026, with early adoption permitted. We are currently evaluating the impact the adoption of this ASU will have on our consolidated financial statements.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*, which clarifies the applicability of interim reporting guidance and interim disclosure requirements under ASC Topic 270, including the addition of a disclosure principle requiring disclosure of material events occurring since the most recent annual reporting period. ASU 2025-11 will become effective for us for interim periods within annual periods beginning after December 15, 2027, with early adoption permitted. We are currently evaluating the impact the adoption of this ASU will have on our consolidated financial statements.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements*, which makes targeted amendments to various topics within the ASC intended to clarify existing guidance and correct minor inconsistencies. ASU 2025-12 will become effective for us for annual periods beginning after December 15, 2026, with early adoption permitted. We are currently evaluating the impact the adoption of this ASU will have on our consolidated financial statements.

(3) Financial Instruments

Our financial instruments consist of warrant liabilities, the contingent earnout liability, a Standby Equity Purchase Agreement ("SEPA"), and the revenue based redemption liability related to the Credit Agreement we entered into with OrbiMed (the "OrbiMed Credit Agreement"). The carrying values of cash and cash equivalents, accounts receivable, net and trade payables approximate fair value through the use of publicly available market prices as of December 31, 2025 and 2024. 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 contingent earnout liability, warrant liabilities, SEPA liability and revenue base redemption liability are measured at fair value on a recurring basis (see Notes 7, 8, 11, and 12, respectively). 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 OrbiMed Warrants (defined in Note 8), contingent earnout liability and SEPA 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 companies.

The fair value of the Public Warrants has been measured based on the quoted price of such warrants on the Nasdaq Global Market (the "Nasdaq"). The Private Placement Warrants and Working Capital Warrants are similar to the Public Warrants and, therefore, use the same fair value as the Public Warrants (see Note 8).

We use a Black-Scholes option pricing model to estimate the fair value of the OrbiMed Warrants (defined in Note 8), 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 a 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 consolidated 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 public companies within the Company's industry that the Company considers to be comparable to its own business.

The estimated fair value of the contingent 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 as further described in Note 7.

The repayment of the loans under the OrbiMed Credit Agreement is referred to as the "revenue base redemption liability" (see Note 12). We determine the value of the revenue base redemption liability using a Monte Carlo simulation of future revenue and valuing the Term Loan (as defined in Note 12) using the with and without method.

The following tables summarize the changes in fair value of our outstanding warrant liabilities, contingent earnout liability, SEPA liability and revenue base redemption liability for the year ended December 31, 2025:

Warrant Liabilities	Fair Value at December 31, 2024	Change in Fair Value (Gains) Losses	Issuances (Settlements)	Fair Value at December 31, 2025
Public Warrants - Level 1	$ 1,927	$ 981	$ —	$ 2,908
Private Placement Warrants - Level 2	$ 4,872	$ 2,480	$ —	$ 7,352
Working Capital Warrants - Level 2	$ 1,100	$ 560	$ —	$ 1,660

Level 3 Liabilities	Fair Value at December 31, 2024	Change in Fair Value (Gains) Losses	Issuances (Settlements)	Fair Value at December 31, 2025
Contingent earnout liability	$ 7,401	$ 2,743	$ —	$ 10,144
SEPA liability	$ 55	$ (55)	$ —	$ —
OrbiMed Warrant liability	$ 362	$ 244	$ 366	$ 972
Revenue base redemption liability	$ 507	$ (124)	$ —	$ 383

The following tables summarize the changes in fair value of our outstanding warrant liabilities, contingent earnout liability, SEPA liability and revenue base redemption liability for the year ended December 31, 2024:

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

(4) Inventory

The components of inventory are summarized as follows:

	December 31, 2025	December 31, 2024
Raw materials	$ 1,289	$ 1,338
Finished goods	1,897	2,720
Reserve for obsolete inventory	(109)	(10)
Inventory, net	$ 3,077	$ 4,048

(5) Property And Equipment

Property and equipment, net consists of the following:

	December 31, 2025	December 31, 2024
Machinery and equipment	$ 1,952	$ 2,636
Computers and software	1,094	1,279
Furniture	163	425
Leasehold improvements	1,571	772
Other property	13	13
Construction in progress	248	331
Gross property and equipment	5,041	5,456
Less accumulated depreciation	(3,233)	(3,787)
Property and equipment, net	$ 1,808	$ 1,669

Depreciation expense for property and equipment for the years ended December 31, 2025 and 2024, was $0.6 million and $0.7 million, respectively.

(6) Accrued Liabilities

Accrued liabilities consists of the following:

	December 31,	
	2025	2024
Accrued liabilities - clinical	$ 1,090	$ 2,297
Accrued incentives	1,920	2,094
Accrued liabilities - general	2,390	1,850
Accrued vacation	401	362
Accrued payroll	2,195	718
Accrued taxes	100	34
Total Accrued Liabilities	$ 8,096	$ 7,355

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

(7) Contingent Earnout Liability

In connection with the Business Combination, MTAC entered into a sponsor support agreement (the "Sponsor Support Agreement"). Pursuant to the Sponsor Support Agreement, the 3,125,000 Sponsor Earnout Share (the "Sponsor Earnout Shares") become unvested and subject to potential forfeiture if certain triggering events are not achieved prior to the fifth anniversary of the Closing Date. Pursuant to the Sponsor Support Agreement, for any 20 trading days within a period of 30 consecutive trading days, (i) 25% of the shares of the unvested Common Stock held by the Sponsor Holders will vest if the volume weighted average price of our Common Stock equals or exceeds $15.00, (ii) 25% of the shares of the unvested Common Stock held by the Sponsor Holders will vest if the volume weighted average price of our Common Stock equals or exceeds $20.00, (iii) 25% of the shares of the unvested Common Stock held by the Sponsor Holders will vest if the volume weighted average price of our Common Stock equals or exceeds $25.00, and (iv) 25% of the shares of the unvested Common Stock held by the Sponsor Holders will vest if the volume weighted average price of our Common Stock equals or exceeds $30.00. Additionally, the Sponsor Earnout Shares will vest if there is a change in control of our company on or before the fifth 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 fifth anniversary of the Closing Date will be forfeited.

The liability was remeasured to its fair value of $10.1 million and $7.4 million as of December 31, 2025 and 2024, respectively, based on a Monte Carlo simulation valuation model. This remeasurement resulted in recording a loss of $2.7 million and a gain of $11.2 million for the years ended December 31, 2025 and 2024, respectively, classified as change in fair value of contingent earnout liability in the consolidated statements of operations. Assumptions used in the valuation are described below:

	December 31, 2025	December 31, 2024
Current stock price	$ 6.98	$ 5.01
Expected share price volatility	70.0 %	70.0 %
Risk-free interest rate	3.5 %	4.3 %
Expected term (years)	2.6	3.6
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 0% based on the fact that we have never paid or declared dividends.

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

(8) Warrants

Warrants that have not been tendered for exchange and outstanding at December 31, 2025 and December 31, 2024, are as follows:

	December 31, 2025	December 31, 2024
Public Warrants	1,751,825	1,751,825
Private Placement Warrants	4,428,648	4,428,648
Working Capital Warrants	1,000,000	1,000,000
OrbiMed Warrants	222,068	130,805
Total warrants	7,402,541	7,311,278

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, 2025 and 2024, there were 1,751,825 Public Warrants outstanding. The Public Warrants expire on August 10, 2028 or earlier upon redemption or liquidation. The Public Warrants expire five years after the completion of the Business Combination or earlier upon redemption or liquidation. We may redeem for cash the outstanding Public 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 Public Warrants become redeemable, we 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, except as described below, the warrants will not be adjusted for issuances of common stock at a price below its exercise price. Additionally, in no event will 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, 2025 and 2024, there were 4,428,648 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.

As of December 31, 2025, the fair values of the Public Warrants, Private Placement Warrants and Working Capital Warrants were $2.9 million, $7.4 million, and $1.7 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. The fair value of the Public Warrants has been measured based on the quoted price of such warrants on the Nasdaq. 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 and SEPA liabilities and an increase to additional paid-in capital on the consolidated balance sheets, 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 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 tables summarizes activity in the Public Warrants, Private Placement Warrants and Working Capital Warrants for the years ended December 31, 2025 and 2024.

Series	Balance at December 31, 2024	Exchanges	Issuances	Retirements / Conversions	Balance at December 31, 2025
Public Warrants	1,751,825	—	—	—	1,751,825
Private Placement Warrants	4,428,648	—	—	—	4,428,648
Working Capital Warrants	1,000,000	—	—	—	1,000,000

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

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 $1.3 million in the aggregate. As of December 31, 2025, the exercise price was $8.8398 per share pursuant to the terms of the Initial OrbiMed Warrant, or approximately $1.2 million in the aggregate. The Initial OrbiMed Warrant expires on April 30, 2031 (the "Expiration Date"). On each of the closings of the Delayed Draw Commitment Amounts (see Note 12), 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. In connection with the First Delayed Draw Term Loan Commitment draw (see Note 12) on February 18, 2025, we issued the OrbiMed operating entities a warrant to purchase 64,748 and 26,515 shares of our common stock (the "Subsequent OrbiMed Warrants"), with the initial exercise price of $5.4787, or approximately $0.5 million. As of December 31, 2025, the Exercise Price was $5.3322 per share pursuant to the terms of the Subsequent OrbiMed Warrant, or approximately $0.5 million in the aggregate. The Subsequent OrbiMed Warrant expires on February 18, 2032 (the "Expiration Date").

The 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 OrbiMed Warrant; or

b. instructing the Company to withhold a number of Warrant Shares then issuable upon exercise of the 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 OrbiMed Warrant (the “Cashless Exercise”).

If either upon (i) the occurrence of the Expiration Date, or (ii) the date on which a Sale of the Company 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 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 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 current Exercise Price and the number of Warrant Shares underlying the OrbiMed Warrants are subject to certain anti-dilutive adjustments. These are triggered by events such as stock splits, reclassification of shares, combinations or substitutions. Additionally, the Exercise Price will be adjusted if shares,which include options and convertible securities settled in common stock) are issued at a price per share less than the current Exercise Price. These adjustments are collectively referred to as "Warrant Adjustments.”

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

Additionally, the OrbiMed Warrants are 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 OrbiMed Warrants 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 OrbiMed Warrants would be less than the amount we would receive immediately prior to such adjustment.

Transfers of OrbiMed Warrant

The 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 OrbiMed Warrants 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 under ASC 815 and will be classified as a liability and is subsequently measured at fair value with changes reported within the change in fair value of SEPA, warrant and revenue base redemption liabilities of the consolidated statement of operations following the proceeds from the issuance of the Initial Term Loan.

Fair Value

The estimated fair value of the OrbiMed Warrant 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 0% 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.

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, 2025	December 31, 2024
Expected term (years)	5.3	6.3
Risk free interest rate	3.8%	4.5%
Expected volatility	70.0%	70.0%
Dividend yield	—%	—%
Exercise price	$8.8398	$9.3722
Stock price	$6.98	$5.01

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

	December 31, 2025	February 18, 2025
Expected term (years)	6.1	7.0
Risk free interest rate	3.9%	4.1%
Expected volatility	70.0%	70.0%
Dividend yield	—%	—%
Exercise price	$5.3322	$5.4787
Stock price	$6.98	$5.69

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

(9) 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, 2025	December 31, 2024
Federal:		
Current	$ (9)	$ (15)
Deferred	—	—
	(9)	(15)
State:		
Current	16	21
Deferred	—	—
	16	21
Income tax expense	$ 7	$ 6

We adopted ASU 2023-09 Income Taxes (Topic 740): *Improvements To Income Tax Disclosures* on a prospective basis beginning with the year ended December 31, 2025. The following table presents required disclosure pursuant to ASU 2023-09 and reconciles the U.S. federal statutory income tax amount and rate to our actual effective amount and rate for the year ended December 31, 2025:

	December 31, 2025	
	Amount	Percent
Statutory rate	$ (8,256)	21.0%
State and local taxes [1]	(1,252)	3.2
Change in valuation allowance	7,446	(18.9)
Other adjustments	248	(0.6)
Permanent differences - change in fair value of contingent earnout liability	576	(1.5)
Permanent differences - change in fair value of SEPA, warrant and revenue base redemption liabilities	858	(2.2)
Permanent differences - other	387	(1.0)
	$ 7	—%

(1) *Tax jurisdictions that comprise more than 50% of state and local income tax expense for the year ended December 31, 2025 consisted of the following (in order of magnitude): California, New York, New Jersey, Pennsylvania, Massachusetts and Louisiana.*

The following table presents the required disclosures prior to our adoption of ASU 2023-09 and reconciles the U.S. federal statutory income tax rate to our actual effective income tax rate for the year ended December 31, 2024:

	December 31, 2024
Statutory rate	21.0%
State and local taxes	5.1
Change in valuation allowance	(33.1)
Other adjustments	1.7
Permanent differences	5.3
	—%

The income tax effects of temporary differences that give rise to significant portions of the deferred income tax assets and liabilities as of December 31, 2025 and 2024 are presented below:

	December 31, 2025	December 31, 2024
Deferred tax assets:		
NOL carryforwards	$ 53,962	$ 44,336
Fixed assets	2,941	2,664
Accrued liabilities	562	140
Inventory	529	652
Interest limitation	—	674
Charitable contributions	26	33
Lease accounting	114	52
Capitalized R&D expenses	8,209	11,919
Stock-based compensation expense	2,731	1,264
Total deferred income tax assets	69,074	61,734
Deferred tax liabilities:		
Prepaid expenses	(342)	(407)
Total deferred income tax assets and liabilities	68,732	61,327
Less: Valuation allowance	(68,732)	(61,327)
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, 2025 and 2024 was $7.4 million and $10.0 million, respectively.

As of December 31, 2025, 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, 2025	
	Federal	State
NOLs expiring between 2029 and 2037	$ 43,912	$ 128,004
NOLs which do not expire	174,705	45,433
Total NOLs	$ 218,617	$ 173,437

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, 2025 and 2024, 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, 2025 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.

(10) 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. Nelitolimod, an investigational agent in development, is a TLR9 agonist which is believed to bind to the TLR9 receptors found on suppressive immune cells including myeloid-derived suppressor cells 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 Locally Advanced Pancreatic Ductal Adenocarcinoma ("LA-PDAC").

Payments under the Dynavax purchase agreement consist of: (a) one upfront payment of $9.0 million, (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 Food and Drug Administration ("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 September 2021, after initiating our clinical study of uveal melanoma liver metastases, $1.0 million in June 2022, after initiating our clinical study for primary liver tumors, and $1.0 million in August 2023, after initiating our clinical study for LA-PDAC. 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 $1.0 billion and 12% for aggregate annual net sales above that amount.

We record the milestone payments in R&D expense when they are incurred. 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. During the years ended December 31, 2025 and 2024, we made no payments to Dynavax.

(11) Standby Equity Purchase Agreement

In October 2023, we entered into a SEPA with Yorkville Advisors Global, LP ("Yorkville"). Pursuant to the SEPA, the Company had 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 our 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 (the "Commitment Period"), which was November 1, 2025. Each issuance and sale to Yorkville under the SEPA (an “Advance”) was 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 for the 10 trading days immediately preceding an Advance notice, or (ii) 1,000,000 shares of Common Stock. During the Commitment Period, the Company had the option to issue and sell shares 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 were subject to certain limitations, including that Yorkville could not purchase any shares that would result in it beneficially owning more than 4.99% of the outstanding voting power or Common Stock. Further, Yorkville could not purchase shares that would result in it acquiring more than 5,260,704 shares of Common Stock, which represented 19.99% of the outstanding Common Stock, as of the effective date of SEPA.

As described in Note 2, the SEPA contract was accounted for as a derivative as it was an equity-linked contract that did not qualify for equity classification under ASC 815. Therefore, the SEPA was recognized as a liability measured each period at fair value in accordance with ASC 820, *Fair Value Measurement,* on the consolidated balance sheets and the change in fair value of the SEPA liability is recorded on the consolidated statements of operations. We did not issue any Advances during the year ended December 31, 2025.

The estimated fair value of the SEPA derivative liability on December 31, 2024 was $0.1 million, which was determined using a scenario-based valuation model. During the year ended December 31, 2025, the liability was remeasured to its fair value of zero as of September 30, 2025, due to not having any intentions to utilize the SEPA prior to its expiration on November 1, 2025. This remeasurement resulted in the recognition of an immaterial gain of $0.1 million for the year ended December 31, 2025, which is included in change in fair value of warrant, SEPA and revenue base redemption liabilities in the consolidated statement of operations. As the SEPA expired on November 1, 2025, no valuation was performed as of December 31, 2025. Assumptions used in the valuation as of December 31, 2024 are described below:

Valuation assumptions:	December 31, 2024
Expected draws	$ 2,000
Expected probability of draws	90.0%
Risk-free interest rate	4.4%

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 through the issuance of multiple separate advances under the Option 2 Pricing Period as of December 31, 2024;

(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.

(12) 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 Company, provided that Product Revenue Base 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 expired on June 30, 2025.

c. An additional $15.0 million term loan available at the election of the Company, provided that Product Revenue Base 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 expired on December 31, 2025.

On April 30, 2024, we borrowed the Initial Term Loan, resulting in gross proceeds of $25.0 million. On February 18, 2025, we borrowed the First Delayed Draw Term Loan Commitment resulting in gross proceeds of $10.0 million based on achieving the trailing 12-month Product Revenue Base of $30.0 million in January 2025. The Initial Term Loan and the First Delayed Draw Term Loan (collectively, the "Term Loan") mature on April 30, 2029 (the "Maturity Date").

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, 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.

As part of the First Amendment to the OrbiMed 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 OrbiMed Credit 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. Effective on April 30, 2025, the Second Amendment to the OrbiMed Credit Agreement allows for the Company to accelerate payment of the Series A Preferred Stock dividends in cash payments in lieu of fractional shares upon conversion of Preferred Stock.

On November 10, 2025, we entered into the Third Amendment to the OrbiMed Credit Agreement ("OrbiMed Third Amendment"), which lowered the minimum cash requirement for the liquidity covenant from $10.0 million to $5.0 million. In addition, we received a waiver for the prior default related to the 30 days written notice of the change in our Chief Financial Officer.

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 Company will start repaying the outstanding principal amount on the Term Loans. 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, 2025	$42,700
March 31, 2026	$46,400
June 30, 2026 and each Fiscal Quarter ending thereafter	$50,000

As of December 31, 2025, 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 [(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 (except PIK Interest) are due on the last day of the month. Whenever a prepayment is made on the principal of the Term Loans, the accrued interest and any applicable Repayment Premium on the amount prepaid is also due on such date.

Warrant

In connection with the closing of the OrbiMed Credit Agreement, we issued OrbiMed the Initial OrbiMed Warrant. Subsequent to achieving the First Delayed Draw Term Loan Commitment revenue requirement, the Subsequent OrbiMed Warrant was issued (see Note 8) for further discussion.

Debt Related Fees

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"). The Exit Fee is amortized over the term of the Term Loans.

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"). The Commitment Fee was recorded as a debt discount and amortized over the life of the Term Loans.

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. The Undrawn Fee is accounted for as a service fee, which is expensed as incurred.

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.

In 2024, we recorded the Initial Term Loan and the First Delay Draw as Long-term debt, and recorded the issuance costs incurred to obtain the loan as contra-debt, in accordance with ASC 470, *Debt*. We incurred $2.6 million in legal, origination and other fees to acquire the OrbiMed Credit Agreement.

During the year ended December 31, 2025, we recorded interest expense of $5.5 million related to borrowings under the OrbiMed Credit Agreement on the consolidated statements of operations, of which $0.8 million was recorded as PIK Interest, $3.7 million was cash interest, and $1.0 million was amortization of debt issuance costs and debt discount.

The following table summarizes activity within the Term Loan for the years ended December 31, 2025 and December 31, 2024:

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	**$**	**22,084**
First Delayed Draw Term Loan Commitment		10,000
Debt issuance costs		
Cash issuance costs		(521)
Noncash issuance costs:		
Warrant liability		(366)
Amortization of debt issuance costs		766
PIK interest		800
Accretion of exit fee liability		283
Balance at December 31, 2025	**$**	**33,046**

(13) Convertible Preferred Stock

As of December 31, 2024, the Company had 3,985,002 shares of Series A Convertible Preferred Stock ("Preferred Stock") outstanding. The original issue price of the Series A Convertible Preferred Stock was $10.00. The Series A Convertible Preferred Stock accrued 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, which were not recorded in our consolidated financial statements, except actual undeclared dividends of $3.2 million as a reconciling item for net loss attributable to common stockholders on the consolidated statements of operations.

On June 23, 2025, the Company commenced an offer (the “Offer”) to all holders of Preferred Stock to exchange their shares of Preferred Stock for Common Stock equal to the sum of the liquidation preference per share price of $10.00 and all accrued and unpaid dividends per share outstanding through August 10, 2027, divided by a $4.00 conversion price per share. The Offer expired at one minute after 11:59 p.m., Eastern Daylight Time, on July 23, 2025. For any Preferred Stock holders that did not participate in the Offer, the Company had the right to call their Preferred Stock shares for conversion into Common Stock shares equal to the sum of the liquidation preference per share price of $10.00 and all accrued and unpaid dividends per share outstanding through the conversion date, divided by a $5.227 conversion price per share.

Approximately 98.8% of the outstanding shares of Preferred Stock shares were tendered through the Offer and were accepted for exchange, resulting in 3,551,502 shares of Preferred Stock converted to 11,719,956 shares of Common Stock. For the holders of Preferred Stock that did not participate in the Offer, the Company called their Preferred Stock and 42,500 shares of Preferred Stock were converted to 93,103 shares of Common Stock. All shares of Preferred Stock were converted for common stock shares on July 31, 2025, resulting in the issuance of 11,813,059 Common Stock shares.

As of December 31, 2025 and subsequent to the Preferred Stock Conversion, there are no outstanding shares of Preferred Stock. The Company is authorized to issue up to 10,000,000 shares of preferred stock with 10,000,000 shares available for issuance.

(14) Stock-Based Compensation

Equity Incentive Plans

We currently maintain the 2023 Equity Incentive Plan (the “2023 Plan”), which our Board of Directors (the "Board") and stockholders approved in connection with the Business Combination, for purposes of granting equity-based incentive awards to our employees, executive officers, directors and consultants. 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 has not been 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.

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 2023 Plan will expire on August 10, 2033, unless modified by the Board of Directors or a duty authorized committee thereof.

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.

The Board delegated the authority to administer the 2009 Plan and the 2023 Plan 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.

As of December 31, 2025, the balances under the two plans are below.

	December 31, 2025		
	Authorized	**Outstanding [1]**	**Available for Issue**
2009 Plan	1,992,689	1,165,317	—
2023 Plan	10,354,247	8,067,960	1,901,532
Total	12,346,936	9,233,277	1,901,532

(1) Outstanding excludes RSU releases and option exercises for the 2009 and 2023 Plans as well as RSU forfeitures for the 2009 Plan as they were not returned to the plan.

Stock Options

Historically, we have used stock 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. Stock options are granted with an exercise price equal to the fair market value of our common stock on the grant date. Stock options generally have a ten-year contractual term and typically have graded vesting over one to four years. We may grant stock options with a performance condition. The performance stock options vest upon meeting the stated performance metric(s) during the stated performance period(s). We assess the probability of the performance stock options meeting the performance metric(s), and if probable, we recognize compensation expense over the requisite service period. We granted one performance stock option award in 2025.

The following table summarizes activity for stock options under the 2009 Plan and 2023 Plan for the year ended December 31, 2025 :

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2025	4,591,539	$ 6.46	6.2	$ 3,864
Granted	3,821,338	5.23		
Exercised	(144,150)	3.43		$ 260
Forfeited	(759,570)	5.54		
Expired	(102,493)	8.87		
Outstanding at December 31, 2025	7,406,664	$ 5.94	7.4	$ 13,358
Exercisable at December 31, 2025	2,942,814	$ 6.02	5.1	$ 6,511

The aggregate intrinsic value of options exercised during the year ended December 31, 2024 was $0.4 million. The related cash received, net of tax, was approximately $0.5 million for the year ended December 31, 2025.

The fair value of each stock option granted during the years ended December 31, 2025 and 2024 was determined using the Black-Scholes option pricing model. The following table summarizes the weighted-average grant date fair value and assumptions used to develop the fair value estimates for the options granted during the years ended December 31, 2025 and 2024, respectively:

	December 31, 2025	December 31, 2024
Weighted-average grant date fair value	$2.90	$4.55
Expected volatility	53.5 %	54.2 %
Risk-free interest rate	4.0 %	4.1 %
Expected term (years)[(1)]	6.2	6.2
Expected dividend yield	— %	— %

(1) Our historical exercise behavior for previous grants does not provide a reasonable estimate for future exercise activity. Therefore, the expected term was calculated using the simplified method, which is the average of the option's vesting and contractual term.

We recorded compensation expense for stock options during the years ended December 31, 2025 and 2024 was $6.3 million and $3.9 million, respectively. As of December 31, 2025, there was $13.2 million of unrecognized compensation expense related to stock options and will be expensed over a weighted average period of 2.9 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 assess the probability of PSUs meeting the performance metric(s), and if probable, we recognize compensation expense over the requisite service period. We granted one PSU award in 2025 and 2024, respectively.

The following table summarize activity for RSUs and PSUs under the 2009 Plan and 2023 Plan for the year ended December 31, 2025:

	Number of Stock Units	Weighted-Average Grant-Date Fair Value per Share
Unvested at January 1, 2025	459,357	$ 9.51
Granted	1,764,736	5.46
Vested	(324,626)	6.92
Forfeited	(72,854)	6.39
Unvested at December 31, 2025	1,826,613	$ 6.18

The weighted-average grant date fair value of RSUs and PSUs granted during the year ended December 31, 2024 was $9.46. The fair value of RSUs and PSUs vested during the years ended December 31, 2025 and 2024 was $1.7 million and $0.1 million, respectively.

We recorded compensation expense for RSUs and PSUs during the years ended December 31, 2025 and 2024 was $2.7 million and $1.3 million. As of December 31, 2025, there was $9.1 million of unrecognized compensation expense related to RSUs and PSUs and will be expensed over a weighted-average period of 3.0 years.

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 2,350,530 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. On January 1, 2025, the authorized shares under ESPP increased by 953,418 shares to 3,303,948.

During the year ended December 31, 2025, 94,066 shares were purchased in an offering under the ESPP, for which we recognized compensation expense of $0.1 million. We record the issuance of shares when they are recorded by the transfer agent and, as such, there could be timing differences between when the expense is recorded and shares are transferred.

(15) 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. As we have reported net losses for the years ended December 31, 2025 and 2024, 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,	
	2025	2024
Preferred stock	—	25,048,584
Common stock warrants	7,402,541	7,311,278
RSUs and PSUs	1,826,613	459,357
Stock options	7,406,664	4,591,539
Shares issuable under the SEPA	—	3,468,998
Total	16,635,818	40,879,756

(16) Leases

We have two property leases in effect as of December 31, 2025, which we account for as operating leases. We lease office, manufacturing and warehouse space under these leases. Both leases contain options to extend the respective lease terms, which were excluded in determining the expected lease term as it was not reasonably certain we would exercise these options.We also have two finance leases for copier equipment and computers in our facilities.

On July 17, 2024, we exercised one of the two options to extend the current lease for our principal administrative and production 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 operating lease and finance lease components included in right-of-use assets, short-term lease liabilities and long-term lease liabilities on our consolidated balance sheets as of December 31, 2025 and 2024, are as follows:

2025	Operating Leases	Finance Leases	
Right-of-use assets	$ 861	$ 79	(1)
Short-term lease liabilities	$ 128	$ 39	
Long-term lease liabilities	$ 1,186	$ 42	

2024	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 property and equipment, net.

The components of lease expense for the years ended December 31, 2025 and 2024, were as follows:

	December 31,	
	2025	2024
Operating lease expense	$ 310	$ 409
Finance lease expense:		
Amortization of ROU assets	29	115
Interest on lease liabilities	3	11
Total finance lease expense	32	126
Total lease expense	$ 342	$ 535

Cash paid for amounts included in the measurement of lease liabilities for the years ended December 31, 2025 and 2024, were as follows:

	December 31,	
	2025	2024
Operating cash flows from operating leases	$ 294	$ 441
Financing cash flows from finance leases	$ 81	$ 84

Maturities of lease liabilities under noncancellable leases as of December 31, 2025, are as follows:

	Operating Leases	Finance Leases
2026	$ 299	$ 46
2027	371	43
2028	300	1
2029	304	—
2030	316	—
Thereafter	329	—
Total undiscounted lease payments	1,919	90
Less imputed interest	(605)	(9)
Total lease liabilities	$ 1,314	$ 81

As of December 31, 2025, the weighted-average remaining lease term of our operating and finance leases is 5.5 years and 2.0 years, respectively. The weighted-average discount rate for operating and finance leases is 13.8% and 11.6%, respectively, which is based on interest rates we paid for our most recent term loan and convertible notes. As of December 31, 2024, the weighted-average life of our operating and finance leases was 6.0 years and 2.0 years, respectively. The weighted-average discount rate for operating and finance leases was 13.8% and 8.1%, respectively, which is based on interest rates we paid for our most recent term loan and convertible notes.

(17) Commitments And Contingencies

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 $0.7 million to the plan for the years ended December 31, 2025 and 2024, 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.

From time to time, we may have certain contingent liabilities, including litigation, which arise in the ordinary course of 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 balance sheets, statements of operations or statements of cash flows.

As part of the Business Combination, we entered into the Amended and Restated Registration Rights Agreement with certain investors in MTAC and Legacy TriSalus. Subject to certain requirements and customary conditions, we granted piggyback registration rights and demand registration rights to the parties thereto, agreed to pay certain expenses related to such registrations and agreed to indemnify the parties thereto against certain liabilities related to such registrations. Our registration obligations under the Amended and Restated Registration Rights Agreement will terminate with respect to any party thereto on the date that such party no longer holds any Registrable Securities (as defined in the Amended and Restated Registration Rights Agreement). The Amended and Restated Registration Rights Agreement does not contain liquidated damages or other cash settlement provisions resulting from delays in registering the Company's securities.

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

(18) Subsequent Events

On February 19, 2026, we entered into an underwriting agreement (the "Underwriting Agreement") with Lake Street Capital Markets, LLC ("LSCM"), as representative of the underwriters named therein (the "Underwriters"), relating to the public offering (the "Offering") of 9,756,100 shares (the "Shares") of common stock of the Company, par value $0.0001 per share (the "Common Stock"), at a price to the public of $4.10 per Share (the "Offering Price"). Pursuant to the terms of the Underwriting Agreement, the Company also granted the Underwriters a 30-day option to purchase up to an additional 1,463,415 shares of Common Stock (the "Option Shares" and together with the Shares, the "Securities") to cover over-allotments, if any, at the Offering Price less the underwriting discounts and commissions.

On February 23, 2026, the Offering closed, which resulted in the issuance of the Shares for net proceeds of approximately $37.0 million. Subsequent to the closing of the Offering, the Underwriters purchased the Option Shares which resulted in additional net proceeds of approximately $5.6 million.

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

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) 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 and accounting 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 as a result of the material weaknesses in our internal control over financial reporting previously identified, which one continues to exist as of December 31, 2025, as discussed below. Management's assessment of the effectiveness of our disclosure controls and procedures is expressed at a level of reasonable assurance because management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives.

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, 2025, 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, 2025, due to the material weakness discussed below.

Remediation of Previously Disclosed Material Weaknesses

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 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) financial reporting, (ii) lease accounting (iii) maintenance and accuracy of our outstanding equity information and accounting for stock-based compensation, (iv) accounting for revenue, (v) accounting for accrued liabilities, including patent costs, (vi) accounting for the previous Business Combination, (vii) accounting for significant transactions, (vii) oversight and accounting of the valuation of financial instruments, and (ix) IT general controls.

During the year ended December 31, 2025, we have taken measures to address the material weaknesses identified in the 2024 Annual Report and enhance our internal control over financial reporting. We have:

- hired additional accounting and financial reporting personnel with U.S. GAAP and SEC reporting experience to facilitate management level reviews, and financial reporting oversight;
- designed and implemented review processes that ensure segregation of duties within the accounting and finance function;
- adequately reviewed the assumptions and inputs into accounting estimates;
- implemented protocols and controls over financial reporting and period end close processes;
- established effective monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our financial statements and related disclosures;

- reviewed and enhanced IT general controls over information systems relevant to financial reporting, including privileged access and segregation of duties; and

- realigned existing personnel and added both internal and external personnel to strengthen management's review and documentation over internal control over financial reporting.

As of December 31, 2025, one material weakness remains unremediated related to accounting for significant transactions. While management implemented revised processes and hired additional resources, sufficient time has not elapsed to demonstrate operating effectiveness. The material weakness will be considered remediated when the controls we have implemented 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 quarter ended December 31, 2025, other than the remediation actions described above, there were no changes to our internal control over financial reporting that materially affected, or are 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 no later than 120 days after the Company's fiscal year ended December 31, 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 and principal financial and accounting officer. 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 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
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
3.4	Certificate of Amendment to Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock of TriSalus Life Sciences, Inc.	Form 8-K	001-39813	3.1	July 24, 2025
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	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
4.5	Description of Securities				
4.6	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	4.10	October 29, 2024
4.7	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	4.11	October 29, 2024

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
4.8	Warrant Certificate, dated February 18, 2025, by and between TriSalus Life Sciences, Inc., and OrbiMed Royalty & Credit Opportunities IV, L.P.	Form 10-K	001-39813	4.10	April 15, 2025
4.9	Warrant Certificate, dated February 18, 2025, by and between TriSalus Life Sciences, Inc., and OrbiMed Royalty & Credit Opportunities IV Offshore, L.P.	Form 10-K	001-39813	4.11	April 15, 2025
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*	Surefire Medical, Inc. 2009 Amended and Restated Equity Incentive Plan.	Form 8-K	001-39813	10.15	August 16, 2023
10.4*	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
10.5*	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
10.6*	Form of Stock Option Grant Notice and Form of Stock Option Agreement under Surefire Medical, Inc. 2009 Amended and Restated Equity Incentive Plan (for grants after 2020).	Form 8-K	001-39813	10.18	August 16, 2023
10.7*	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
10.8*	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
10.9*	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
10.10*	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
10.11*	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

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
10.12*##	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
10.13*##	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
10.14*##	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
10.15*##	Executive Employment Agreement, dated November 4, 2022, by and between TriSalus Life Sciences, Inc. and Bryan F. Cox, Ph.D.	Form S-4/A	333-269138	10.19	April 21, 2023
10.16*##	Amended and Restated Executive Employment Agreement, Dated January 6, 2025, by and between TriSalus Life Sciences, Inc. and Jodi Devlin.	Form 10-K	001-39813	10.22	April 15, 2025
10.17*##	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	10.20	April 21, 2023
10.18*##	Office/Warehouse Lease, dated February 4, 2014 between Colorado Industrial Portfolio LLC and Surefire Medical, Inc., as amended.	Form S-4/A	333-269138	10.25	July 6, 2023
10.19##	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
10.20##	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.	Form 10-K	001-39813	10.26	April 15, 2025
10.21*	Amendment No. 1 to Amended and Restated Executive Employment Agreement, dated January 24, 2024, by and between TriSalus Life Sciences, Inc. and Richard Marshak.	Form 10-K	001-39813	10.30	April 15, 2025
10.22*	Amendment No. 2 to Amended and Restated Executive Employment Agreement, dated January 6, 2025, by and between TriSalus Life Sciences, Inc. and Richard Marshak.	Form 10-K	001-39813	10.31	April 15, 2025

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
10.23	Second Amendment to Credit Agreement 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, 2025
10.24##	Amendment No. 1 to 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	10-Q	001-39813	10.2	May 15, 2025
10.25	Securities Purchase Agreement dated April 30, 2025, by and among TriSalus Life Sciences, Inc. and the persons party thereto	8-K	001-39813	10.1	April 30, 2025
10.26	Form of Registration Rights Agreement	8-K	001-39813	10.2	April 30, 2025
10.27	Tender and Support Agreement, dated April 30, 2025, by and among TriSalus Life Sciences, Inc. and the persons party thereto	8-K	001-39813	10.3	April 30, 2025
10.28*	Executive Employment Agreement by and between the Company and David Patience, dated May 27, 2025	Form 10-Q	001-39813	10.1	August 12, 2025
10.29*	Sign-on Bonus Agreement by and between the Company and David Patience, dated May 27, 2025	Form 10-Q	001-39813	10.2	August 12, 2025
10.30*	Consulting Agreement, by and between the Company and David Patience, dated June 2, 2025	Form 10-Q	001-39813	10.3	August 12, 2025
19.1	TriSalus Life Sciences, Inc. Insider Trading Policy	Form 10-K	001-39813	19.1	April 15, 2025
21.1	List of Subsidiaries	Form 10-K	001-39813	21.1	April 15, 2025
23.1	Consent of Grant Thornton LLP, independent registered public accounting firm of TriSalus.				
24.1	Power of Attorney (see signature page).				

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibits	Filing Date
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.				
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.

@ 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.

TriSalus Life Sciences, Inc.

By: /s/ David Patience

Name: David Patience
Title: Chief Financial Officer
Date: March 5, 2026

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mary Szela and David Patience, 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)*	March 5, 2026
/s/ David Patience David Patience	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 5, 2026
/s/ Mats Wahlström Mats Wahlström	Director and Chairman of the Board	March 5, 2026
/s/ Michael P. Stansky Michael P. Stansky	Director	March 5, 2026
/s/ Gary Gordon Gary Gordon	Director	March 5, 2026
/s/ Kerry Hicks Kerry Hicks	Director	March 5, 2026
/s/ David J. Matlin David J. Matlin	Director	March 5, 2026
/s/ William Valle William Valle	Director	March 5, 2026