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

FORM 10-K

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

For the fiscal year ended March 31, 2025

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41940

AUTONOMIX MEDICAL, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-1607810**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

21 Waterway Avenue, Suite 300
The Woodlands, Texas 77380
(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, including Area Code: (713) 588-6150

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, $0.001 par value	**AMIX**	**The Nasdaq Stock Market**

Securities Registered Pursuant to Section 12(g) of the Act:
None
(Title of Class)

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 periods as 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth 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 the registrant's voting equity held by non-affiliates of the registrant, computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter, was $8,113,215. In determining the market value of the voting equity held by non-affiliates, securities of the registrant beneficially owned by directors, officers and 10% or greater shareholders of the registrant have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the registrant's common stock outstanding as of May 22, 2025 was 2,780,480.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2025 Annual Meeting of Stockholders to be filed with the SEC no later than 120 days after the end of the registrant's fiscal year are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

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References in this Annual Report on Form 10-K to "we," "us," "its," "our" or the "Company" are to Autonomix Medical, Inc. ("Autonomix"), as appropriate to the context.

Cautionary Statement About Forward-Looking Statements

This Annual Report on Form 10-K (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations, the Annual Report) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. In some cases, you can identify these statements by forward-looking words such as "may," "might," "should," "would," "could," "will", "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "seek," "contemplate," "project," "potential," "continue," or "ongoing" and the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to known and unknown risks, uncertainties and assumptions about us, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements. In particular, you should consider the numerous risks and uncertainties described under "Risk Factors" and in other filings made by us from time to time with the SEC.

While we believe we have identified material risks, these risks and uncertainties are not exhaustive. Other sections of this Annual Report on Form 10-K may describe additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible to predict all risks and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of any of these forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We are under no duty to update any of these forward-looking statements after the date of this Annual Report on Form 10-K to conform our prior statements to actual results or revised expectations, and we do not intend to do so.

Forward-looking statements include, but are not limited to, statements about:

- our ability to continue as a going concern in the near term is dependent upon us successfully raising additional equity or debt financing to fund our operations;
- the success of our future clinical trials;
- we currently have no source of product sales revenue;
- competition from existing products or new products that may emerge;
- if we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm our business;
- we may be unable to obtain U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates;
- the implementation of our business model and strategic plans for our business, technologies and product candidates;
- potential product liability claims;
- our dependency on third-party supply and manufacturing partners to supply the materials and components for, and manufacture, our research and development, preclinical and clinical trial devices;
- our ability to establish or maintain collaborations, licensing or other arrangements and retain commercial rights for our product candidates subject to collaborations;
- our ability and third parties' abilities to protect intellectual property rights and our ability to operate our business without infringing the intellectual property rights of others;
- our ability to adequately support future growth;
- our estimates of our expenses, ongoing losses, future revenue and capital requirements;
- our ability to attract and retain key management personnel and technical personnel to manage our business effectively;
- risks associated with our identification of material weaknesses in our control over financial reporting;

- our use of net proceeds received by us from any subsequent private placement or public financing;
- natural disasters affecting us, our primary manufacturer or our suppliers;
- our ability to establish relationships with health care professionals and organizations;
- general economic uncertainty that adversely affects spending on medical procedures;
- volatility in the market price of our stock; and
- potential dilution to current stockholders from the issuance of equity awards.

We caution you not to place undue reliance on the forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K in the case of forward-looking statements contained in this Annual Report on Form 10-K.

You should not rely upon forward-looking statements as predictions of future events. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Therefore, you should not rely on any of the forward-looking statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I

Item 1. Business

Overview

We are a development-stage medical device company focused on advancing innovative technologies for sensing and treating disorders relating to the nervous system. Our first-in-class technology platform includes a catheter-based microchip-enabled sensing array that can detect and differentiate neural signals with a high degree of sensitivity as demonstrated in animal studies. We are initially developing our technology for patients with pancreatic cancer, a condition that can cause debilitating pain and needs a more effective solution. However, we believe our technology constitutes a platform with the potential to address dozens of indications in a range of areas including chronic pain management from all causes, hypertension, cardiovascular disease and a wide range of other nerve-related disorders.

As we calculate sensitivity as a function of the minimum signal detection voltage, measured in microvolts (μV), multiplied by the area of the electrode (in square millimeters). This combined measure reflects the system's signal resolving power and spatial resolution. For comparison, the Boston Scientific Orion device has a signal detection threshold of approximately 10 μV with electrode dimensions of roughly 0.4 mm by 0.5 mm. In contrast, the Autonomix system is designed to have signal detection thresholds below 5 μV, with prototype electrode dimensions as small as approximately 0.02 mm by 0.03 mm. These metrics indicate a substantially higher sensitivity relative to currently marketed devices.

We believe that, if validated in clinical trials, this enhanced sensitivity may enable a novel method of transvascular nerve targeting, treatment, and confirmation across a broad range of neurological conditions. A key enabler of this approach is the ability to process neural signals with our proprietary microchip in immediate proximity to the antenna, minimizing signal degradation and preserving fidelity at the point of detection. This local processing capability is critical to achieving real-time, high-resolution signal capture within the vascular system. Such a capability does not exist in currently available systems and may address significant unmet medical needs. While we have the technical capability to manufacture electrodes at these small dimensions, ongoing development work suggests that reliable nerve signal detection may be achievable with larger electrode sizes. This could reduce manufacturing complexity, lower development risk, and accelerate timelines without compromising performance.

Our development efforts can be divided into two parts: diagnostic sensing and therapeutic radiofrequency ablation, where diagnostic is focused on sensing and identifying disorder-related neuronal activity with enough precision to enable targeted therapy with ablation. Our sensing technology has already successfully demonstrated, in animal models, the ability to successfully identify a signal from a specific nerve bundle before ablation and confirmation of termination of that signal from the treated nerves after ablation. We are now in the process of improving the design of this catheter to meet the standards required for human use. In parallel with this effort, we completed our initial trial phase of our first-in-human proof-of-concept trial ("PoC 1") evaluating the safety and effectiveness of delivering transvascular energy to ablate relevant problematic nerves and mitigate pain in patients with pancreatic cancer pain, with the intent to bring sensing and treatment together in a future pivotal clinical trial to enable the commercial launch of our technology. As a result of the positive results from PoC 1, we have expanded the protocol into a follow-on phase ("PoC 2"), now including pain management for additional visceral cancers, like pancreatic, gall bladder, liver, and bile duct, with potential further expansion in oncology, gastroenterology, and other sectors, as well as earlier stage pancreatic cancer patients experiencing moderate to severe pain.

We are a development-stage company and there is no guarantee that the results of any trials will produce positive results or that the results will support our claims.

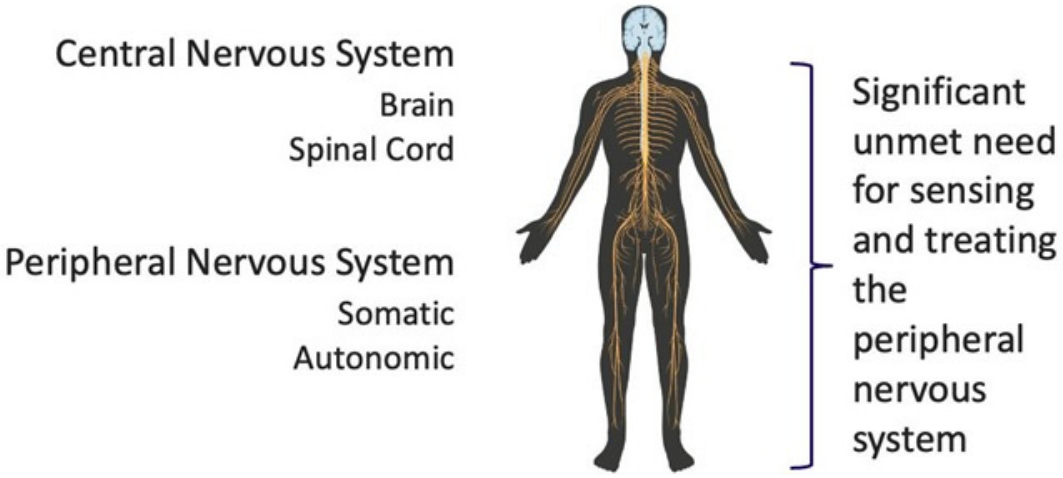
We believe one of the most demanding aspects of our commercialization plan will be scaling up from our existing sensing prototype to a robust commercial version. Today, our sensing device is hand built and includes a combination of hand-crafted and 3D printed parts. We have not yet assembled or tested what will be the commercial version of our proposed device. Even if our proposed device is cleared for commercial use, there is no assurance that we will be able to successfully build such device on a commercial scale.

As of March 31, 2025, we had an accumulated deficit of $50.4 million, negative cash flows from operating activities of $8.3 million and working capital of $7.9 million, which raises substantial doubt about our ability to continue as a going concern. Further, we have incurred and expect to continue to incur significant costs in pursuit of our business plans. We cannot assure you that we will be successful in raising additional funds. These factors, among others, raise substantial doubt about our ability to continue as a going concern.

Our Technology

Targeting the Peripheral Nervous System

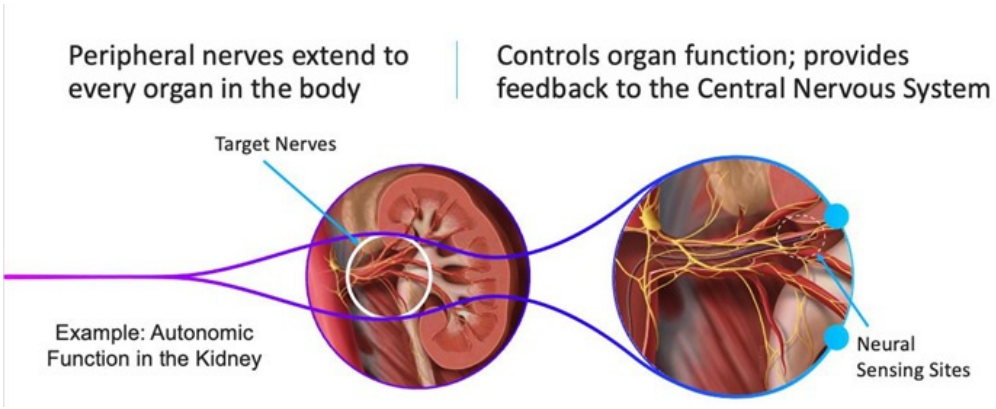
The peripheral nervous system comprises a vast network of nerve fibers extending throughout the human body and interacting with every organ. Peripheral nerves can be further classified as autonomic (supplying sympathetic and parasympathetic nerve signals from the brain to tissue and organs, i.e., fear inducing production of adrenaline) and somatosensory (supplying signals to the brain from tissue and organs, i.e., the sensation of pain). Whether as a root cause or a manifestation of resulting symptoms, these nerves play a role in virtually all diseases.



Unfortunately, we believe that very few tools currently exist for the sensing and targeting of nerve fibers within the peripheral nervous system. At Autonomix, our primary goal is to provide a breakthrough in sensing technology that will become an indispensable tool for diagnosing, targeting, and treating disorders relating to the peripheral nervous system. And, although our Company's name hails from the autonomic subgroup of the peripheral nervous system, our technology is intended for both the autonomic and somatosensory systems and could eventually find uses within the central nervous system.

Exploiting the Vascular Superhighway

The Autonomix system we are developing is primarily catheter based, meaning that our sensing equipment will be delivered to its targeted location via a lumen within the body. While this could include oral, urethral, and other natural openings of the body, our primary focus is using the vasculature, most often arteries, to reach our target. Fortunately, nature has endowed us with "superhighway" access in the form of our arterial structure, as most of the peripheral nerves travel along our arteries. As can be seen in this cross-sectional view of the kidney and renal artery, the web of peripheral nerve fibers (shown in yellow) parallels the renal artery, and this form of nerve pathway development is typical throughout the body.



Our sensing catheter has been designed to be introduced by a small incision into an artery (such as the femoral artery) and with a conventional guide wire or sheath be directed to any organ in the body where it will be close enough to the nerve fibers servicing that organ to sense, target and treat the nerves associated with that targeted disorder, and to confirm that the intended treatment was successful.

The Sensing Problem

Although this vascular superhighway has long been utilized for certain catheter-based evaluation and intervention, we believe its use throughout the body has been limited by the lack of adequate sophistication of catheter systems. According to a Markets and Markets report, titled "Electrophysiology Market Global Forecast to 2027" published in February 2023, the global electrophysiology market in terms of revenue was estimated to be $6.8 billion in 2021 and is expected to reach $11.6 billion by 2027. The report cites as a driver for such market the increased incidence of cardiovascular disease and the use of catheters to deliver corrective ablation in the field of cardiology. Most commonly, radio frequency (RF) energy is emitted from inside the walls of the heart or arteries sufficient to ablate (destroy) a cardiomyocyte or nerve within its path. This "transvascular" use of ablation forms the basis for treating atrial fibrillation, for example.

More recently, companies like Medtronic have successfully used transvascular ablation of the nerves surrounding the renal artery to treat refractory hypertension (high blood pressure that has been resistant to standard drug therapy). One of the challenges they face however is that the nerves they are targeting operate at much lower voltage levels than, say, the level emitted by a cardiomyocyte. In cardiology, there are sensing systems capable of sensing down to a level of about 10 to 15 microvolts. That's more than enough sensitivity to detect (and target) a cardiomyocyte that is emitting 100 microvolts per pulse, but the nerves around the renal artery (and around most peripheral nerve targets throughout the body) are operating at around 1 to 2 microvolts; much too low to be detected by existing sensing technology.

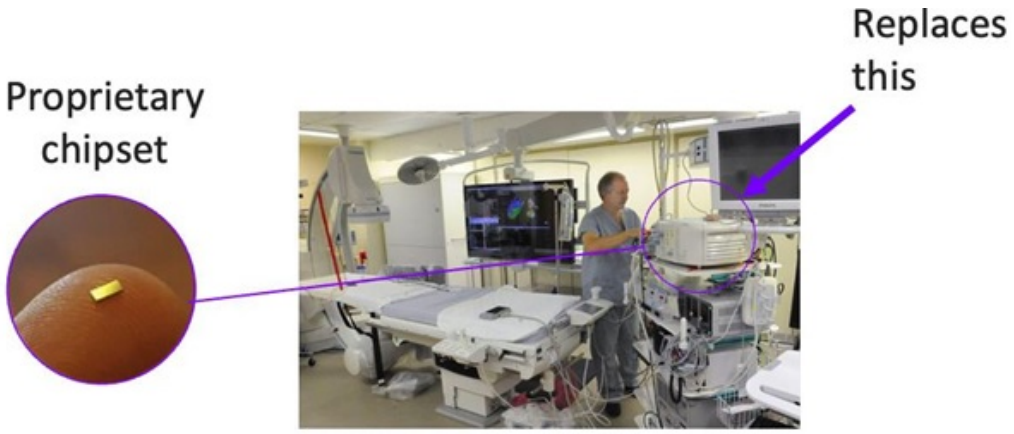
What this means is that the ablation of nerves from within the renal artery is essentially conducted "blind." Without a sensing system capable of detecting and targeting signals from nerves within the nervous system, clinicians cannot see the nerves causing hypertension in the patient. As a result, they are forced to hypothesize and treat one small area at a time, hoping they hit the desired target without hitting an unintended target. Over-treating the area could relegate the patient to life in a wheelchair by destroying their ability to regulate blood pressure.

The Autonomix Solution

We believe the reason no one has commercialized a sensing system capable of solving this problem is that the physics involved demanded a major technological breakthrough. By their very nature, electrical signals from the body are analog and even though a 10-milivolt signal can be detected and transmitted down the roughly 2 meters of wire required to travel along the catheter, outside the patient, and into the necessary processing equipment shown in this picture below of a typical catheter lab, this isn't feasible with the 10 to 500 microvolt signal from a typical peripheral nerve. Given the cacophony of other signals emitted throughout the body and by other equipment in the lab as well as degradation of the signal due to the distance traveled along the catheter, these faint signals become lost or are rendered meaningless.

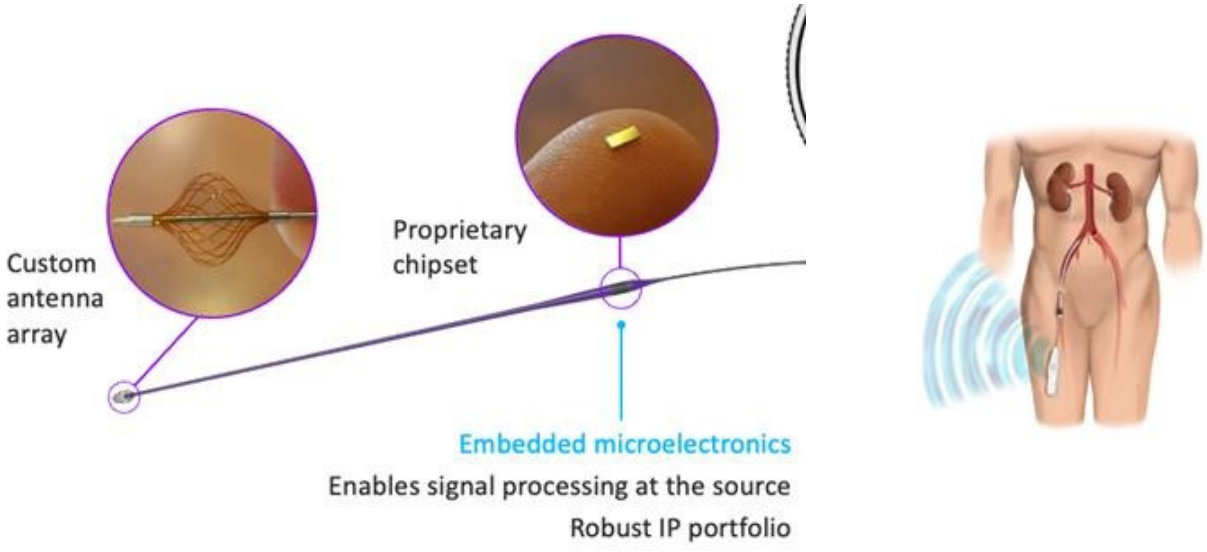
We are seeking to solve this problem through our design, which is still in development, of a proprietary sensor comprised of multiple key components, such as an electrode antenna and a microchip that processes data acquired through the antenna. Each antenna spline is comprised of 2 small differential electrodes and 1 reference electrode that can detect the presence of voltage down to as little as 2 microvolts, giving us sufficient sensitivity to register the impulse of a nearby nerve bundle that might typically be generating 10 to 500 microvolts, depending on the type of nerve fiber (i.e., parasympathetic, sympathetic, somatic, etc.). Our current design connects 8 splines to our proprietary chipset, which is designed to handle up to 16 differential electrodes, where an onboard amplifier and analog to digital converter convert each signal into a digital form. The chipset also includes a digital domain intended to enable the transmission of data from each of the antennae simultaneously down the catheter body to the catheter handle. The Wi-Fi handpiece then transmits this data to a nearby laptop for viewing and analysis by the clinician.

In a typical catheter lab, these signal conversion functions are often carried out by "briefcase" sized devices processing the raw analog signals that must travel the full length of the catheter, outside the patient's body and then from the patient to the equipment. While this is feasible for higher voltage signals from the heart, the signals from peripheral nerve bundles are often too faint to travel all this distance without loss or corruption and yet the typical catheter lab equipment is far too big to fit inside a catheter. The patented Autonomix solution shrinks these processes down to a microchip small enough to place immediately adjacent to the antennae detecting the signals, greatly reducing the distance the signals must travel. The picture of the "proprietary chipset" below is our actual chipset and is not a rendering.



Typical Cather Lab

As shown in the diagram below, this basket antenna array is built from a micro-thin, laser-cut flexible circuit board. We believe the special arrangement of the antennae will make it possible to effectively geolocate the nerve in 3-dimensional space for targeting treatment.



Sense, Ablate, Confirm

This sensing system is currently being developed to be deployed alongside a separate radio frequency ablation catheter system for a combined diagnostic and therapeutic solution which will require the use of two separate catheters that will be used during the procedure. However, our longer-term design is intended to combine the two catheters into one device so that the combined system could be capable of sensing, treating (ablating) and confirming successful treatment all with one relatively simple and minimally invasive procedure.

Focus on Pancreatic Cancer Patients

We believe the Autonomix sensing technology has the potential to provide a level of detail and resolution in navigating the peripheral nervous system that until now has simply not been possible. As such, we believe this platform, if shown to be effective, could be applied to a wide range of disorders throughout the body. With that said, our experience tells us that the best way to develop a new technology like this is to narrowly focus on a proof of concept that we think will reflect the capabilities of our system while providing the most expeditious pathway to regulatory clearance, commercialization and revenue generation.

For this reason, we are initially focusing on the treatment of pain associated with pancreatic cancer and we have designed our commercialization efforts around this as our first proposed indication for use.

We believe this is a good choice for several reasons:

Significant Unmet Need

According to a report by The Oncologist, titled "Pancreas Cancer-Associated Pain Management" first published April 22, 2021, "[p]ain is highly prevalent in patients with pancreas cancer," "90% of these patients reported discussing pain with their health care provider," and "50% of the respondents reported visits to the emergency room for symptoms related to pain." One of the tragedies of this condition is that most pancreatic cancer patients have a short time to live and the debilitating pain resulting from the tumor can significantly reduce the quality of that remaining time. Moreover, we believe that prolonged pain can diminish a patient's will to live, making that remaining time even shorter.

The standard of care for managing chronic abdominal pain due to pancreatic cancer typically begins with medical management, including non-opioid medications such as acetaminophen and NSAIDs. When this approach fails to provide adequate relief, second-line therapy often involves opioid pharmacotherapy. However, long-term opioid use is associated with tolerance, dependency, and adverse side effects that can ultimately outweigh the benefits.

The most common alternative method of treatment is a neurolytic celiac plexus blockade ("NCPB"), which is a percutaneous (via needle through the skin) ethanol injection guided by imaging, such as ultrasound or CT scan, to attempt to direct the ethanol (which will destroy neural tissue on contact) to the area of the pancreatic tumor and related peripheral nerves. Regardless of this initial targeting, the varied structure of the abdominal cavity leads to the potential for ethanol to either miss the intended target or migrate to unintended areas creating unwanted side effects.

Furthermore, according to a study titled "Neurolytic Celiac Plexus Block for Pain Control in Unresectable Pancreatic Cancer" published by the American Journal of Gastroenterology, 2007, Vol.102 (2), p.430-438, Article 430, meta-analysis from multiple randomized controlled trials suggests that patient benefits from NCPB are only marginally better than opioids and may not be outweighed by the potential risks. The most common side effects are diarrhea, transient hypotension, constipation, nausea and vomiting, and lethargy while rare major adverse events reported in the literature include infectious complications, bowel perforation, intraabdominal hemorrhage, fistula formation, stomach paralysis, partial paralysis of the lower limbs or loss of other motor function, chronic diarrhea, arterial damage, water on the lung, and death.

In contrast, we believe the Autonomix procedure could represent a much safer and more reliable treatment. This has the potential to significantly increase remaining quality of life for pancreatic cancer patients, and in so doing, even potentially extend overall survival.

To begin with, our entire approach is via arterial catheter, inserted in most cases via the femoral or brachial artery. We believe this method of access should significantly reduce the potential for complications as compared with NCPB. We believe our sensing technology has the potential to identify and target the nerves that are responsible for the pain signal and with the ability to focus the ablative energy on that target, we should have a much greater degree of accuracy, control and reliability as compared with NCPB.

When comparing to the use of opioids, we believe the potential benefits are even more obvious. The Autonomix procedure we are developing is, by design, targeted directly to the nerves responsible for the pain being treated and offers the potential for "one and done" durability, whereas opioids are systemic treatments subjecting the entire body to unnecessary exposure, requiring constant dosing, and inducing debilitating chronic systemic side effects as a consequence.

Beneficial Clinical Trial Dynamics/Expedited Regulatory Process

Despite the significant unmet need, there are very few clinical trials worldwide focused on improving pain management for pancreatic cancer patients and currently none that we are aware of in the proposed location of our planned first-in-human proof of concept study. We believe this means there is limited competition for such patients, making it theoretically easier to recruit for our trial.

At the same time, because we are focusing on palliative care for patients whose lives are being limited by a rare cancer, we believe regulatory authorities are willing to consider lower preclinical hurdles and smaller and simpler trial designs to help encourage trial sponsors to seek improved treatment options. However, these decisions are under the exclusive control of regulatory authorities and there is no guarantee that our trial designs will be approved. If regulatory authorities are willing to consider lower preclinical hurdles and smaller and simpler trial designs, this would translate into lower preclinical and clinical trial cost, as well as shorter completion times. Furthermore, study duration is also shortened by the very nature of the indication and primary efficacy endpoint: reduction of pain associated with pancreatic cancer.

Specifically, we intend for each patient to need only one treatment and we expect we will be able to immediately determine if there is any reduction of pain from our procedure such that an initial indication of pain reduction will likely be provided by patients upon conclusion of that treatment. Although follow-up visits will be required to assess continuing safety and durability of efficacy over a span of several months, an initial indication of efficacy will be available almost as quickly as patients are treated. For this reason, we are hopeful that the overall duration of this first trial will be measured in months rather than years, as is often the case for clinical trials with longer treatment durations or where a clinically significant response takes more time to be produced.

Meaningful Commercial Market

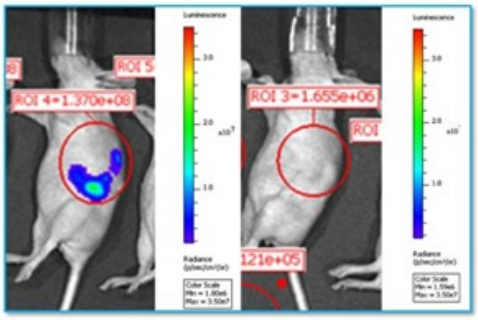
Although pancreatic cancer is considered a rare disease, according to the American Cancer Society "Key Statistics for Pancreatic Cancer" (https://www.cancer.org/cancer/types/pancreatic-cancer/about/key-statistics.html), the American Cancer Society estimates in 2023 that approximately 64,000 will be diagnosed with pancreatic cancer in the U.S. on an annual basis and an article in the International Journal of Cancer (Int. J. Cancer. 2021;149:993–1001) indicates that annual new cases in the European Union reached 109,000 in 2019 and are expected to grow. A market analysis published by Precedence Research (https://www.precedenceresearch.com/ pancreatic-cancer-market) reported that the global market for treatment of pancreatic cancer in 2022 was estimated to be $2.2 billion. Published research by The Oncologist, titled "Pancreas Cancer-Associated Pain Management" stated that "90% of patients [with pancreatic cancer] reported discussing pain with their health care provider". As a point of reference, a one-month course of Abraxane (a commonly prescribed drug for the treatment of pancreatic cancer) has a retail price of more than $10,000. While this should not be considered an indicator of how an Autonomix procedure will ultimately be priced, we believe it reflects the magnitude of potential market size and helps form the basis for expecting a significant revenue opportunity from this indication.

The incidence of pancreatitis, a non-cancerous condition that can also result in chronic pain, is estimated to be as much as three times that of pancreatic cancer. We believe that, if our procedure is cleared for use in treating pancreatic cancer pain, we should be able to eventually expand that clearance to include pain resulting from pancreatitis.

The Potential to Impact Cancer

Recent independent research has indicated that neural pathways may play an insidious role in cancer progression. An article published in Metastatic Cancer: Clinical and Biological Perspectives, titled "Sympathetic Nervous System Regulation of Metastasis" demonstrates that as pancreatic tumors progress to invade the liver (a common occurrence in patients with pancreatic cancer and a significant driver of morbidity) they do so by traveling along local neural pathways. Our development team speculated that disruption of these pathways might have the potential to slow or stop the progression of the primary tumor.

In collaboration with a specialist in pancreatic cancer, we conducted a study in mice to see if ablation (in this study, ethanol ablation was used, similar to its use with NCPB in humans) of the nerve fibers around the pancreas might have an effect on tumor progression. As can be seen in this study summary, there was a reduction in tumor progression in this model. This was a small study, and we can't be certain that these results are indicative of the potential for impacting tumor progression in humans, but we do see this as encouraging further study and may represent a future opportunity beyond pain management.



IVIS comparison between median response subject of each group: control (left) and ablation group (right)

Pancreatic Cancer Pilot Mouse Study

Metastasis Site	Control Group	Ablation Group
Local invasion	5/5	2/5
Spleen	4/5	4/5
Liver	2/5	0/5
Stomach	1/5	0/5

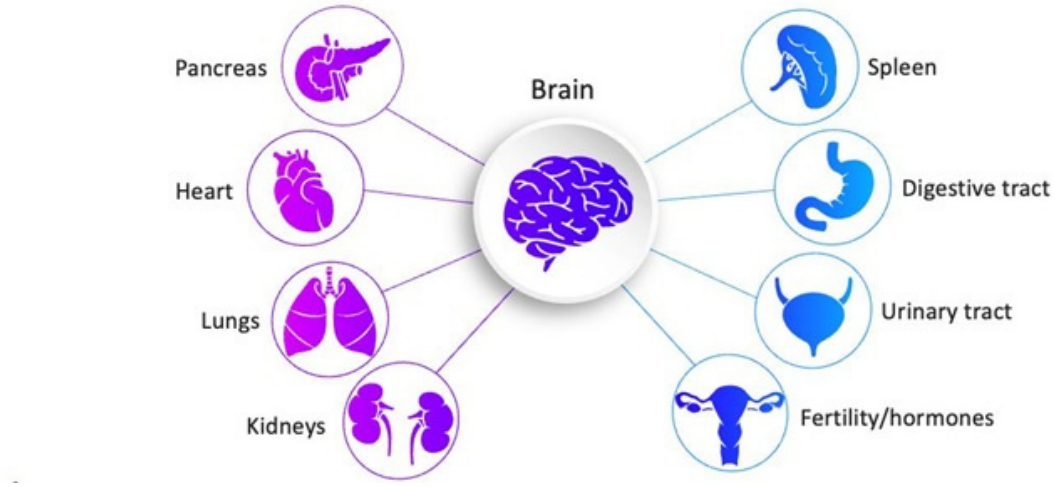
Experimental group showed:

- Statistically significant reduction of metastases
- Statistically significant reduction in tumor mass
- Expectation of pain treatment without complications
- No health issues

Indicative of Additional Market Potential

We believe pancreatic cancer pain management is a "proof of concept," and we believe success here will be indicative of the potential of our system in a wide range of disorders where the peripheral nervous system is involved.

Examples of future potential additional uses include expanding to other visceral cancers that transmit pain through the celiac plexus, like pancreatic, gall bladder, liver, and bile duct, renal denervation for treating hypertension, addressing other sources of pain including lower back and other joint locations, Complex Regional Pain Syndrome ("CRPS"), and pelvic pain, pulmonary disorders such as chronic obstructive pulmonary disease, and urinary tract and digestive disorders, and enabling more targeted treatments in cardiology, just to name a few.



A Markets and Markets report, titled "Electrophysiology Market Global Forecast to 2027" published in February 2023 describes the global electrophysiology (EP) market as representing approximately $6.8 billion in 2021 in annual global revenue, and is expected to reach $11.6 billion by 2027. The vast majority of this market today is represented by cardiology related diagnosis and intervention. Our vision for the Autonomix technology is to help expand electrophysiology well beyond cardiology to include nearly all reaches of the peripheral nervous system and we believe doing so will ultimately result in a market opportunity much greater than the current projections for the EP.

We believe enabling targeted transvascular treatment of pain will enable us to access the $75 billion pain management market, as cited in the Mordor Intelligence Pain Management Market Industry Report (https://www.mordorintelligence.com/industry-reports/pain-management-market). Additionally, facilitating a safer, more targeted method for renal denervation should enable us to access the $23 billion hypertension market, as indicated by Polaris Market Research (https://www.polarismarketresearch.com/industry-analysis/global-hypertension-drug-market). When additional indications such as COPD, irritable bowl syndrome, and overactive bladder are included, we believe the Autonomix platform has the potential to address more than $100 billion in market opportunities.

Commercialization Plan

Regulatory Pathway

The most likely regulatory pathway for our technology is the De Novo classification request. This pathway is distinct from the more common 510(k) clearance process, which is only applicable when a legally marketed "predicate" device exists that performs the same function in a substantially equivalent manner. It is also different from the more rigorous Premarket Approval ("PMA") pathway, which is typically reserved for high-risk devices with no prior precedent or those requiring extensive clinical validation.

In our case, while sensing and ablation technologies are well-established, there is no existing device that combines our level of signal sensitivity or targets the specific indications we are pursuing. As such, we anticipate that the De Novo pathway—designed for novel, moderate-risk devices without a direct predicate—will be the most likely route to market.

Whether in the United States or EU, we must demonstrate that our technology is safe and effective. The safety standard is ultimately met through a combination of animal studies, independent laboratory testing, a design history file documenting compliance with established standards and, ultimately, human clinical trials. Many of these requirements are staged such that not all must be met on the front end of development. In addition, efficacy must be based on a sound scientific rationale and ultimately demonstrated in a human clinical trial.

Human trials are often designed to begin with a Proof of Concept ("PoC"); the US Food and Drug Administration ("FDA") sometimes refers to these as Early Feasibility Studies ("EFS") and then progress to a Pivotal, or approval, Trial ("Pivotal Trial"). The design and endpoints of Pivotal Clinical Trials are often negotiated with the relevant regulatory authority (i.e., FDA in the United States, EMA or country-specific Competent Authority ("CA") in Europe). Our regulatory package for authorization to conduct our initial phase of our first-in-human proof of concept trial ("PoC 1") was approved by the Ethics Committee ("EC") at our intended clinical site hospital outside the United States. This approval allowed the initial PoC trial to begin. The regulatory package submitted included not only a detailed clinical protocol for conducting the study, but also an extensive Investigator's Brochure ("IB") setting forth details about the equipment to be used, historical safety of human procedures conducted with this equipment and details of our animal studies using this equipment for the first time in the area of the pancreas. With the success of our PoC 1, we will initiate a follow-on PoC 2 phase in a market expansion opportunity that has the potential to double the addressable market beyond pancreatic cancer pain by evaluating additional visceral cancers that signal pain through the celiac plexus and earlier stage pancreatic cancers with moderate to severe pain. The PoC 1 trial protocol will be amended to include the gathering of additional interventional pain management information that will continue to advance key learnings and used to inform future clinical studies.

We are actively engaging with the FDA through the pre-submission process as we work toward initiating our U.S.-based IDE clinical trials. We intend to start with a small, single-site EFS study leading into a larger, multi-centered pivotal trial. The first PoC trial is not designed to replace the pivotal trial that will be required by the FDA to support our submissions for clearance in the United States, but rather to provide key learnings and procedural knowledge going into our FDA clinical trials.

According to an article by Applied Clinical Trials, titled "Medical Device Development: U.S. and EU Differences" published August 1, 2006 "[t]he way in which devices are regulated in the EU is very different from the way they are regulated in the United States,… [which] has introduced significant differences in time-to-market approval for the United States versus the EU, particularly in the case of high-risk Class III and Class IIb implantable devices." While this is changing based on the advent of a new EU regulation called Medical Device Regulation ("MDR") that is expected to make the EU process more like the FDA process, MDR is being rolled out country by country. We believe the approval process in some EU countries for utilizing CE marked devices off label is less demanding than in the US. As a result, we have decided to conduct the PoC in Europe instead of the US.

Once the PoC is established, however, there are compelling reasons to focus the approval process first and foremost in the US. One reason is that therapeutic procedures in the US will usually command higher prices and once those prices are set, EU pricing authorities will often index off of the US price. Another is that product launches are usually easier in the US where a single sales force can serve the entire region (as opposed to country-specific distribution teams in the EU) and where one regulatory standard applies across the board.

Upon completion of the Pivotal Trial, we expect to be in a position to submit our de novo application to the FDA, the review of which is expected to require approximately 170 days. We believe this entire timeline supports an ultimate FDA clearance (applications like this are not technically "approved" but rather "allowed" or "cleared") in 2027. The foregoing timeline is not guaranteed and is subject to many of the risks and uncertainties disclosed in this Annual Report on Form 10-K and is subject to change.

Technology Development

Commercialization of our technology can be thought of in three distinct phases: (1) sensing, (2) ablation, and (3) the combination of these two technologies into an integrated device. We believe that commercial success can be achieved with either of the two technologies and is not dependent upon successful integration (meaning two distinct systems, one for sensing and one for ablation could also be viable, even if not optimal).

Similarly, our clinical development plan reflects the fact that the sensing and ablation systems are at different stages of development. Extensive testing in pigs (whose abdominal structure is considered similar to humans) has demonstrated that our sensing technology is capable of locating and targeting individual nerves around the renal artery. Considering the similarity in anatomy, both between pigs and humans and between the renal artery (supplying the kidneys) and the celiac and related arteries supplying the pancreas, we believe our sensing system may also be effective in humans and that the primary remaining risk relating to the sensing system is commercial execution.

Specifically, we believe one of the most demanding aspects of our commercialization plan will be scaling up from our existing sensing prototype to a robust commercial version. Today, our sensing device is hand built and includes a combination of hand-crafted and 3D printed parts, but we are actively engaged in the development of a more robust version which will meet requirements to be used in human clinical trials. We will divide this device into two subsets: (a) an electronics package (subassembly) that relies on semi-automated production of printed flexible circuit boards and electrical leads that is supplied to (b) a qualified catheter production process that will be contracted to a catheter production facility already experienced and certified in the "art" of catheter assembly. We expect the human clinical version to be completed in 2026 and the commercial scale up process to be completed by mid-2027, although there is no assurance that we will be able to meet such timeline.

Regarding the ablation system, safe and reliable off-the-shelf RF systems are currently available for use in cardiology and other electrophysiology indications. We are currently using one of these existing systems "off label" (in an area of the body for which the system is not yet approved by the relevant regulatory agency) in our proof-of-concept study to ablate the nerves near the pancreas of pancreatic cancer patients to demonstrate, for the first time ever, that transvascular ablation of those nerves may reduce pain in this patient population. The regulatory package submitted includes not only a detailed clinical protocol for conducting the study, but also an extensive Investigator's Brochure (IB) setting forth details about the equipment to be used, historical safety of human procedures conducted with this equipment and details of our animal studies using this equipment for the first time in the area of the pancreas. To be clear, this first PoC trial is being conducted without the benefit of our sensing system because it has not yet been cleared by the FDA for use in humans.

The fact that this first PoC is essentially being performed "blind" (as all denervation procedures are currently done) simply means that it will not be as accurate as it could be. However, we believe if we successfully demonstrate that transvascular ablation is capable of mitigating pancreatic cancer pain, this would be a medical "first" and would represent an important breakthrough for the electrophysiology community. Likewise, we believe it could help support a request to the FDA to be granted "Breakthrough" status, which could accelerate our future commercialization efforts.

Also, what we are learning in the trial, about how to optimize ablation catheters for use outside the cardiology space, is being incorporated into the design of a customized RF catheter design for use in our own therapeutic device.

It is possible to receive clearance from the FDA (and EMA) based on a prototype system that is not optimized for manufacturing and for the necessary design for manufacturability process to be running in the background with the goal of having the commercial version ready for launch shortly after the prototype platform is FDA cleared. We would then use our existing de novo cleared device as our own predicate for 510(k) clearance of the commercial version.

Our plan is then to launch the commercial version of our system, most likely to a controlled region or list of KOLs (Key Opinion Leaders) to debug and optimize the commercial strategy before committing to a national/global launch.

Accordingly, our planning considers both the possibility of a stand-alone commercial launch or a licensing arrangement with a larger player. As we get closer to an actual FDA device clearance, our strategy approach will be reviewed and adjusted for practicality. The Autonomix management team, however, has experience with both approaches.

The following graphic sets forth our planned development timeline, however, these timeframes are not guarantees and this timeline is subject to many of the risks and uncertainties disclosed in this Annual Report on Form 10-K and is subject to change:

Revenue Model

We envision our device revenue model on several levels: (a) purely as a targeted therapy for disorders associated with pancreatic tumors (and pancreatitis), (b) as a standalone sensing technology for broad based diagnostics use and/or use in conjunction with other ablation systems or (c) as a combined sensing and ablation system targeting a wide array of disorders throughout the body.

There are four key elements of our device that will be provided to the user (hospital) to facilitate our technology: (1) a disposable sensing catheter with a handpiece (that connects to the catheter and could be partially or entirely disposable), (2) an RF catheter designed to reach the target nerves in the peripheral nervous system, (3) an RF energy source to power our custom RF ablation catheter, and (4) a user interface comprised primarily of software (translating data received from the catheter microchip and activating ablative energy in integrated systems) that could reside on existing hospital personal computer, or PC, systems or a dedicated PC system.

In general, we believe that hospitals place a high premium on disposability (maximizes patient safety, avoids complications of on-site sterilization) and that, if we can avoid the need for a significant outlay in "capital equipment" we should, since high-dollar capital equipment authorizations often involve additional bureaucracies within the hospital and complicate the sell-in process.

An important benefit of the Autonomix platform will be that it will rely on catheter systems and techniques that are familiar to interventional radiologists (our expected primary users) and should require a minimum of training for successful use.

Our selection of radio frequency as an energy source was made based upon what we believe is the well-understood status of the technology within the industry and the FDA. Additionally, we have found in pre-clinical testing that this energy source appears to provide a very effective method of ablating neural tissue. The software required in our device's user interface will likely be provided at no or a nominal charge.

For the reasons described above, we believe the primary revenue model for Autonomix will be the sale of single-use disposable catheters to existing hospital catheter labs and that revenue volume will likely be a direct function of the number of procedures performed.

Intellectual Property

Patents and Pending Patent Applications

The Company has 18 patent families (representing various inventions relating to different aspects of its technology) comprising 86 issued patents (41 in the US thus far) and 41 pending patent applications. All patents and patent applications were originated by our co-founders, Mr. Toth and/or Dr. Schwartz, with filing dates ranging from 2012 through 2025.

The following table shows our material patents and the expiration dates (assuming maintenance/annuity fees are paid as required) as of May 22, 2025:

Issued Patents

Patent No.	Jurisdiction	Title	Patent Expiration Date
2013211951	Australia	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
2,862,862	Canada	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
3,151,885	Canada	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
ZL201380016637.3	China	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
ZL201710440397.X	China	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
2,804,527	European Patent Ratified in France, Germany, Ireland, Netherlands, UK	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
497881	India	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
6,552,824	Japan	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
347625	Mexico	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
372926	Mexico	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
11201406006X	Singapore	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
10,470,684	United States of America	Controlled Sympathectomy and Micro-Ablation Systems and Methods	11/10/2034
9,649,064	United States of America	Controlled Sympathectomy and Micro-Ablation Systems and Methods	4/28/2033
10,022,085	United States of America	Controlled Sympathectomy and Micro-Ablation Systems and Methods	1/25/2033
11,013,459	United States of America	Controlled Sympathectomy and Micro-Ablation Systems and Methods	6/30/2033
12,257,071	United States of America	Controlled Sympathectomy and Micro-Ablation Systems and Methods	11/12/2033
2,874,620	Canada	Endoscopic Sympathectomy Systems and Methods	5/28/2033
2,852,339	European Patent Ratified in France; Germany; Ireland; UK	Endoscopic Sympathectomy Systems and Methods	5/28/2033
11201407873R	Singapore	Endoscopic Sympathectomy Systems and Methods	5/28/2033
9,968,790	United States of America	Endoscopic Sympathectomy Systems and Methods	7/14/2033
10,226,633	United States of America	Endoscopic Sympathectomy Systems and Methods	5/28/2033
11,344,731	United States of America	Endoscopic Sympathectomy Systems and Methods	5/28/2033
12,053,634	United States of America	Endoscopic Sympathectomy Systems and Methods	5/28/2033
2,876,080	Canada	Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder	6/13/2033
2,861,145	European Patent Ratified in France; Germany; Ireland; Netherlands; UK	Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder	6/13/2033
6,335,888	Japan	Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder	6/13/2033
6,672,370	Japan	Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder	6/13/2033
11201408219T	Singapore	Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder	6/13/2033
10,206,616	United States of America	Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder	9/10/2034
11,564,616	United States of America	Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder	8/18/2033
2013337879	Australia	Systems and Methods for Treatment of Tissues Within and/or Through a Lumen Wall	10/31/2033
2,889,674	Canada	Systems and Methods for Treatment of Tissues Within and/or Through a Lumen Wall	10/31/2033
2,914,334	European Patent Ratified in France; Germany; Ireland; Netherlands; UK	Systems and Methods for Treatment of Tissues Within and/or Through a Lumen Wall	10/31/2033
406600	India	Systems and Methods for Treatment of Tissues Within and/or Through a Lumen Wall	10/31/2033
11201503472P	Singapore	Systems and Methods for Treatment of Tissues Within and/or Through a Lumen Wall	10/31/2033
9,956,034	United States of America	Systems and Methods for Treatment of Tissues Within and/or Through a Lumen Wall	10/18/2034

10,905,495	United States of America	Systems and Methods for Treatment of Tissues Within and/or Through a Lumen Wall	11/6/2033
12,011,214	United States of America	Systems and Methods for Treatment of Tissues Within and/or Through a Lumen Wall	5/13/2034
2013354932	Australia	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development	12/9/2033
2,892,449	Canada	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development	12/9/2033
388850	India	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development	12/9/2033
11201504119V	Singapore	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development	12/9/2033
10,674,963	United States of America	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development	6/1/2036
10,363,359	United States of America	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development	2/25/2036
11,478,582	United States of America	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development	8/2/2034
2,907,625	Canada	Systems and Methods for Neurological Traffic and/or Receptor Functional Evaluation and/or Modification	3/27/2034
2,978,372	European Patent Ratified in France; Germany; Ireland; Italy; UK	Systems and Methods for Neurological Traffic and/or Receptor Functional Evaluation and/or Modification	3/27/2034
11201507936U	Singapore	Neurological Traffic and Receptor Functional Evaluation and Modification	3/27/2034
10,004,458	United States of America	Systems and Methods for Neurological Traffic and/or Receptor Functional Evaluation and/or Modification	1/16/2035
10,765,370	United States of America	Systems and Methods for Neurological Traffic and/or Receptor Functional Evaluation and/or Modification	4/10/2034
11,589,820	United States of America	Systems and Methods for Neurological Traffic and/or Receptor Functional Evaluation and/or Modification	12/4/2034
12,279,889	United States of America	Systems and Methods for Neurological Traffic and/or Receptor Functional Evaluation and/or Modification	3/27/2034
2014337552	Australia	Systems and Methods for Treating Cancer and/or Augmenting Organ Function	10/14/2034
2,926,088	Canada	Systems and Methods for Treating Cancer and/or Augmenting Organ Function	10/14/2034
443928	India	Systems and Methods for Treating Cancer and/or Augmenting Organ Function	10/14/2034
364705	Mexico	Systems and Methods for Treating Cancer and/or Augmenting Organ Function	10/14/2034
10,143,419	United States of America	Systems and Methods for Treating Cancer and/or Augmenting Organ Function	2/6/2035
11,272,877	United States of America	Systems and Methods for Treating Cancer and/or Augmenting Organ Function	2/6/2035
12,064,256	United Sates of America	Systems and Methods for Treating Cancer and/or Augmenting Organ Function	3/6/2035
10,136,944	United States of America	Systems and Methods for Treating Cancer and/or Augmenting Organ Function	5/24/2035
11,382,687	United States of America	Systems and Methods for Treating Cancer and/or Augmenting Organ Function	4/3/2035
2015302050	Australia	ANS Assessment Systems, Kits, and Methods	8/7/2035
2,957,766	Canada	ANS Assessment Systems, Kits, and Methods	8/7/2035
3,177,201	European Patent Ratified as Unitary Patent and in Ireland and UK	ANS Assessment Systems, Kits, and Methods	8/7/2035
369552	India	ANS Assessment Systems, Kits, and Methods	8/7/2035
11201701018P	Singapore	ANS Assessment Systems, Kits, and Methods	8/7/2035

10,791,924	United States of America	ANS Assessment Systems, Kits, and Methods	9/2/2037
11,883,103	United States of America	ANS Assessment Systems, Kits, and Methods	10/13/2036
3,226,792	European Patent to be Ratified as Unitary Patent and in Ireland and UK	Systems And Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development	12/4/2035
ZL201680068094.3	China	Controlled and Precise Treatment of Cardiac Tissues	10/20/2036
3,364,869	European Patent Ratified as Unitary Patent and in Ireland and UK	Controlled and Precise Treatment of Cardiac Tissues	10/20/2036
11,154,239	United States of America	Controlled and Precise Treatment of Cardiac Tissues	5/28/2038
3,697,298	European Patent to be Ratified as Unitary Patent and in Ireland and UK	Medical Devices with Circuitry for Capturing and Processing Physiological Signals	10/17/2038
11,521,738	United States of America	Medical Devices with Circuitry for Capturing and Processing Physiological Signals	4/14/2039
11,848,078	United States of America	Medical Devices with Circuitry for Capturing and Processing Physiological Signals	10/17/2038
12,217,863	United States of America	Medical Devices with Circuitry for Capturing and Processing Physiological Signals	10/17/2038
3,304,565	European Patent to be Ratified as Unitary Patent and in Ireland and UK	Elongated Conductors and Methods of Making and Using the Same	5/19/2036
9,730,639	United States of America	Elongated Conductors and Methods of Making and Using the Same	5/19/2036
10,092,241	United States of America	Elongated Conductors and Methods of Making and Using the Same	5/19/2036
10,238,340	United States of America	Elongated Conductors and Methods of Making and Using the Same	5/19/2036
10,485,484	United States of America	Elongated Conductors and Methods of Making and Using the Same	5/19/2036
10,869,635	United States of America	Elongated Conductors and Methods of Making and Using the Same	5/19/2036
11,445,979	United States of America	Elongated Conductors and Methods of Making and Using the Same	5/19/2036
12,070,334	United States of America	Elongated Conductors and Methods of Making and Using the Same	5/19/2036
10,874,830	United States of America	Smart Torquer and Methods of Using the Same	6/14/2037
12,295,646	United States of America	Smart Torquer and Methods of Using the Same	6/14/2037

The following table shows our material pending patent applications as of May 22, 2025, (note that no expiration dates are specified for the pending patent applications since, in certain jurisdictions, e.g., United States of America, the patent expiration date is calculated at the time of issue/grant):

Pending Patent Applications

Application No.	Filing Date	Jurisdiction	Title
3239581	5/24/2024	Canada	Controlled Sympathectomy and Micro-Ablation Systems and Methods
21168169.7	5/13/2021	European Patent Office	Controlled Sympathectomy and Micro-Ablation Systems and Methods
16/591,126	10/2/2019	United States of America	Controlled Sympathectomy and Micro-Ablation Systems and Methods
19/054,104	2/14/2025	United States of America	Controlled Sympathectomy and Micro-Ablation Systems and Methods
3158197	5/4/2022	Canada	Endoscopic Sympathectomy Systems and Methods
18/771,099	7/12/2024	United States of America	Endoscopic Sympathectomy Systems and Methods
3184524	12/15/2022	Canada	Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder
202448028613	4/8/2024	India	Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder
18/079,361	12/12/2022	United States of America	Devices, Systems, and Methods for Diagnosis and Treatment of Overactive Bladder
3183802	12/9/2022	Canada	Systems and Methods for Treatment of Tissues Within and/or Through a Lumen Wall
18/656,031	5/6/2024	United States of America	Systems and Methods for Treatment of Tissues Within and/or Through a Lumen Wall
3151434	3/9/2022	Canada	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development

24170108.5	4/12/2024	European Patent Office	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development
16/855,080	4/22/2020	United States of America	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development
17/971,202	10/21/2022	United States of America	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development
3,205,904	7/10/2023	Canada	Systems and Methods for Neurological Traffic and/or Receptor Functional Evaluation and/or Modification
202348081808	12/1/2023	India	Systems and Methods for Neurological Traffic and/or Receptor Functional Evaluation and/or Modification
19/169,668	4/3/2025	United States of America	Systems and Methods for Neurological Traffic and/or Receptor Functional Evaluation and/or Modification
3182302	11/28/2022	Canada	Systems and Methods for Treating Cancer and/or Augmenting Organ Function
22175617.4	5/26/2022	European Patent Office	Systems and Methods for Treating Cancer and/or Augmenting Organ Function
18/772,819	7/15/2024	United States of America	Systems and Methods for Treating Cancer and/or Augmenting Organ Function
17/833,964	6/7/2022	United States of America	Systems and Methods for Treating Cancer and/or Augmenting Organ Function
23182480.6	6/29/2023	European Patent Office	ANS Assessment Systems, Kits, and Methods
3,210,898	9/1/2023	Canada	ANS Assessment Systems, Kits, and Methods
10202300654X	3/10/2023	Singapore	ANS Assessment Systems, Kits, and Methods
18/543,538	12/18/2023	United States of America	ANS Assessment Systems, Kits, and Methods
23171646.5	5/4/2023	European Patent Office	Systems and Methods for Treating Cancer and/or Augmenting Organ Function
25151120	1/10/2025	European Patent Office	Systems and Methods for Regulating Organ and/or Tumor Growth Rates, Function, and/or Development
202210497355	5/9/2022	China	Controlled and Precise Treatment of Cardiac Tissues
23170175.6	4/26/2023	European Patent Office	Controlled and Precise Treatment of Cardiac Tissues
17/501,502	10/14/2021	United States of America	Controlled and Precise Treatment of Cardiac Tissues
19/004,748	12/30/2024	United States of America	Medical Devices with Circuitry for Capturing and Processing Physiological Signals
3,264,031	2/3/2025	Canada	Medical Devices Configured for Therapeutic Electroporation of Biologic Tissues
23853213.9	2/28/2025	European Patent Office	Medical Devices Configured for Therapeutic Electroporation of Biologic Tissues
19/099,897	1/30/2025	United States of America	Medical Devices Configured for Therapeutic Electroporation of Biologic Tissues
18/779,387	7/22/2024	United States of America	Elongated Conductors and Methods of Making and Using the Same
19/180,938	4/16/2025	United States of America	Smart Torquer and Methods of Using the Same
16854068	4/9/2018	European Patent Office	Smart Torquer and Methods of Using the Same
PCT/US2025/025299	4/18/2025	Patent Cooperation Treaty (PCT) / United States of America, Receiving Office	Medical Devices Configured for Temperature-Controlled Therapeutic Electroporation
PCT/US2025/025305	4/18/2025	Patent Cooperation Treaty (PCT)/ United States of America, Receiving Office	Medical Devices Configured for Therapeutic Electroporation with Adjustable Sections of an Elongate Member
PCT/US2025/025307	4/18/2025	Patent Cooperation Treaty (PCT)/ United States of America, Receiving Office	Medical Device Guide Sheaths with Return Electrodes for Bipolar Therapeutic Electroporation

Trademarks

The Company has one trademark for the mark "AUTONOMIX" in the United States, Australia, China, the European Union, India, Japan, Mexico, and Singapore. The registrations of these trademarks are effective for varying periods of time and may be renewed periodically provided we comply with all applicable renewal requirements, including, where necessary, the continued use of the trademarks in the applicable jurisdictions in connection with certain goods and services.

Competition

The electrophysiology market is served by a number of very large players including, for example, Medtronic and Boston Scientific, all of whom have substantially greater resources than Autonomix.

While the current standards of care for treating pancreatic cancer pain are comprised largely of generic drugs and injections, we are not aware of any person or company working on a transvascular sensing and ablation method for treating this indication. Although competitors like Medtronic are expanding the use of transvascular ablation techniques, we are not aware of anyone developing a sensing technology similar in capability to our technology.

Recent tests using Endoscopic Ultrasound-Guided Ablation to treat pancreatic cancer pain have claimed outcomes that may be better than NCPB, however this is still a percutaneous technique that we believe involves similar inherent risks of infection and internal damage as does NCPB. Conversely, we believe these risks are significantly reduced using a transvascular approach such as the Autonomix technology.

Description of Property

The Company leases office space as its headquarters in Texas and has access to a research and development facility in Pennsylvania.

Employees

As of March 31, 2025, we have 11 employees providing services to the Company, eight on a full-time basis and three on a part-time basis. Accordingly, a high percentage of the work performed for our development projects is conducted by qualified part-time staff and independent contractors.

Legal Proceedings

From time to time, we may become involved in litigation matters relating to claims arising from the ordinary course of business. While the results of such claims and legal actions cannot be predicted with certainty, our management does not believe that there are claims or actions, pending or threatened against us, the ultimate disposition of which would have a material adverse effect on our business, results of operations, financial condition, or cash flows.

Regulation of Our Business

Our product candidate and operations are subject to extensive and rigorous regulation by the U.S. Food and Drug Administration ("FDA"), under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and it's implementing regulations, guidance documentation, and standards. Our sensing device and catheters are regulated by the FDA as medical devices. The FDA regulates the design, development, research, testing, manufacturing, safety, labeling, storage, record keeping, promotion, distribution, sale and advertising of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. The FDA also regulates the export of medical devices manufactured in the United States to international markets. Any violations of these laws and regulations could result in a material adverse effect on our business, financial condition and results of operations. In addition, if there is a change in law, regulation or judicial interpretation, we may be required to change our business practices, which could have a material adverse effect on our business, financial condition and results of operations.

Unless an exemption applies, before we can commercially distribute medical devices in the United States, we must obtain, depending on the type of device, either prior premarket clearance or premarket approval (PMA), from the FDA. The FDA classifies medical devices into one of three classes:

- Class I devices, which are subject to only general controls (e.g., labeling, medical devices reporting, and prohibitions against adulteration and misbranding) and, in some cases, to the premarket clearance requirements;
- Class II devices, generally requiring premarket clearance before they may be commercially marketed in the United States; and
- Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, generally requiring submission of a PMA supported by clinical trial data.

Our current product candidates are all class II devices and will require submission of a premarket notification.

510(k) Clearance Pathway

When a 510(k) clearance is required, we must submit a premarket notification demonstrating that our proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a PMA, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision.

PMA Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. During the review period, the FDA will typically request additional information or clarification of the information already provided. Also, 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 pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the QSRs.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel.

de novo Classification

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. The FDA 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 application. Prior to the enactment of the FDA Safety and Innovation Act of 2012, or the FDASIA, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the de novo application. 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. In addition, 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.

Clinical Trials

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) or de novo clearance. Such trials generally require an investigational device exemption application, or IDE, approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, record keeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, or IRB, for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S. Similarly, in Europe the clinical study must be approved by a local ethics committee (EC) and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include:

- Product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the U.S., which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions.

Furthermore, our products could be subject to voluntary recall if we or the FDA determine, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death.

The FDA has broad post-market and regulatory enforcement powers. Once we have a marketed product, we will be subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing premarket clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Glossary

Unless we otherwise indicate, or unless the context requires otherwise, any references in this Annual Report on Form 10-Kto the following medical terms have the respective meanings set forth below:

ablation: the removal or destruction of a body part or tissue or its function. This is often conducted with energy-based devices utilizing radio frequency or pulsed electrical field energy.

cardiomyocyte: the cell responsible for the contraction of the heart.

catheter: a thin tube made from medical grade materials serving a broad range of functions; catheters are medical devices that can be inserted in the body to treat diseases or perform a surgical procedure.

celiac plexus: also known as the solar plexus because of its radiating nerve fibers, is a complex network of nerves located in the abdomen, near where the celiac trunk, and other arteries branch from the abdominal aorta.

electrophysiology: the branch of physiology that deals with the electrical phenomena associated with nervous and other bodily activity.

hypertension: high blood pressure.

microvolt: one millionth of a volt.

palliative care: specialized medical care for people living with a serious illness focused on providing relief from the symptoms and stress of serious illness.

renal artery: the main blood vessel that supplies blood to a kidney.

transvascular: across the wall of a blood vessel (or similar vessel).

unresectable: unable to be removed with surgery.

Available Information

Our Internet address is www.autonomix.com. On this website, we post the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission ("SEC"): our Annual Reports on Form 10-K; our Quarterly Reports on Form 10-Q; our Current Reports on Form 8-K; our proxy statements related to our annual stockholders' meetings; and any amendments to those reports or statements. All such filings are available on our Web site free of charge. The charters of our audit, nominating and governance and compensation committees and our Code of Business Conduct and Ethics Policy are also available on our Web site and in print to any stockholder who requests them. The content on our Web site is not incorporated by reference into this Annual Report on Form 10-K.

Item 1A. Risk Factors.

Summary of Risk Factors:

Below is a summary of the principal factors that make an investment in our Company speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary and other risks that we face, can be found below, after this summary, and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC, before making an investment decision in our securities.

Risks Related to Our Overall Business

- Factors raise substantial doubt about our ability to continue as a going concern;
- We have no approved products, and we cannot assure you that we will generate revenue or become profitable in the future;
- We will need additional financing over the longer term to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all;
- We intend to utilize a single manufacturer for the manufacture of our lead product candidate and expect to continue to do so for commercial products. Risks associated with the manufacturing of our products could reduce our gross margins and negatively affect our operating results;
- We are a developmental stage Company and have not yet had a history of generating revenue;
- Our business may be adversely affected by the state of the global economy, uncertainties in global financial markets, and possible trade tariffs and trade restrictions;
- We have limited experience in assembling and testing our products and may encounter problems or delays in the assembly of our products or fail to meet certain regulatory requirements which could result in an adverse effect on our business and financial results;
- Rapidly changing technology in life sciences could make the products we are developing obsolete;
- Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations;
- We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights;
- Catastrophic events and disaster recovery may disrupt business continuity;
- We may fail to meet the Sarbanes-Oxley regulations and may lack the financial controls and safeguards required of public companies;
- While our Company's management is working to improve our internal controls and procedures, at present management has determined that our internal controls were deemed to be inadequate, which could cause our financial reporting to be unreliable and lead to misinformation being disseminated to the public;
- Because of the specialized nature of our business, the termination of relationships with our key employees, consultants and advisors may prevent us from successfully operating our business, including developing our products, conducting clinical studies, commercializing our products and obtaining any necessary financing; and
- Our Certificate of Incorporation and Bylaws, each as amended to date, provide for indemnification of officers and directors at the expense of the Company and limit their liability that may result in a major cost to us and hurt the interests of our stockholders because corporate resources may be expended for the benefit of officers and/or directors.

Risks Related to Government Regulation and Product Approvals

- Changes to United States federal and state regulatory agencies may cause disruptions and delays in approval of the government approval processes and regulation relating to our products;
- There is no guarantee that the FDA will grant 510(k) or de novo clearance or a premarket approval application ("PMA") of our future products and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business;
- Our product development for our sensing and ablation technologies may not meet the necessary validation requirements to achieve regulatory approvals, or our internal specifications for commercial viability;
- Modifications to our future products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained;
- The results of our future clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects;
- We are conducting our initial Proof of Concept trial outside the United States using commercially available RF ablation equipment in a new anatomical region to assess clinical response. We plan to present the relevant data from this trial to the FDA to support the clinical requirements for clearance in the United States. However, there is no assurance that the FDA will accept this data;
- Our clinical studies could be delayed or otherwise adversely affected by many factors, including difficulties in enrolling patients;
- We may have limitations in generating statistically significant long-term clinical data and gaining extended-duration indications from clinical studies involving terminal patients;
- Even if our products are cleared or approved by the FDA, if we or our suppliers fail to comply with ongoing FDA requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market;
- Our products may in the future be subject to product recalls that could harm our reputation, business, and financial results;
- If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions;
- Certain parts used in the manufacturing of our equipment may experience shortages in global supply which could impact our ability to manufacture our device for customers or maintain research and development timelines;
- U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained;
- Failure to secure and maintain adequate coverage and reimbursement from third-party payers could adversely affect acceptance of our products, if approved, and reduce our revenues;
- We may not be successful in securing and maintaining reimbursement codes necessary to facilitate accurate and timely billing for our products or physician services attendant to our products;
- If we are unable to establish good relationships with physicians, our business could be negatively affected; and
- There is no assurance that Medicare or the Medicare Administrative Contractors will provide coverage or adequate payment rates for our products.

Risks Related to Intellectual Property

- If third parties claim that our products infringe their intellectual property rights, we may be forced to expend significant financial resources and management time defending against such actions and our financial condition and our results of operations could suffer;
- If we are unable to protect the intellectual property used in our products, others may be able to copy our innovations which may impair our ability to compete effectively in our markets;
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers;
- If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected; and
- We may not be able to protect our intellectual property rights throughout the world.

Risks Related to Information Technology

- Our business and operations would suffer in the event of third-party computer system failures, cyberattacks on third-party systems or deficiency in our cybersecurity;
- Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information and personal data; and
- Cybersecurity risks and cyber incidents could adversely affect our business and disrupt operations.

Risks Related to our Common Stock

- Concentration of ownership of our common stock among our existing executive officers and directors may prevent new investors from influencing significant corporate decisions;
- We do not intend to pay cash dividends on our common stock in the foreseeable future;
- If our stock price fluctuates, you could lose a significant part of your investment;
- Techniques employed by short sellers may in the future drive down the market price of our common stock;
- If securities or industry analysts do not publish research or reports about us, or if they adversely change their recommendations regarding our common stock, then our stock price and trading volume could decline;
- The market price of our stock may be highly volatile, and you could lose all or part of your investment;
- Your ownership may be diluted if additional capital stock is issued to raise capital, to finance acquisitions or in connection with strategic transactions;
- We may be required to issue up to 271,846 shares of common stock in connection with the reverse stock split we completed on October 24, 2024, and we may be subject to potential liability if it is determined that we are required to issue such shares and fail to issue such shares on a timely basis; and
- If we are unable to maintain compliance with the listing requirements of The Nasdaq Capital Market, our common stock may be delisted from The Nasdaq Capital Market which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares.
- Provisions of the Series A Warrants we issued in our offering could discourage an acquisition of us by a third party.

General Risks

- Shareholder activism could cause material disruption to our business;
- As an “emerging growth company” under the Jumpstart Our Business Startups Act, or JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements;
- Our Certificate of Incorporation includes a forum selection provision, which could result in less favorable outcomes to the plaintiff(s) in any action against us;
- The requirements of being a public company may strain our resources, divert management’s attention and affect our ability to attract and retain qualified board members; and
- We may be at an increased risk of securities class action litigation.

Risks Related to Our Overall Business

Factors raise substantial doubt about our ability to continue as a going concern.

As of March 31, 2025, we had an accumulated deficit of $50.4 million, negative cash flows from operating activities of $8.3 million and working capital of $7.9 million, which raises substantial doubt about our ability to continue as a going concern. Further, we have incurred, and expect to continue to incur, significant costs in pursuit of our business plans. We cannot assure you that our plans to raise sufficient capital to fund our business will be successful. These factors, among others, raise substantial doubt about our ability to continue as a going concern. The financial statements contained elsewhere in this Annual Report on Form 10-K do not include any adjustments that might result from our inability to raise additional capital or our inability to continue as a going concern.

We have no approved products, and we cannot assure you that we will generate revenue or become profitable in the future.

Our products may never be cleared by the United States Food & Drug Administration ("FDA") or become commercially viable or accepted for use. We have incurred significant losses since our inception and expect to continue to experience operating losses and negative cash flow for the foreseeable future. We expect to expend significant resources on hiring of personnel, continued scientific and product research and development, product testing and preclinical and clinical investigation, intellectual property development and prosecution, marketing and promotion, capital expenditures, working capital, general and administrative expenses, and fees and expenses associated with our capital raising efforts. We expect to incur costs and expenses related to consulting costs, hiring of scientists, engineers, science and other operational personnel, and the continued development of relationships with strategic partners.

We will need additional financing over the longer term to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all.

We believe our existing capital resources, will be sufficient to fund our operations into the first calendar quarter of 2026 without additional capital infusion.

We will require significant capital to complete clinical trials, seek approval of our products, mount a major sales and marketing effort and execute our business plan. We cannot give any assurance that we will be able to obtain all the necessary funding that we may need. We may pursue additional funding through various financing sources, including additional equity offerings, the issuance of debt securities, fees associated with licensing some or all of our technology, joint ventures with capital partners and project type financing. There can be no assurance that funds will be available on commercially reasonable terms, if at all. If financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations, in which case you may lose some or all of your investment.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operation plans.

Alternatively, we may consider changes in our business plan that might enable us to achieve aspects of our business objectives and lead to some commercial success with a smaller amount of capital, but we cannot assure that changes in our business plan will result in revenues or maintain any value in your investment.

We intend to utilize a single manufacturer for the manufacture of our lead product candidate and expect to continue to do so for commercial products. Risks associated with the manufacturing of our products could reduce our gross margins and negatively affect our operating results.

We do not have any manufacturing facilities or direct manufacturing personnel. We currently rely, and expect to continue to rely, on a single manufacturer for the manufacture of our lead product candidate for commercial manufacture. As such, we are subject to numerous risks relating to our reliance on a single manufacturer. If they encounter problems in manufacturing our product candidate, then our business could be significantly impacted. These problems include:

- inability to secure product components in a timely manner, insufficient quantities or on commercially reasonable terms;
- failure to increase production to meet demand;
- inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;
- difficulty identifying and qualifying alternative manufacturers in a timely manner;
- inability to establish agreements with future third-party manufacturers or to do so on acceptable terms; or
- potential damage to or destruction of our manufacturers' equipment or facilities.

If demand for our future products increases, our manufacturer will need to invest additional resources to purchase components, hire and train employees, and enhance their manufacturing processes. If they fail to increase production capacity efficiently, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. We do not have a long-term agreement with our manufacturer and there is no assurance that they will continue to provide us with manufacturing services in the future.

We are a developmental stage company and have not yet had a history of generating revenue.

As a development-stage entity, we have not generated any revenues. Investors are subject to all the risks incident to the creation and development of a new business and each investor should be prepared to withstand a complete loss of investment. We have not emerged from the development stage and may be unable to raise further equity. These factors raise substantial doubt about our ability to continue as a going concern.

Our business may be adversely affected by the state of the global economy, uncertainties in global financial markets, and possible trade tariffs and trade restrictions.

Our operations and performance will depend significantly on worldwide economic and geopolitical conditions. Uncertainty about global economic conditions could result in potential customers postponing purchases of our future products in response to tighter credit, unemployment, negative financial news and/or declines in income or asset values and other macroeconomic factors, which could have a material negative effect on demand for our future products and, accordingly, on our business, results of operations or financial condition. For example, current global financial markets continue to reflect uncertainty, which has been heightened by the COVID-19 pandemic and the ongoing military conflict between Russia and Ukraine and the ongoing conflict in Israel. Given these uncertainties, there could be further disruptions to the global economy, financial markets and consumer confidence. If economic conditions deteriorate unexpectedly, our business and results of operations could be materially and adversely affected. For example, our future customers, including our distributors and their customers, may have trouble obtaining the working capital and other financing necessary to support historical or projected purchasing patterns, which could negatively affect our results of operations.

Recent global economic slowdowns could continue and potentially result in certain economies dipping into economic recessions, including in the United States. A weak or declining economy may in the future strain our manufacturers or suppliers, possibly result in supply disruptions. General trade tensions between the United States and the world have recently been escalated by the current U.S. administration, which has recently proposed or enacted significant tariffs and substantial changes to trade policies, which could adversely affect our business. For example, the U.S. administration has imposed significant tariff increases on foreign products, including most recently from Canada, Mexico and China, that in the past have resulted in, and may result in, future retaliatory tariffs on U.S. goods and products or potential currency devaluations. We cannot predict whether these policies will continue, or if new policies will be enacted, or the impact, if any, that any policy changes could have on our business. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely affect our business. Additionally, increased inflation around the world, including in the United States, applies pressure to our costs. Continued economic slowdowns or recessions and inflationary pressures could have a negative impact on our business, including decreased demand, increased costs, and other challenges. Government actions to address economic slowdowns and increased inflation, including increased interest rates, also could result in negative impacts to our growth.

Additionally, Russia's invasion of Ukraine in early 2022 triggered significant sanctions from U.S. and European countries. Resulting changes in U.S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including China, resulting in a potential trade war. Furthermore, if the conflict between Russia and Ukraine continues for a prolonged period of time, or if other countries, including the U.S., become involved in the conflict, we could face significant adverse effects to our business and financial condition. For example, if our supply or customer arrangements are disrupted due to expanded sanctions or involvement of countries where we have operations or relationships in the future, our business could be materially disrupted. Further, the use of cyberattacks could expand as part of the conflict, which could adversely affect our ability to maintain or enhance our cybersecurity and data protection measures.

The current U.S. administration took several executive actions, including the issuance of a number of executive orders, that imposed significant burdens on, or otherwise materially delayed, the FDA's ability to engage in routine oversight activities, such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these orders will be rescinded and replaced under the current or future administrations.

The inability to obtain adequate financing from debt or capital sources in the future could force us to self-fund strategic initiatives or even forego certain opportunities, which in turn could potentially harm our performance.

We have limited experience in assembling and testing our products and may encounter problems or delays in the assembly of our products or fail to meet certain regulatory requirements which could result in an adverse effect on our business and financial results.

We have limited experience in assembling and testing our planned device and no experience in doing so on a commercial scale. To become profitable, we must assemble and test our planned device in commercial quantities in compliance with regulatory requirements and at an acceptable cost. Increasing our capacity to assemble and test our products on a commercial scale will require us to improve internal efficiencies. We may encounter a number of difficulties in increasing our assembly and testing capacity, including:

- managing production yields;
- maintaining quality control and assurance;
- providing component and service availability;
- maintaining adequate control policies and procedures;
- hiring and retaining qualified personnel; and
- complying with state, federal and foreign regulations.

If we are unable to satisfy commercial demand for our planned device due to our inability to assemble and test our planned device, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected and customers may instead purchase or use, our competitors' products.

Rapidly changing technology in life sciences could make the products we are developing obsolete.

The medical device and life-science industry in general is characterized by rapid and significant technological changes, frequent new product introductions and enhancements and evolving industry standards. Our future success will depend on our ability to continually develop and then improve the products that we design and to develop and introduce new products that address the evolving needs of our customers on a timely and cost-effective basis.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") (now a division of First Citizens Bank), was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver, which has been followed by the collapse of Signature Bank Corp. ("Signature"), Silvergate Capital Corp. and First Republic Bank. Although we were not a borrower under or party to any material letter of credit or any other such instruments with SVB, Signature or any other financial institution, if we enter into any such instruments and any of our lenders or counterparties to such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any of our partners, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to credit agreements and arrangements with these financial institutions, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of these financial institutions and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates.

Our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, any financial institutions with which we enter into credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These risks include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- inability to enter into credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses or other obligations, financial or otherwise, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our partners, vendors, or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a partner may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a vendor or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. The bankruptcy or insolvency of any partner, vendor or supplier, or the failure of any partner to make payments when due, or any breach or default by a partner, vendor or supplier, or the loss of any significant supplier relationships, could cause us to suffer material losses and may have a material adverse impact on our business.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

We may from time to time seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property. If we choose to enforce our patent rights against a party, then that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced. Additionally, the validity of our patents and the patents we have licensed may be challenged if a petition for post grant proceedings such as inter-parties review and post grant review is filed within the statutorily applicable time with the U.S. Patent and Trademark Office (“USPTO”). These lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our intellectual property rights. In addition, in recent years the U.S. Supreme Court modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of a challenge of any patents we obtain or license.

Catastrophic events and disaster recovery may disrupt business continuity.

A disruption or failure of our systems or operations in the event of a natural disaster or severe weather event, including, but not limited to, earthquakes, wildfires, droughts, flooding, tornadoes, hurricanes or tsunamis, health pandemic, such as an influenza outbreak within our workforce, or man-made catastrophic event could cause delays in completing sales, continuing production or performing other critical functions of our business, particularly if a catastrophic event were to occur at our premises. Global climate change could result in certain natural disasters occurring more frequently or with greater intensity. Any of these events could severely affect our ability to conduct normal business operations and, as a result, our operating results could be adversely affected. There may also be secondary impacts that are unforeseeable as well, such as impacts on our customers, which could cause delays in new orders, delays in completing sales or even order cancellations.

We may fail to meet the Sarbanes-Oxley regulations and may lack the financial controls and safeguards required of public companies.

Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our management has concluded that our internal controls over financial reporting are ineffective and has identified material weaknesses in our internal controls in areas such as the lack of segregation of duties; general technology controls; and financial statement reporting. While management is working to remediate the material weaknesses, there is no assurance that such changes, when economically feasible and sustainable, will remediate the identified material weaknesses or that the controls will prevent or detect future material weaknesses. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business. We may discover additional material weaknesses in our internal financial and accounting controls and procedures that need improvement from time to time.

Management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles. Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within our company will have been detected.

We are required to comply with Section 404 of the Sarbanes-Oxley Act in connection with this annual report on Form 10-K and future quarterly reports on Form 10-Q. We expect to expend significant resources in developing the necessary documentation and testing procedures required by Section 404. We cannot be certain that the actions we will be taking to improve our internal controls over financial reporting will be sufficient, or that we will be able to implement our planned processes and procedures in a timely manner. In addition, if we are unable to produce accurate financial statements on a timely basis, investors could lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

While our Company's management is working to improve our internal controls and procedures, at present management has determined that our internal controls were deemed to be inadequate, which could cause our financial reporting to be unreliable and lead to misinformation being disseminated to the public.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. As defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), internal control over financial reporting is a process designed by, or under the supervision of, the principal executive and principal financial officer and effected by the board of directors, management and other personnel, 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 and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and/or directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

We are required to include a report of management on the effectiveness of our internal control over financial reporting. We expect to incur additional expenses and diversion of management's time as a result of performing the system and process evaluation, testing and remediation required in order to comply with the management certification requirements.

Presently, we do not have a sufficient number of employees to segregate responsibilities and may be unable to afford increasing our staff or engaging outside consultants or professionals to overcome our lack of employees. During the course of our testing, we may identify other deficiencies that we may not be able to timely remediate. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock, if a market ever develops, could drop significantly.

Because of the specialized nature of our business, the termination of relationships with our key employees, consultants and advisors may prevent us from successfully operating our business, including developing our products, conducting clinical studies, commercializing our products and obtaining any necessary financing.

We are highly dependent on the members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment or consulting agreements with each of our key executives, any of them could leave our employment at any time. We do not have "key person" insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our business objectives.

The competition for qualified personnel in the medical device fields is intense and we rely heavily on our ability to attract and retain qualified scientific, technical, and managerial personnel. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. In order to commercialize our products successfully, we will be required to expand our workforce, particularly in the areas of research and development and clinical studies, finance, accounting and reporting, sales and marketing and supply chain management. These activities will require the addition of new personnel and the development of additional expertise by existing management personnel. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. We may not be able to attract and retain these individuals on acceptable terms or at all. Failure to do so could materially harm our business.

Our Certificate of Incorporation and Bylaws, each as amended to date, provide for indemnification of officers and directors at the expense of the Company and limit their liability that may result in a major cost to us and hurt the interests of our stockholders because corporate resources may be expended for the benefit of officers and/or directors.

Our Certificate of Incorporation and Bylaws, each as amended to date, provide for the indemnification of our officers and directors. We have been advised that, in the opinion of the SEC, indemnification for liabilities arising under federal securities laws is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Risks Related to Government Regulation and Product Approvals

Changes to United States federal and state regulatory agencies may cause disruptions and delays in approval of the government approval processes and regulation relating to our products.

The results of the 2024 federal elections in the U.S., including the Presidency and both houses of Congress, federal and statement government agencies may be subject to change as a result of political, legislative, regulatory, administrative developments and judicial proceedings. It is also possible that the current administration could institute significant changes to certain regulatory agencies and seek to institute the Department of Government Efficiency ("DOGE"), tasked with making changes to eliminate regulations, cut expenditures and restructure federal agencies, some of which could impact public companies. For example, the incoming administration has discussed several changes to the reach and oversight of the Food and Drug Administration, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs, as well as oversight over clinical trials and pharmaceutical development, all of which could pose risks (or opportunities) for companies in related industries. Similarly, there have been discussions of "reigning in" regulatory agencies such as the Federal Trade Commission, the Federal Communications Commission and the Federal Energy Regulatory Commission, all of which could impact how companies do business and could pose risks related to our business operations and financial outlook.

There is no guarantee that the FDA will grant 510(k) or de novo clearance or a premarket approval application ("PMA") of our future products and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Our lead product candidate will require FDA clearance of a 510(k) or de novo application or may require FDA approval of a PMA. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for premarket clearance or premarket approval of new products, new intended uses or modifications to existing products. Failure to receive clearance or approval for our products would have an adverse effect on our ability to continue or expand our business.

If we fail to obtain and maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our device, our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

Our products will be subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA, unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other 510(k)-cleared products or through a de novo process if substantial equivalence is not available. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) or de novo clearance processes. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. We believe our current product candidate will require clearance through the 510(k) or de novo process.

Our product development for our sensing and ablation technologies may not meet the necessary validation requirements to achieve regulatory approvals, or our internal specifications for commercial viability.

We are developing proprietary sensing and ablation technologies that represent novel applications within the medical device space. As such, these technologies are subject to stringent validation and verification processes, both internally and by regulatory bodies such as the FDA. There is no assurance that our products will meet the safety, efficacy, and performance criteria required to obtain regulatory approvals. Additionally, even if our technologies are shown to be safe and effective in preclinical or early-stage clinical studies, they may not meet the technical, usability, cost, or performance benchmarks necessary for commercial viability. Any delays or failures in validation, or changes in FDA requirements or guidance, could significantly impact our development timelines, increase our costs, and delay or prevent our ability to bring our products to market.

Modifications to our future products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Modifications to our future products may require new regulatory approvals or clearances, including 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. Once we have a commercialized product, we may make modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for these modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

Where we determine that modifications to our products require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

The results of our future clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

We have not completed any clinical trials and we cannot be certain that their results will support our product candidate claims or that the FDA will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

We are conducting our initial Proof of Concept trial outside the United States using commercially available RF ablation equipment in a new anatomical region to assess clinical response. We plan to present the relevant data from this trial to the FDA to support the clinical requirements for clearance in the United States. However, there is no assurance that the FDA will accept this data.

Human trials are often designed to begin with a Proof of Concept ("PoC") trial and then progress to a "Pivotal" or approval, trial. We have started a PoC trial outside the United States using commercially available RF ablation devices, and upon completion, we intend to present the data to the FDA in a pre-submission meeting and use key learnings to inform the protocol for our US-based clinical trials. The first trial is not designed to replace the pivotal trial that will be required by the FDA to support clearance in the United States, but rather to potentially impact the size of that trial. There is no guarantee that our devices will perform the same as commercially available RF ablation equipment or that the results from this PoC trial will be replicated with our own devices. Additionally, there is no assurance that the FDA will accept the data from our international trial or that they will not require us to conduct additional Early Feasibility Studies ("EFS") to supplement a pivotal trial. Any additional trials required by the FDA could be costly, time-consuming, and may necessitate raising additional financing, for which we have no commitments.

Our clinical studies could be delayed or otherwise adversely affected by many factors, including difficulties in enrolling patients.

Clinical testing can be costly and take many years and the outcome is uncertain and susceptible to varying interpretations. Moreover, success in pre-clinical and early clinical studies does not ensure that large-scale studies will be successful or predict final results. Acceptable results in early studies may not be replicable in later studies. A number of companies have suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. Negative or inconclusive results or adverse events or incidents during a clinical study could cause the clinical study to be redone or terminated. In addition, failure to appropriately construct clinical studies could result in high rates of adverse events or incidents, which could cause a clinical study to be suspended, redone or terminated. Our failure or the failure of third-party participants in our studies to comply with their obligations to follow protocols and/or legal requirements may also result in our inability to use the affected data in our submissions to regulatory authorities.

The timely completion of clinical studies depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical studies for a variety of reasons, including:

- the severity of the disease under investigation;
- the limited size and nature of the patient population;
- the patient eligibility criteria defined in our protocol and other clinical study protocols;
- the nature of the study protocol, including the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects;
- difficulties and delays in clinical studies that may occur as a result of the COVID-19 pandemic;
- the ability to obtain institutional review board ("IRB") approval at clinical study locations;
- clinicians' and patients' perceptions as to the potential advantages, disadvantages and side effects of our products in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are pursuing;
- the possibility or perception that enrolling in a product's clinical study may limit the patient's ability to enroll in future clinical studies for other therapies due to protocol restrictions;
- the possibility or perception that our software is not secure enough to maintain patient privacy;
- the ability to monitor patients adequately during and after treatment;
- the availability of appropriate clinical study investigators, support staff, drugs and other therapeutic supplies and proximity of patients to clinical sites;
- physicians' or our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical studies will choose to withdraw from or otherwise not be able to complete a clinical study.

If we have difficulty enrolling and retaining a sufficient number or diversity of patients to conduct our clinical studies as planned, or encounter other difficulties, we may need to delay, terminate or modify ongoing or planned clinical studies, any of which would have an adverse effect on our business.

We may have limitations in generating statistically significant long-term clinical data and gaining extended-duration indications from clinical studies involving terminal patients.

Our clinical studies, particularly those involving terminal patients with pancreatic cancer, may face significant challenges in generating long-term data and developing extended indications. Given the nature of pancreatic cancer, many patients enrolled in our studies may have a limited life expectancy, which could hinder our ability to gather statistically significant long-term clinical data that may be crucial for establishing broader longer-term indications for our products. The inability to collect sufficient data from these patients may limit the scope of our clinical findings and the potential for additional indications beyond the initial use cases. As a result, the progress of our clinical trials, and the expansion of indications could be delayed and our ability to secure regulatory approvals for longer-term uses may be impacted.

Even if our products are cleared or approved by the FDA, if we or our suppliers fail to comply with ongoing FDA requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we, and our suppliers, will be required to comply with FDA's Quality System Regulations, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. FDA enforces the QSR and other regulations through periodic inspections. 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, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing premarket clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not 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.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

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. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, 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 financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they 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 the recalls when they were conducted.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Certain parts used in the manufacturing of our equipment may experience shortages in global supply, which could impact our ability to manufacture our device for customers or maintain research and development timelines.

There are a number of component parts used in the manufacture of our device that are used by many manufacturers in a variety of products. We will compete with other manufacturers for the supply of these components. Additionally, certain parts that are currently in our design may be discontinued by our supplier requiring us to find alternative parts. This issue may require us to change the design of our device or purchase significant inventories of these parts in order to protect against manufacturing delays. We may not be able to procure alternative components or adequate raw material inventories which would result in an inability to produce our device.

U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Failure to secure and maintain adequate coverage and reimbursement from third-party payers could adversely affect acceptance of our products, if approved, and reduce our revenues.

Assuming we receive approval of our products, we expect that the vast majority of our revenues will come from third-party payers, either directly to us in markets where we plan to provide our device candidates to patients, or indirectly via payments made to hospitals or other entities, which may in the future provide our device candidates to patients.

In the U.S., private payers cover the largest segment of the population, with the remainder either uninsured or covered by governmental payers. The majority of the third-party payers outside the U.S. are government agencies, government sponsored entities or other payers operating under significant regulatory requirements from national or regional governments.

Third-party payers may decline to cover and reimburse certain procedures, supplies or services. Additionally, some third-party payers may decline to cover and reimburse our products for a particular patient even if the payer has a favorable coverage policy addressing our products or previously approved reimbursement for our products. Additionally, private and government payers may consider the cost of a treatment in approving coverage or in setting reimbursement for the treatment.

Private and government payers around the world are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of governments around the world. Adoption of additional price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenues and operating results. If third-party payers do not consider our products or the combination of our products with additional treatments to be cost-justified under a required cost-testing model, they may not cover our products for their populations or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

Reimbursement for the treatment of patients with medical devices around the world is governed by complex mechanisms established on a national or sub-national level in each country. These mechanisms vary widely among countries, can be informal, somewhat unpredictable, and evolve constantly, reflecting the efforts of these countries to reduce public spending on healthcare. As a result, obtaining and maintaining reimbursement for the treatment of patients with medical devices has become more challenging globally. We cannot guarantee that the use of our products will receive reimbursement approvals and cannot guarantee that our existing reimbursement approvals will be maintained in any country.

Because our technology introduces a novel approach to nerve sensing and ablation, including applications for conditions that are not well served by current therapies, third-party payers may require more extensive clinical and economic evidence than is typically needed for coverage of established technologies. In particular, demonstrating long-term safety, effectiveness, and cost-efficiency in real-world use may be necessary to obtain or maintain reimbursement. The absence of established coding, clinical guidelines, or historical reimbursement precedents for our system may further complicate this process. As a result, lack of adequate reimbursement could delay or limit commercial adoption of our products, even if we obtain regulatory clearance or approval.

Our failure to secure or maintain adequate coverage or reimbursement for our products by third-party payers in the U.S., or in the other jurisdictions in which we market our products, could have a material adverse effect on our business, revenues and results of operations.

We may not be successful in securing and maintaining reimbursement codes necessary to facilitate accurate and timely billing for our products or physician services attendant to our products.

Third-party payers, healthcare systems, government agencies or other groups often issue reimbursement codes to facilitate billing for products and physician services used in the delivery of healthcare. Within the U.S., the billing codes most directly related to our products are contained in the Healthcare Common Procedure Coding System ("HCPCS code set"). The HCPCS code set contains Level I codes that describe physician services, also known as Common Procedural Terminology codes ("CPT codes") and Level II codes that primarily describe products. Centers for Medicare & Medicaid Services ("CMS") is responsible for issuing the HCPCS Level II codes. The American Medical Association issues HCPCS Level I codes.

No HCPCS codes or CPT codes currently exist to describe physician services related to the delivery of therapy using our products. We may not be able to secure HCPCS codes and CPT codes for physician services related to our products. Our future revenues and results may be affected by the absence of CPT codes, as physicians may be less likely to prescribe the therapy when there is no certainty that adequate reimbursement will be available for the time, effort, skill, practice expense and malpractice costs required to provide the therapy to patients.

Outside the U.S., we have not secured codes to describe our products or to document physician services related to the delivery of therapy using our products. The failure to obtain and maintain these codes could affect the future growth of our business.

If we are unable to establish good relationships with physicians, our business could be negatively affected.

Our business model will require us to build and maintain good relationships with physicians who will have a significant source of patients that will generate treatment revenues for both the physician and the Company. If we are unable to establish good relationships with physicians and maintain them, it will jeopardize our ability to generate future revenues.

There is no assurance that Medicare or the Medicare Administrative Contractors will provide coverage or adequate payment rates for our products.

We anticipate that a significant portion of patients using our products will be beneficiaries under the Medicare fee-for-service program. Failure to secure or maintain coverage or maintain adequate reimbursement from Medicare would reduce our revenues and may also affect the coverage and reimbursement decisions of other third-party payers in the U.S. and elsewhere.

Medicare may classify our medical device as durable medical equipment ("DME"). Medicare has the authority to issue national coverage determinations or to defer coverage decisions to its regional Medicare Administrative Contractors ("MACs"). The fact that only two MACs administer the entire DME program may negatively affect our ability to petition individual medical policy decision-makers at the MACs for coverage. The absence of a positive coverage determination or a future restriction to existing coverage from Medicare or the DME MACs would materially affect our future revenues.

Additionally, Medicare has the authority to publish the reimbursement amounts for DME products. Medicare may in the future publish reimbursement amounts for our products that do not reflect then-current prices for our products. Medicare fee schedules are frequently referenced by private payers in the U.S. and around the world. Medicare's publication of reimbursement amounts for our products that are below our products' established prices could materially reduce our revenues and operating results with respect to non-Medicare payers in the U.S. and our other active markets.

Even if our products were authorized by Medicare, CMS requires prior authorization for certain DME items. Claims for such items that did not receive prior authorization before they were furnished to a beneficiary will be automatically denied. In the event Medicare adds one of our products to the list of items requiring prior authorization, our ability to bill and secure reimbursement for patients who would otherwise be covered to use our product under the Medicare fee-for-service program may be reduced.

We cannot provide any assurance that we can access transitional, expedited, or expanded Medicare coverage for our products. CMS is expected to issue rules regarding coverage of emerging technologies; however, no specific information is available about the content of the expected rules and we cannot provide any assurance that any new rules regarding emerging technologies would be applicable to our future products.

Risks Related to Intellectual Property

If third parties claim that our products infringe their intellectual property rights, we may be forced to expend significant financial resources and management time defending against such actions and our financial condition and our results of operations could suffer.

Third parties may claim that our products infringe their patents and other intellectual property rights. Identifying third-party patent rights can be particularly difficult because, in general, patent applications can be maintained in secrecy for a prolonged period after their earliest priority date. Historically, there has been substantial litigation regarding patents and other intellectual property rights in the medical device and related industries. If a competitor were to challenge our patents or other intellectual property rights, or assert that our products infringe its patent or other intellectual property rights, we could incur substantial litigation costs, be forced to make expensive changes to our product design, pay royalties or other fees to license rights in order to continue manufacturing and selling our products, or pay substantial damages. Third-party infringement claims, regardless of their outcome, would not only consume our financial resources but also divert our management's time and effort.

If we are unable to protect the intellectual property used in our products, others may be able to copy our innovations which may impair our ability to compete effectively in our markets.

The strength of our patents involves complex legal and scientific questions and can be uncertain. These patent applications may be challenged or fail to result in issued patents, or if issued, these patents and our existing patents may be too narrow to prevent third-parties from developing or designing around our intellectual property and in that event, we may lose competitive advantage, which could result in harm to our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the medical device industry, we may employ individuals who were previously employed at other medical device companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure to or misappropriation by third-parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third-parties. While we require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff were previously employed by other pharmaceutical, medical technology or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their medical device development activities for us.

We may not be able to protect our intellectual property rights throughout the world.

We are dependent on patents. Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These infringing products may compete with the product candidates we may develop, without any available recourse.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, it could be difficult for us to stop the infringement, misappropriation or violation of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and other proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors 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.

Risks Related to Information Technology

Our business and operations would suffer in the event of third-party computer system failures, cyberattacks on third-party systems or deficiency in our cybersecurity.

We rely on information technology ("IT") systems, including third-party "cloud based" service providers, to keep financial records, maintain laboratory data, clinical data, and corporate records, to communicate with staff and external parties and to operate other critical functions. This includes critical systems such as email, other communication tools, electronic document repositories and archives. If any of these third-party information technology providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication failures, electrical failures, cyberattacks or cyber-intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised, and we are unable to connect with third-party IT providers. The risk of a security breach or disruption, particularly through cyberattacks or cyber-intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, we rely on those third parties to safeguard important confidential personal data regarding our employees and subjects enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in a third-party IT provider's operation, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidates could be delayed or could fail.

Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Cybersecurity risks and cyber incidents could adversely affect our business and disrupt operations.

Cyber incidents can result from deliberate attacks or unintentional events. These incidents can include, but are not limited to, gaining unauthorized access to digital systems for purposes of misappropriating assets or sensitive information, corrupting data, or causing operational disruption. The result of these incidents could include, but are not limited to, disrupted operations, misstated financial data, liability for stolen assets or information, increased cybersecurity protection costs, litigation and reputational damage adversely affecting customer or investor confidence. We are in the process of implementing systems and processes to focus on identification, prevention, mitigation and resolution. However, these measures cannot provide absolute security, and our systems may be vulnerable to cybersecurity breaches such as viruses, hacking, and similar disruptions from unauthorized intrusions. In addition, we rely on third party service providers to perform certain services, such as payroll and tax services. Any failure of our systems or third-party systems may compromise our sensitive information and/or personally identifiable information of our employees or patient health information subject to HIPAA confidentiality requirements. While we are in the process of securing cyber insurance to potentially cover certain risks associated with cyber incidents, there can be no assurance the insurance will be sufficient to cover any such liability.

Risks Related to our Common Stock

Concentration of ownership of our common stock among our existing executive officers and directors may prevent new investors from influencing significant corporate decisions.

Our executive officers and directors, and their affiliates, who are our principal stockholders, in the aggregate, beneficially own approximately 14.2% of our outstanding common stock as of the date hereof. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions. The minority stockholders have no way of overriding decisions made by our principal stockholders. This level of control may also have an adverse impact on the market value of our shares because our principal stockholders may institute or undertake transactions, policies or programs that result in losses and may not take any steps to increase our visibility in the financial community and/or may sell sufficient numbers of shares to significantly decrease our price per share.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid cash dividends on our capital stock. Subject to any series of preferred stock we may issue in the future, we intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Accordingly, shareholders may have to sell some or all of their shares of our common stock in order to generate cash flow from an investment in our common stock.

If our stock price fluctuates, you could lose a significant part of your investment.

The market price of our common stock may be subject to wide fluctuations in response to, among other things, the risk factors described in this filing and other factors beyond our control, such as fluctuations in the valuation of companies perceived by investors to be comparable to us. Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political, and market conditions, such as recessions, interest rate changes or international currency fluctuations, may negatively affect the market price of our common stock. In the past, many companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Techniques employed by short sellers may in the future drive down the market price of our common stock.

Short selling is the practice of selling securities that the seller does not own but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have led to selling of shares in the market. Issuers that have common stock with limited trading volumes and/or have been susceptible to relatively high volatility levels, can be particularly vulnerable to such short seller attacks. The publication of any such articles regarding us in the future may bring about a temporary, or possibly long-term, decline in the market price of our common stock. If we continue to be the subject of unfavorable allegations, we may have to expend a significant amount of resources to investigate such allegations and/or defend ourselves. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which we can proceed against the relevant short seller by applicable state law or issues of commercial confidentiality. Such a situation could be costly, and time-consuming, and could be distracting for our management team.

If securities or industry analysts do not publish research or reports about us, or if they adversely change their recommendations regarding our common stock, then our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us, our industry and our market. If no analyst elects to cover us and publish research or reports about us, the market for our common stock could be severely limited and our stock price could be adversely affected. As a small-cap company who has recently completed its IPO pursuant to Regulation A, we are more likely than our larger competitors to lack coverage from securities analysts. In addition, even if we receive analyst coverage, if one or more analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. If one or more analysts who elect to cover us issue negative reports or adversely change their recommendations regarding our common stock, our stock price could decline.

The market price of our stock may be highly volatile, and you could lose all or part of your investment.

The market for our common stock may be characterized by significant price volatility when compared to the shares of larger, more established companies that have large public floats, and we expect that our stock price will be more volatile than the shares of such larger, more established companies for the indefinite future. The stock market in general, and the market for stocks of technology companies in particular, has recently been highly volatile. Furthermore, there have been recent instances of extreme stock price run-ups followed by rapid price declines and stock price volatility following a number of recent initial public offerings, particularly among companies with relatively smaller public floats. We may also experience such volatility, including stock run-ups, which may be unrelated to our actual or expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our common stock.

Your ownership may be diluted if additional capital stock is issued to raise capital, to finance acquisitions or in connection with strategic transactions.

We intend to seek to raise additional funds, finance acquisitions or develop strategic relationships by issuing equity or convertible debt securities, which would reduce the percentage ownership of our existing stockholders. Our board of directors has the authority, without action or vote of the stockholders, to issue all or any part of our authorized but unissued shares of common or preferred stock. Our certificate of incorporation authorizes us to issue up to 500,000,000 shares of common stock and 10,000,000 shares of preferred stock. Future issuances of common or preferred stock would reduce your influence over matters on which stockholders vote and would be dilutive to earnings per share. In addition, any newly issued preferred stock could have rights, preferences and privileges senior to those of the common stock. Those rights, preferences and privileges could include, among other things, the establishment of dividends that must be paid prior to declaring or paying dividends or other distributions to holders of our common stock or providing for preferential liquidation rights. These rights, preferences and privileges could negatively affect the rights of holders of our common stock, and the right to convert such preferred stock into shares of our common stock at a rate or price that would have a dilutive effect on the outstanding shares of our common stock.

We may be required to issue up to 271,846 shares of common stock in connection with the reverse stock split we completed on October 24, 2024, and we may be subject to potential liability if it is determined that we are required to issue such shares and we fail to issue such shares on a timely basis.

On October 24, 2024, we completed a one-for-twenty reverse stock split of our common stock. In connection with the approval of the reverse stock split, we agreed that no fractional shares will be issued in connection with the reverse stock split and that we would issue one full share of the post-reverse stock split common stock to any shareholder who would have been entitled to receive a fractional share as a result of the process. On November 1, 2024, we received notice from DTCC on behalf of the brokerage firms that hold the shares of our common stock held in "street name" that in connection with the foregoing rounding of shares we would need to issue 271,846 shares of common stock.

We do not believe the number of shares being requested is correct based on the historical number of shareholders of our common stock and have begun an inquiry into the calculations set forth in the request. During the pendency of this inquiry, we do not expect to issue any shares in connection with the fractional shares being requested. We may face potential liability for our failure to issue the shares of common stock if it is determined that we are required to issue such shares. In addition, our shareholders will be diluted to the extent of any issuances of shares of common stock in connection with the foregoing.

If we are unable to maintain compliance with the listing requirements of The Nasdaq Capital Market, our common stock may be delisted from The Nasdaq Capital Market which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares.

Our common stock is listed on The Nasdaq Capital Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly held shares, market value of listed shares, minimum bid price per share, and minimum stockholder's equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from The Nasdaq Capital Market.

We have in the past, and we may again in the future, fail to comply with the continued listing requirements of the Nasdaq Capital Market, which would subject our common stock to being delisted. Delisting from The Nasdaq Capital Market would adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

Provisions of the Series A Warrants we issued in our offering could discourage an acquisition of us by a third party.

The Series A Warrants we issued in our November 2024 offering provide that in the event of a "Fundamental Transaction" (as defined in the related warrant agreement, which generally includes any merger with another entity, the sale, transfer or other disposition of all or substantially all of our assets to another entity, or the acquisition by a person of more than 50% of our common stock), each Series A Warrant holder will have the right at any time prior to the consummation of the Fundamental Transaction to require us to repurchase the common warrant for a purchase price in cash equal to the Black-Scholes value (as calculated under the warrant agreement) of the then remaining unexercised portion of such Series A Warrant on the date of such Fundamental Transaction, which may materially adversely affect our financial condition and/or results of operations and may prevent or deter a third party from acquiring us.

General Risks

Shareholder activism could cause material disruption to our business.

Publicly traded companies have increasingly become subject to campaigns by activist investors advocating corporate actions such as actions related to environment, social and governance (ESG) matters, among other issues. Responding to proxy contests and other actions by such activist investors or others in the future could be costly and time-consuming, disrupt our operations and divert the attention of our Board of Directors and senior management from the pursuit of our business strategies, which could adversely affect our results of operations and financial condition.

As an "emerging growth company" under the Jumpstart Our Business Startups Act, or JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements.

As an "emerging growth company" under the JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. We are an emerging growth company until the earliest of:

- the last day of the fiscal year during which we have total annual gross revenues of $1.235 billion or more;
- the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common equity pursuant to an effective registration statement under the Securities Act of 1933;
- the date on which we have, during the previous 3-year period, issued more than $1 billion in non-convertible debt; or
- the date on which we are deemed a "large accelerated issuer" as defined under the federal securities laws.

For so long as we remain an emerging growth company, we will not be required to:

- have an auditor report on our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;
- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis);
- submit certain executive compensation matters to shareholders advisory votes pursuant to the "say on frequency" and "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010;
- include detailed compensation discussion and analysis in our filings under the Securities Exchange Act of 1934, as amended, and instead may provide a reduced level of disclosure concerning executive compensation;
- may present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A; and
- are eligible to claim longer phase-in periods for the adoption of new or revised financial accounting standards under §107 of the JOBS Act.

We intend to take advantage of all of these reduced reporting requirements and exemptions.

- Certain of these reduced reporting requirements and exemptions will already be available to us due to the fact that we also qualify as a "smaller reporting company" under Commission rules. For instance, smaller reporting companies are not required to obtain an auditor attestation and report regarding management's assessment of internal control over financial reporting; are not required to provide a compensation discussion and analysis; are not required to provide a pay-for-performance graph or CEO pay ratio disclosure; and may present only two years of audited financial statements and related MD&A disclosure.

We cannot predict if investors will find our securities less attractive due to our reliance on these exemptions. If investors were to find our common stock less attractive as a result of our election, we may have difficulty raising all of the proceeds in any future offering.

Our Certificate of Incorporation includes a forum selection provision, which could result in less favorable outcomes to the plaintiff(s) in any action against us.

Our Certificate of Incorporation includes a forum selection provision that requires any claims against us by stockholders not arising under the federal securities laws to be brought in the Court of Chancery State in the state of Delaware. This forum selection provision may limit investors' ability to bring claims in judicial forums that they find favorable to such disputes and may discourage lawsuits with respect to such claims. In addition, this forum selection provision may impose additional litigation costs on stockholders in pursuing the claims identified above, particularly if the stockholders do not reside in or near the State of Delaware.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

As a public company, we incur accounting, legal and other expenses that we did not incur as a private company. We incur costs associated with our public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, as well as rules and regulations implemented by the United States Security and Exchange Commission ("SEC") and Nasdaq. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. Furthermore, these rules and regulations could make it more difficult or costlier for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We are currently evaluating and monitoring developments with respect to these rules and regulations and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We recognize that cybersecurity is integral to safeguarding our operations, intellectual property, patient data and stakeholder trust. Our cybersecurity risk management processes are designed to assess, identify and mitigate material risks from cybersecurity threats. Despite our best efforts to improve cybersecurity measures, there can be no assurance that our initiatives will fully mitigate the risks posed by cyber threats. The landscape of cybersecurity risks is constantly evolving and we will continue to assess and update our cybersecurity measures in response to emerging threats.

Risk Assessment and Identification

We have implemented security measures as part of an evolving cybersecurity posture and will continue to devote resources to address security vulnerabilities in an effort to prevent cyberattacks and mitigate the damage that could result from such an attack. As the Company does not have a physical office location, it does not have a local network or in-house servers and proprietary applications. We therefore utilize third-party applications and resources to support our information technology ("IT") needs. All applications utilized by the Company are Software as a Service ("SaaS") offerings. As our applications are developed and managed by third parties, we are dependent on these providers for many functions including disaster recovery during a disaster or cyber incident. We prioritize risks based on their potential impact to our financial condition, operational continuity and reputation. Our goal is to only utilize the most secure and trusted providers for our IT needs.

Risk Management Processes

Our cybersecurity strategy integrates multiple layers of defense to manage identified risks:

- Preventive Controls: We deploy advanced firewalls, endpoint protection and intrusion detection systems to secure our network infrastructure. Multi-factor authentication and encryption are enforced across critical systems and data repositories.
- Monitoring and Detection: Continuous monitoring of our IT environment is facilitated through our third-party service provider.
- Incident Response: We maintain an incident response plan that outlines procedures for containment, eradication, and recovery from cybersecurity incidents.
- Employee Training: All employees receive mandatory cybersecurity awareness training at onboarding, covering phishing prevention, secure data handling and how to recognize common attack strategies and reporting suspicious activities.

Third-Party Risk Management

We rely on third-party vendors for certain operational and IT services. To mitigate risks associated with these vendors, we will implement a vendor risk management program that includes:

- Due diligence reviews of third-party vendors' cybersecurity policies and practices prior to, and during, potential engagement.
- Contractual requirements for third-party vendors to maintain robust security controls, where applicable, and report incidents promptly.

Material Impact of Cybersecurity Risks

Cybersecurity threats have the potential to disrupt operations, compromise sensitive data or lead to regulatory penalties. Our proactive risk management processes are designed to minimize the likelihood and impact of such events. As of March 31, 2025, we did not experience any cybersecurity incidents.

Cybersecurity Governance

The Audit Committee is responsible for oversight of cybersecurity risk. Our Chief Executive Officer and Chief Financial Officer are the members of management responsible for managing and assessing our cybersecurity practices. Our Chief Executive Officer and Chief Financial Officer have each served as executive officers of public companies in the past. The plan for the future is that they will report to the Audit Committee on cybersecurity on a semi-annual basis. Should any cybersecurity threat or incident be detected, our senior management team would timely report such threat or incident to the Audit Committee and provide regular communications and updates throughout the incident and any subsequent investigation, in order that the impact, materiality, and reporting requirements of such incident are appropriately identified and assessed for further necessary or appropriate action to be taken.

We believe we are appropriately staffed (as supported by our outsourced IT provider) to support a healthy cybersecurity posture given our size and scope. Our Chief Financial Officer, who reports to the Chief Executive Officer, is directly responsible for IT functions.

To date, there have been no risks identified from cybersecurity threats or previous cybersecurity incidents that have materially affected or are reasonably likely to materially affect the company. However, despite all of the above aforementioned efforts, a cyberattack, if it occurred, could cause system operational problems, disrupt service to clinical trial sites, compromise important data or systems or result in an unintended release of confidential information. See “Item 1A. Risk Factors” for additional discussion of cybersecurity risks impacting our Company.

Item 2. Properties.

We do not own any real property. Our corporate and executive offices are located in a facility in The Woodlands, Texas for which we are under a membership agreement. The current membership agreement terminates in March 2026. We believe that our facilities are sufficient to meet our current needs and that suitable space will be available as and when needed.

Item 3. Legal Proceedings.

From time to time in the ordinary course of our business, we may be involved in legal proceedings, the outcomes of which may not be determinable. The results of litigation are inherently unpredictable. Any claims against us, whether meritorious or not, could be time-consuming, result in costly litigation, require significant amounts of management time and result in diversion of significant resources. However, we are currently not a party to any pending legal actions. We have insurance policies covering any potential losses where such coverage is cost effective.

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.

Our common stock has been listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "AMIX" since our initial public offering ("IPO") on January 29, 2024.

Holders of Common Equity

As of May 1, 2025, we had approximately 4,800 stockholders of record of our common stock. This does not include beneficial owners of our common stock.

Dividends

We have never paid any dividends on our common stock. The payment of dividends in the future will be contingent upon our revenues and earnings, if any, capital requirements and general financial condition. It is the present intention of our board of directors (the "Board") to retain all earnings, if any, for use in our business operations and, accordingly, our Board does not anticipate declaring any dividends in the foreseeable future.

Recent Sales of Unregistered Securities

On March 17, 2025, we granted a new employee a ten-year option (the "Inducement Options") to purchase 7,500 shares of common stock at an exercise price equal to the closing price of our common stock on the date of the employment. The option vests in four equal annual installments (or 1,875 shares each installment) on each of the succeeding four anniversary dates of the execution of the date of employment, provided the employee is employed by us on each vesting date.

On April 17, 2025, we granted a new employee a ten-year option (the "Inducement Options") to purchase 5,000 shares of common stock at an exercise price equal to the closing price of our common stock on the date of the employment. The option vests in four equal annual installments (or 1,250 shares each installment) on each of the succeeding four anniversary dates of the execution of the date of employment, provided the employee is employed by us on each vesting date.

The two Inducement Options above were granted outside of our 2023 Stock Plan as an inducement material to the employee entering into employment with us in accordance with Nasdaq Stock Market Listing Rule 5635(c)(4). All the securities were issued in reliance on the exemption provided by Section 4(a)(2) of the Securities Act for the offer and sale of securities not involving a public offering, and/or Regulation D promulgated under the Securities Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the year ended March 31, 2025.

Shares Forgone to Pay Exercise Price of Shares

During the year ended March 31, 2025, 892,432 shares of common stock were issued to shareholders as their warrants were exercised. The terms of the warrants provide that a holder may conduct a cashless exercise of the warrants. For the year ended March 31, 2025, 2,602 shares of common stock were forfeited by shareholders through cashless exercises with an average price paid per share of $0.20.

Stock Performance Graph

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties, including those set forth under "Cautionary Statement About Forward-Looking Statements." Actual results and the timing of events could differ materially from those discussed and other expectations expressed in our forward-looking statements as a result of many factors, including but not limited to those discussed in this Item and in Item 1A - "Risk Factors.". Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We are a development stage medical device company focused on advancing innovative technologies for sensing and treating disorders relating to the nervous system. Our first-in-class technology platform includes a catheter-based microchip-enabled sensing array that can detect and differentiate neural signals with a high degree of sensitivity as demonstrated in animal studies.

We are initially developing our technology for patients with pancreatic cancer, a condition that can cause debilitating pain and need a more effective solution. However, we believe our technology constitutes a platform with the potential to address dozens of indications in a range of areas including chronic pain management from all causes, hypertension, cardiovascular disease and a wide range of other nerve-related disorders.

Our development efforts can be divided into two parts: diagnostic sensing and therapeutic radiofrequency ablation, where diagnostic is focused on sensing and identifying disorder-related neuronal activity with enough precision to enable targeted therapy with ablation. Our sensing technology has already successfully demonstrated, in animal models, the ability to successfully identify a signal from a specific nerve bundle before ablation and confirmation of termination of that signal from the treated nerves after ablation. We are now in the process of improving the design of this catheter to meet the standards required for human use. In parallel with this effort, we completed our initial trial phase of our first-in-human proof-of-concept trial ("PoC 1") evaluating the safety and effectiveness of delivering transvascular energy to ablate relevant problematic nerves and mitigate pain in patients with pancreatic cancer pain, with the intent to bring sensing and treatment together in a future pivotal clinical trial to enable the commercial launch of our technology. As a result of the positive results from PoC 1, we have expanded the protocol into a follow-on phase ("PoC 2"), now including pain management for additional visceral cancers, like pancreatic, gall bladder, liver, and bile duct, with potential further expansion in oncology, gastroenterology, and other sectors, as well as earlier stage pancreatic cancer patients experiencing moderate to severe pain.

Recent Developments

On February 28, 2025, we entered into an At Market Issuances Sales Agreement (the "ATM Agreement") with Ladenburg Thalmann & Co. Inc. (the "Agent"). Pursuant to the terms of the ATM Agreement, the we may sell from time to time through the Agent, as sales agent or principal, shares of our common stock with an initial aggregate sales price of up to $2.1 million (the "Shares"). Any sale of Shares pursuant to the ATM Agreement will be made under our "shelf" registration statement on Form S-3 filed on February 28, 2025 with the Securities and Exchange Commission. Under the ATM Agreement, we may sell Shares through the Agent by any method that is deemed an "at the market offering" (as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended). Under the ATM Agreement, the Agent will also be able to sell shares of common stock by any other method permitted by law, including in negotiated transactions with our prior written consent. We will pay a commission to the Agent of 3.0% of the gross proceeds of the sale of the Shares sold under the ATM Agreement and reimburse the Agent for certain expenses.

Results of Operations for the Year Ended March 31, 2025 Compared to the Year Ended March 31, 2024

Below is a summary of the results of operations (in thousands):

	Year Ended March 31,			
	2025	2024	Change ($)	Change (%)
Operating expenses:				
General and administrative	$ 6,863	$ 5,249	$ 1,614	31%
Research and development	4,725	2,225	2,500	112%
Warrant expense - termination agreement	—	4,556	(4,556)	—
Total operating expenses	$ 11,588	$ 12,030	$ (442)	-4%

General and Administrative ("G&A"). G&A expenses increased by $1.6 million compared to the same period in 2024, primarily due to increases in officer and employee compensation and benefits of $1.5 million, stock-based compensation of $0.9 million, legal and professional fees of $0.4 million, insurance expense of $0.3 million, franchise tax of $0.3 million, board of directors compensation of $0.1 million offset by a decrease in advertising expense of $1.8 million related to our IPO in 2024 and travel and entertainment expense of $0.1 million.

Research and Development ("R&D"). R&D expenses increased by $2.5 million compared to the same period in 2024, primarily due to clinical trial execution and product development cost. We expect to incur increased research and development costs in the future as we continue our clinical trial and product development efforts.

Warrant expense – termination agreement

Warrant Expense – termination agreement was $0 in 2025. Warrant Expense – termination agreement was $4.6 million in 2024. related to a license termination agreement. See *Note 2 - Warrant Liability and Fair Value of Financial Instruments* to the financial statements for additional information.

Other Income/Expense

Warrant liability mark-to-market

Warrant Liability - mark-to market adjustment was $0 in 2025. Warrant Liability - mark-to market adjustment was $3.4 million in 2024.

Interest expense

Interest expense was $0.2 million in 2025 and $0.1 million in 2024 related to the amortization of debt discounts.

Interest income

Interest income was $0.4 million in 2025 and $0.1 million in 2024 due to relatively higher cash balances throughout the year in 2025 as compared to 2024.

Liquidity and Capital Resources

On March 31, 2025, we had cash of $9.1 million and working capital of $7.9 million. We have historically funded our operations from proceeds from debt and equity sales.

In June 2023, we completed a financing with several accredited investors for the sale of 71,001 shares of common stock with gross proceeds of $2.8 million. Additionally, we received proceeds of $2.0 million in unsecured, non-interest bearing convertible promissory notes (the “Notes”) and accompanying warrants (the “Bridge Financing Warrants”) (collectively, the “Bridge Offering”) that will mature on December 31, 2025. On January 26, 2024, we completed our IPO of common stock. In the IPO, we sold a total of 111,962 shares of common stock at a purchase price of $100.00 per share for gross proceeds of $11.2 million and net proceeds of $9.8 million.

On November 22, 2024, we completed a firm commitment underwritten public offering (the "Offering") of: (i) 458,691 common units (the "Common Units"), each Common Unit consisting of one share of common stock and one series A warrant to purchase one share of common stock (the "Series A Warrants"); and (ii) 917,596 pre-funded units (the "Pre-Funded Units") and together with the Common Units, the "Units", each Pre-Funded Unit consisting of one pre-funded warrant to purchase one share of common stock (the "Pre-Funded Warrant") and one Series A Warrant. The purchase price of each Common Unit was $6.540, and the purchase price of each Pre-Funded Unit was $6.539. In addition, we granted the underwriters in the Offering a 45-day option to purchase an additional 206,422 shares of common stock, and/or an additional 206,422 Series A Warrants, solely to cover over-allotments, if any. The Pre-Funded Warrants have an exercise price of $0.001 per share, are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The Series A Warrants have an exercise price of $6.540 per share, are immediately exercisable and may be exercised at any time until the five-year anniversary of the date of issuance. Both the Pre-Funded Warrants and the Series A Warrants are subject to a beneficial ownership limitation of 4.99%. The Offering closed on November 25, 2024. On November 22, 2024, the underwriters partially exercised their over-allotment option with respect to 156,809 shares of common stock and 156,809 Series A Warrants. The aggregate gross proceeds, including the partial exercise of the over-allotment option, were approximately $10.0 million, before deducting underwriting discounts and other expenses by us of $1.5 million, including $0.5 million of non-cash expenses. The net cash proceeds to us were approximately $9.0 million.

On February 28, 2025, we entered into an ATM Agreement. Pursuant to the terms of the ATM Agreement, we may sell, from time to time, shares of our common stock with an initial aggregate sales price of up to $2.1 million (the "Shares"). As of March 31, 2025, we have sold 800 Shares pursuant to the ATM Agreement for net proceeds of approximately $1,746.

We estimate our current cash resources are sufficient to fund our operations into but not beyond the first calendar quarter of 2026.

Our plan of operations is primarily focused on developing our product candidate, with the product candidate in the proof-of-concept stage at this time. We are initially focusing on the treatment of pain associated with pancreatic cancer and we have designed our commercialization efforts around this as our first proposed indication for use.

We will need to raise additional capital to meet our obligations and execute our business plan. We estimate that we will require additional financing in the range of $32 to $40 million to fund our operations through initial commercial launch. The timing and costs of clinical trials are difficult to predict and trial plans may change in response to evolving circumstances and as such the foregoing estimates may prove to be inaccurate. If we are unable to raise sufficient funds, we will be required to develop and implement an alternative plan to further extend payables, reduce overhead or scale back our business plan until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

Summary of Cash Flows

Cash used in operating activities

Net cash used in operating activities was $8.3 million during the year ended March 31, 2025, consisting of a net loss of $11.4 million and an increase in operating assets and liabilities of $1.2 million. The change in operating assets and liabilities included sources of cash from a decrease in other current assets of $0.3 million and an increase in accounts payable of $0.2 million and accrued expenses of $0.7 million. The increases in accounts payable and accrued expenses were driven primarily by increased research and development costs for the development of our medical devices, general and administrative costs consisting of professional fees, officer compensation and legal expenses. The increase in other current assets was driven primarily by prepaid insurance costs. Non-cash items consisted of stock-based compensation of $1.6 million, depreciation and amortization of $0.2 million and issuance of common stock, net of discount for lack of marketability of $0.1 million.

Net cash used in operating activities was $6.6 million during the year ended March 31, 2024, consisting of a net loss of $15.4 million and an increase in operating assets and liabilities of $0.1 million. The change in operating assets and liabilities included sources of cash from an increase in accounts payable of $0.3 million and accrued expenses of $0.3 million offset by a use of cash for other current assets of $0.5 million. The increases in accounts payable and accrued expenses were driven primarily by increased research and development costs for the development of our medical devices, general and administrative costs consisting of professional fees, officer compensation and legal expenses. The increase in other current assets was driven primarily by prepaid insurance costs. Non-cash items consisted of $4.6 million for warrant expense – termination agreement, $3.4 million for warrant liability – mark-to-market adjustment, stock-based compensation of $0.6 million and depreciation and amortization of $0.1 million.

Cash used in investing activities

Net cash used in investing activities was $14 thousand and $19 thousand, respectively, for the year ended March 31, 2025 and March 31, 2024, respectively, related to the purchase of computer hardware and software.

Cash provided by financing activities

Net cash provided by financing activities was $8.8 million for the year ended March 31, 2025, consisting of $10.0 million of gross proceeds from the Offering. We also paid $1.1 million in issuance costs for this Offering and $0.2 million in issuance costs for a subsequent registration statement.

Net cash provided by financing activities was $14.4 million for the year ended March 31, 2024, consisting of $10.9 million of gross proceeds from our IPO, $2.8 million from a financing with several accredited investors and $2.0 million from the Notes. We also paid $1.3 million in issuance costs related to our IPO.

Contractual Obligations and Commitments

None.

Employment Arrangements

We have agreements with key employees to provide certain benefits, including salary and other wage-related benefits, in the event of termination. In addition, we have adopted a severance policy for certain key members of executive management to provide certain benefits, including salary and other wage-related benefits, in the event of termination without cause. In total, these benefits would amount to a range of $1.1 million to $1.6 million using the rate of compensation in effect at March 31, 2025.

Off-balance Sheet Arrangements

As of March 31, 2025 and March 31, 2024, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Significant Judgments and Estimates

The financial statements in this annual report have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). The preparation of financial statements in conformity with GAAP requires management to make estimates, assumptions and judgments that affect the amounts reported in the financial statements, including the notes thereto. We consider critical accounting policies to be those that require more significant judgments and estimates in the preparation of our financial statements, including the following: research and development expenses, warrants, and stock-based compensation. Management relies on historical experience and other assumptions believed to be reasonable in making its judgments and estimates. Actual results could differ materially from those estimates.

Management believes its application of accounting policies, and the estimates inherently required therein, are reasonable. These accounting policies and estimates are periodically reevaluated, and adjustments are made when facts and circumstances dictate a change.

Our accounting policies are more fully described under the heading "Description of the Business, Basis of Presentation and Summary of Significant Accounting Policies" in Note 1 to our Financial Statements included in this Annual Report on Form 10-K.

We believe that the following accounting policies are the most critical to aid in fully understanding and evaluating our reported financial results, and they require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain.

Components of our Results of Operations and Financial Condition

Operating expenses

We classify our operating expenses into three categories: (i) research and development, (ii) general and administrative and (iii) warrant expense – termination agreement.

Research and development. Research and development expenses consist primarily of:

- costs incurred to conduct research, such as animal research;
- costs related to the design and development of our technology, including fees paid to contract engineering firms and contract manufacturers;
- salaries and expenses, including stock-based compensation, related to our employees primarily engaged in research and development activities;
- fees paid to clinical consultants, clinical trial sites and vendors, including clinical research organizations, in preparation for clinical trials and our applications with the FDA;
- costs to develop our intellectual property; and
- costs related to compliance with regulatory requirements.

We expect our research and development expenses to increase in the future as we advance our product into and through clinical trials, pursue additional regulatory approvals of our product in the United States, and continue commercial development of our device(s). The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The probability of success for our technology may be affected by a variety of factors including: the quality of our product, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability. We may not succeed in achieving all necessary regulatory approvals for our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development process or when and to what extent, if any, we will generate revenue from the commercialization and sale of our device.

General and administrative

General and administrative expenses consist of personnel related costs, which include salaries, as well as the costs of professional services, such as accounting and legal, facilities, information technology, stock-based compensation for general and administrative personnel, insurance, travel costs and other administrative expenses and costs to defend our patents. We expect our general and administrative expenses to increase due to the anticipated growth of our business and related infrastructure, as well as accounting, insurance, investor relations and other costs associated with being a public company.

Advertising

It is our policy to expense advertising costs as incurred. Advertising expenses are included within general and administrative expenses within the statement of operations. For the years ended March 31, 2025 and 2024, the Company recorded less than $0.1 million and $1.8 million, respectively.

Stock-based compensation

Stock-based compensation transactions are recognized as compensation expense in the statements of operations based on their fair values on the date of the grant. The expense for equity awards expected to vest is recognized over the applicable vesting period of the stock award using either the straight-line method or the accelerated method, depending on the vesting structure, and is included in general and administrative. We estimate the fair value of options granted using the Black-Scholes option pricing model. This estimate uses assumptions regarding a number of inputs that require us to make significant estimates and judgments. The expected volatility assumption was based on industry peer information.

Accounting for Warrants

We issued warrants to purchase shares of common stock (i) in connection with the Bridge Offering, (ii) in connection with the Exclusive License Termination Agreement (the "Termination Agreement"), and (iii) as part of selling agent compensation in our IPO and as part of the November 2024 financing. We accounted for such warrants in accordance with Accounting Standards Codification ("ASC") Topic 480-10, *Distinguishing Liabilities from Equity* and ASC Topic 815-40*, Derivatives and Hedging – Contracts in Entity's Own Equity.* Based on this guidance, we determined that warrants issued in connection with the Termination Agreement should be accounted for as a liability and the remaining warrants issued meet the requirements for equity classification. Liability classified warrants are subject to remeasurement at each balance sheet date, while equity classified warrants are valued at inception only.

Bridge Financing Warrants

The fair value of the Bridge Financing Warrants is estimated using a Monte Carlo simulation model with probability-weighted expected return method ("PWERM") based on the probabilities of different potential outcomes for the Notes issued with the Bridge Financing Warrants. The outcomes considered included (i) qualified financing as part of our planned IPO at various points in time and (ii) repayment in cash at maturity. Any increase in the amount of time expected until a qualified financing event and/or a reduction in the likelihood of a qualified financing event occurring during the term of the Notes would likely increase the fair value of the warrant, while the inverse of each scenario would have the opposite effect. The significant judgments and assumptions to the Monte Carlo simulation include the Company's stock price, volatility based on a selection of publicly held peer companies, discount rate, and a discount for lack of marketability.

Common Stock Fair Value – The fair value of our common stock price was determined through a back solve, solving for the stock price that results in the average total value of the Notes and the warrants being equal to the cash proceeds received in the transaction it was issued at across one million iterations of the simulation.

Historical Volatility – We determine the expected volatility by weighing the historical average volatilities of publicly traded industry peers. Our intention is to consistently apply this methodology using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our common stock becomes available. We will monitor our peer group for circumstances that may require a change to the composition or make-up of the entities and will identify if/when more suitable companies whose stock prices are publicly available would be utilized in the calculation.

Discount Rate - The rate is chosen based on private equity rates of return as described in the AICPA Practice Aid on Valuation of Privately-Held-Company Equity securities Issued as Compensation, choosing the rate at the lower end of the range.

Credit Rating – Our credit rating impacts the identification and calculation of the discount rate.

Discount for lack of marketability – Subsequent to the IPO, any shares issued pursuant to an exercise of the Bridge Financing Warrants, would be subject to a six-month lock-up. Consistent with AICPA's Accounting and Valuation Guide: Valuation of Privately-Held-Company Equity Securities Issued as Compensation, the Finnerty model was used to estimate the discount for lack of marketability.

The fair value of the Notes and Bridge Financing Warrants is calculated such that they will combine to equal the cash purchase price of the Bridge Offering. Any changes in these assumptions will impact how the transaction price from the Bridge Offering is distributed between the Notes and the Bridge Financing Warrants.

Termination Agreement Warrants

The fair value of the Termination Agreement Warrants is estimated using a discounted cash flow model under various scenarios and used the probability-weighted expected return method ("PWERM") comparing the probabilities of different outcomes. The outcomes considered included (i) qualified financing as part of our planned IPO at various points in time and (ii) possibility of default whereby the investor receives nothing. Any increase in the amount of time expected until a qualified financing event and/or a reduction in the likelihood of a qualified financing event occurring during the term of the warrant would decrease the fair value of the warrant, while the inverse of each scenario would have the opposite effect.

Additional significant assumptions and judgments used in preparing the discounted cash flow model include:

Discount Rate - The rate is chosen based on private equity rates of return as described in the AICPA Practice Aid on Valuation of Privately-Held-Company Equity Securities Issued as Compensation, choosing the rate at the lower end of the range.

Credit Rating – Our credit rating impacts the identification and calculation of the discount rate.

Any ongoing improvements in our credit rating would have the effect of driving down the discount rate used in the periodic re-measurement of the Termination Agreement warrants. Reductions in the Company's discount rate would increase the fair value of the Termination Agreement warrants, while an increase in this factor will have an opposite effect.

Other Warrants

The fair value of equity-based warrants issued is estimated using the Black-Scholes option pricing model. The significant judgments and assumptions used in applying the Black-Scholes option pricing model include the underlying common stock at the measurement dates, the expected term, expected dividend yield and historical volatility of comparable companies' stock.

Common Stock Fair Value – Prior to our IPO, we periodically sold shares of our common stock for cash in an arms-length transaction. We consider these transactions as indicative of the fair value of our common stock when applying the Black-Scholes option pricing model. Subsequent to our IPO, we base the value of our shares on observable share data.

Expected Term – The estimate of the expected term of awards was determined in accordance with the contractual term of the arrangement.

Expected Dividend Yield – We have not declared or paid any cash dividends and do not presently intend to pay any in the foreseeable future. We have no plans or expectations that this assumption will change in the foreseeable future.

Historical Volatility – We determine the expected volatility by weighing the historical average volatilities of publicly traded industry peers. Our intention is to consistently apply this methodology using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our common stock becomes available. We will monitor our peer group for circumstances that may require a change to the composition or make-up of the entities and will identify if/when more suitable companies whose stock prices are publicly available would be utilized in the calculation.

A decrease in volatility and expected term will decrease the estimated fair value of the warrant, while an increase in these factors will have an opposite effect.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Shareholders, Board of Directors, and Audit Committee
Autonomix Medical, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Autonomix Medical, Inc. (the "Company") as of March 31, 2025 and 2024, the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended March 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of March 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years in the two-year period ended March 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has an accumulated deficit since inception, has not generated revenue from operations, and does not expect to experience positive cash flows from operating activities in the near term. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to this matter are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits.

We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 include 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.

/s/ Forvis Mazars, LLP

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

Atlanta, Georgia
May 29, 2025

Autonomix Medical, Inc.
Balance Sheets

(in thousands, except par value and share data)	As of March 31, 2025	As of March 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 9,136	$ 8,608
Other current assets	473	783
Total current assets	9,609	9,391
Long-term assets:		
Fixed assets, net	21	16
Deferred offering costs	176	—
Total long-term assets	197	16
Total Assets	**$ 9,806**	**$ 9,407**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 676	$ 492
Accrued expenses	1,031	285
Total current liabilities	1,707	777
Long-term liabilities:		
Long term debt - convertible notes, net of unamortized debt discount	—	1,002
Total long-term liabilities	—	1,002
Total Liabilities	**1,707**	**1,779**
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of March 31, 2025 and March 31, 2024, respectively.	—	—
Common stock, $0.001 par value, 500,000,000 shares authorized, 2,497,033 and 942,575 shares issued and outstanding as of March 31, 2025 and March 31, 2024, respectively.	2	1
Additional paid-in capital	58,476	46,596
Accumulated deficit	(50,379)	(38,969)
Total Stockholders' Equity	**8,099**	**7,628**
Total Liabilities and Stockholders' Equity	**$ 9,806**	**$ 9,407**

See accompanying notes to the financial statements

Autonomix Medical, Inc.
Statements of Operations

(in thousands, except share and per share data)	For the Years Ended March 31, 2025	2024
Operating expenses:		
General and administrative	$ 6,863	$ 5,249
Research and development	4,725	2,225
Warrant expense - termination agreement	—	4,556
Total operating expenses	11,588	12,030
Loss from operations	(11,588)	(12,030)
Other income (expense):		
Warrant liability - mark-to-market	—	(3,444)
Interest expense	(176)	(79)
Interest income	354	127
Total other income (expense)	178	(3,396)
Loss before income taxes	(11,410)	(15,426)
Income taxes	—	—
Net loss	$ (11,410)	$ (15,426)
Loss per share - basic and diluted	$ (6.46)	$ (14.82)
Weighted average shares outstanding - basic and diluted	1,766,425	1,040,720

See accompanying notes to the financial statements

Autonomix Medical, Inc.
Statements of Changes in Stockholders' Equity

(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance March 31, 2023	**617**	**$ 1**	**$ 24,186**	**$ (23,543)**	**$ 644**
Net loss	—	—	—	(15,426)	(15,426)
Stock-based compensation	—	—	618	—	618
Issuance of common stock	105	—	2,840	—	2,840
Issuance of common stock from IPO, net of costs	111	—	9,875	—	9,875
Issuance of common stock for extinguishment of convertible debt	17	—	500	—	500
Issuance of common stock - warrants exercised	91	—	—	—	—
Issuance of restricted common stock	2	—	—	—	—
Warrants issued for debt issuance costs	—	—	577	—	577
Fair value of warrants issued - termination agreement	—	—	8,000	—	8,000
Balance March 31, 2024	**943**	**1**	**46,596**	**(38,969)**	**7,628**
Net loss	—	—	—	(11,410)	(11,410)
Stock-based compensation	—	—	1,628	—	1,628
Issuance of common stock	13	—	103	—	103
Issuance of common stock - warrants exercised	892	1	—	—	1
Issuance of common shares and equity classified warrants, net of offering costs	616	—	8,972	—	8,972
Issuance of common stock for extinguishment of convertible debt	33	—	1,177	—	1,177
Balance March 31, 2025	**2,497**	**$ 2**	**$ 58,476**	**$ (50,379)**	**$ 8,099**

See accompanying notes to the financial statements

Autonomix Medical, Inc.
Statements of Cash Flows

(in thousands)	For the Years Ended March 31, 2025	2024
Cash Flows from Operating Activities:		
Net loss	$ (11,410)	$ (15,426)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,628	618
Depreciation and amortization expense	183	81
Issuance of common stock, net of discount for lack of marketability	101	—
Warrant expense - termination agreement	—	4,556
Warrant liability - mark-to-market	—	3,444
Changes in operating assets - (increase)/decrease:		
Other current assets	310	(478)
Changes in operating liabilities - increase:		
Accounts payable	184	320
Accrued expenses	746	237
Net cash used in operating activities	**(8,258)**	**(6,648)**
Cash Flows from Investing Activities:		
Purchase of property and equipment	(14)	(19)
Net cash used in investing activities	**(14)**	(19)
Cash Flows from Financing Activities (increase/decrease):		
Issuance of common stock, pre-funded and common warrants	10,025	—
Payment of issuance costs for financing	(1,052)	—
Payment of issuance costs for registration statement	(176)	—
Proceeds from exercise of warrants	1	—
Proceeds from sales of common stock	2	—
Issuance of common stock	—	2,840
Issuance of convertible debt	—	2,000
Issuance of common stock from IPO	—	10,866
Payment of issuance costs for IPO	—	(1,296)
Net cash provided by financing activities	**8,800**	14,410
Net change in cash and cash equivalents	528	7,743
Cash and cash equivalents, at beginning of period	8,608	865
Cash and cash equivalents, at end of period	$ **9,136**	$ **8,608**
Supplemental cash flow disclosures:		
Non-cash financing activities:		
Warrants issued for equity issuance costs	$ 479	$ —
Proceeds from cashless exercise of warrants	$ 39	$ 2
Warrants issued for debt issuance costs	$ —	$ 577
Fair value of warrants issued for issuance costs as part of IPO	$ —	$ 225
Holdback of IPO proceeds	$ —	$ 305
Convertible notes converted into common stock	$ 1,330	$ 670
Settlement/conversion to common shares for debt issuance costs	$ (153)	$ (170)

See accompanying notes to the financial statements

Autonomix Medical, Inc.
Notes to the Financial Statements

Note 1 – Description of the Business, Basis of Presentation and Summary of Significant Accounting Policies

Description of the Business

Autonomix Medical, Inc ("we," "our," the "Company") is a medical device company organized as a Delaware corporation on June 10, 2014. The Company is a pre-revenue, clinical stage life sciences company focused on advancing innovative technologies for sensing and treating disorders relating to the peripheral nervous system.

Reverse Stock Split

The Company held its annual meeting of stockholders (the "Annual Meeting") on October 17, 2024. In that Annual Meeting, stockholders of the Company approved an amendment to the Company's amended and restated certificate of incorporation (the "Amendment") to effect the reverse stock split at a ratio in the range of 1-for-2 to 1-for-50, with such ratio to be determined in the discretion of the Company's board of directors and with such reverse stock split to be effected at such time and date, if at all, as determined by the Company's board of directors in its sole discretion prior to the one-year anniversary of the Annual Meeting.

Pursuant to such authority granted by the Company's stockholders, the Company's board of directors approved a one-for- twenty (1:20) reverse stock split (the "Reverse Stock Split") of the Company's common stock and the filing of the Amendment to effectuate the Reverse Stock Split. The Amendment was filed with the Secretary of State of the State of Delaware and the Reverse Stock Split became effective in accordance with the terms of the Amendment at 11:59 p.m. Eastern Time on October 24, 2024 (the "Effective Time"), and the Company's common stock opened for trading on The Nasdaq Capital Market on October 25, 2024 on a post-split basis, under the existing ticker symbol "AMIX" but with a new CUSIP number 05330T205. The Amendment provided that, at the Effective Time, every twenty shares of the Company's issued and outstanding common stock automatically combined into one issued and outstanding share of common stock, without any change in par value per share, which remained $0.001.

The number of authorized shares of common stock remained at 500 million shares. As a result of the Reverse Stock Split, proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all outstanding stock options, restricted stock unit awards, warrants and convertible notes, which resulted in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock unit awards, warrants and convertible notes and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants.

The Company's stock option awards did not automatically adjust for the Reverse Stock Split. However, the Company chose to exercise its rights under the agreements to adjust the exercise price and number of shares exercisable or issuable upon vesting proportionately for the Reverse Stock Split. Based on the analysis performed, the Company does not need to recognize any additional compensation expense as a result of the modification.

In addition, the number of shares reserved for issuance under the Company's equity compensation plan immediately prior to the Effective Time was reduced proportionately.

No fractional shares were issued as a result of the Reverse Stock Split. Any stockholder who would have been entitled to receive a fractional share as a result of the process was entitled to the rounding up of the fractional share to the nearest whole number. See " Fractional Shares" in Note 5 for further disclosure regarding fractional shares.

The Reverse Stock Split has been retroactively adjusted throughout these interim financial statements and footnotes for all periods presented, including exercise prices and share data. As a result of the Reverse Stock Split, the Company reclassified approximately $18 thousand between common stock par value and additional paid-in capital.

Liquidity and Going Concern

The Company's financial statements are prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company is an early-stage company that is subject to all the risks associated with early-stage and emerging growth companies and has incurred losses since inception.

For the years ended March 31, 2025 and 2024, the Company has net losses of approximately $11.4 million and $15.4 million, respectively and had net cash flows used in operating activities of $8.3 million and $6.6 million, respectively. The Company had no revenues for the years ended March 31, 2025 and 2024, respectively. The Company had an accumulated deficit of $50.4 million and working capital of approximately $7.9 million as of March 31, 2025. The Company does not expect to generate positive cash flows from operating activities in the near future. These conditions, and the Company's ability to comply with such conditions, raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying financial statements have been prepared on a going concern basis and do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

On January 26, 2024, the Company completed its IPO, pursuant to which it sold a total of 111,962 shares of common stock at a purchase price of $100.00 per share for gross proceeds of $11.2 million and net proceeds of $9.8 million.

On November 22, 2024, the Company completed a firm commitment underwritten public offering (the “Offering”) of: (i) 458,691 common units (the “Common Units”), each Common Unit consisting of one share of Company common stock and one series A warrant to purchase one share of common stock (the “Series A Warrants”); and (ii) 917,596 pre-funded units (the “Pre-Funded Units”) and together with the Common Units, the "Units", each Pre-Funded Unit consisting of one pre-funded warrant to purchase one share of common stock (the “Pre-Funded Warrant”) and one Series A Warrant. The purchase price of each Common Unit was $6.540, and the purchase price of each Pre-Funded Unit was $6.539. In addition, the Company granted the underwriters in the Offering a 45-day option to purchase an additional 206,422 shares of common stock, and/or an additional 206,422 Series A Warrants, solely to cover over-allotments, if any. The Pre-Funded Warrants have an exercise price of $0.001 per share, are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The Series A Warrants have an exercise price of $6.540 per share, are immediately exercisable and may be exercised at any time until the five-year anniversary of the date of issuance. Both the Pre-Funded Warrants and the Series A Warrants are subject to a beneficial ownership limitation of 4.99%. The Offering closed on November 25, 2024. On November 22, 2024, the underwriters partially exercised their over-allotment option with respect to 156,809 shares of common stock and 156,809 Series A Warrants. The aggregate gross proceeds to the Company, including the partial exercise of the over-allotment option, were approximately $10.0 million, before deducting underwriting discounts and other expenses by the Company of $1.5 million, including $0.5 million of non-cash expenses. The net cash proceeds to the Company were approximately $9.0 million.

On February 28, 2025, the Company entered into an At Market Issuances Sales Agreement (the “ATM Agreement”) with Ladenburg Thalmann & Co. Inc. (the “Agent”). Pursuant to the terms of the ATM Agreement, the Company may sell from time to time through the Agent, as sales agent or principal, shares of the Company’s common stock with an initial aggregate sales price of up to $2.1 million (the “Shares”). Any sale of Shares pursuant to the Agreement will be made under the Company’s “shelf” registration statement (the “Registration Statement”) on Form S-3 filed on February 28, 2025 with the Securities and Exchange Commission (the “SEC”). Under the ATM Agreement, the Company may sell Shares through the Agent by any method that is deemed an “at the market offering” (as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended). Under the ATM Agreement, the Agent will also be able to sell shares of Common Stock by any other method permitted by law, including in negotiated transactions with the Company’s prior written consent. The Company will pay a commission to the Agent of 3.0% of the gross proceeds of the sale of the Shares sold under the ATM Agreement and reimburse the Agent for certain expenses. As of March 31, 2025, the Company sold 800 shares pursuant to the ATM Agreement for net proceeds of approximately $1,746

The Company estimates its current cash resources are sufficient to fund its operations into but not beyond the first calendar quarter of 2026. The Company recognizes it will need to raise additional capital to continue to execute its business plan, including obtaining regulatory clearance for its products currently under development and commercializing and generating revenues from products under development. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company. A failure to raise sufficient capital, generate sufficient product revenues, control expenditures and regulatory matters, among other factors, will adversely impact the Company’s ability to meet its financial obligations as they become due and payable and to achieve its intended business objectives. If the Company is unable to raise sufficient additional funds, it will have to scale back its operations.

Basis of Presentation

The annual financial statements and disclosures have been prepared using the accrual basis of accounting in accordance with U.S. generally accepted accounting principles (“GAAP”).

Use of Estimates in Financial Statement Presentation

The preparation of these financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company's significant estimates and assumptions include the valuation of equity related instruments, and initial and recurring fair value measurements for the warrant liability. Although the Company believes that its estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Some of these judgments can be subjective and complex, and, consequently, actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid accounts with original maturities of three months or less at the date of acquisition to be cash equivalents. Periodically, the Company may carry cash balances at financial institutions in excess of the federally insured limit of $250,000. The Company has not experienced losses on these accounts and management believes, based upon the quality of the financial institutions, that the credit risk with regard to these deposits is not significant.

Offering and Financing Costs

Offering costs consist of professional costs incurred through the balance sheet date that were direct and incremental to the Company’s equity financing activities. Specifically, offering costs were incurred on the Company's IPO, the Offering and the Registration Statement. The costs for the Registration Statement are recorded in deferred offering costs on the balance sheet as of March 31, 2025. Costs associated with salaries and other period costs were expensed as incurred.

During the year ended March 31, 2024, the Company paid $1.3 million of issuance costs related to its IPO.

During the year ended March 31, 2025, the Company paid $1.1 million of issuance costs related to its Offering and $0.2 million of offering costs related to its Registration Statement.

Property and Equipment

Property and equipment are stated at historical cost and depreciated on a straight-line basis over their estimated useful lives, generally three years. Upon disposition of the assets, the costs and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations.

Convertible Notes

The Company evaluates embedded redemption, conversion and other features within its debt to determine whether any embedded features should be bifurcated from the host instrument and accounted for as a derivative at fair value, with changes in fair value recorded in the statement of operations.

The Company’s debt is carried on the balance sheet on a historical cost basis net of unamortized discounts and premiums because the Company has not elected the fair value option of accounting. Costs associated with acquiring debt, including detachable warrants issued in connection with the financing, are capitalized as a debt discount. The debt discount is presented in the balance sheet as a direct deduction from the carrying amount of the debt liability. The costs are amortized over the estimated contractual life of the related debt instrument using the effective interest method and are included in interest expense in the statement of operations.

If the Company incurs costs associated with its convertible notes, in advance of the receipt of proceeds, the Company will record a deferred asset. Upon receipt of proceeds the Company will reclassify the deferred asset as a direct deduction from the carrying amount, as described above.

In addition, since the instruments included a substantive conversion feature at the time of issuance, the issuance of equity securities were accounted for as a contractual conversion with no gain or loss recognized related to the equity securities issued to settle the instrument.

Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The Company utilizes a three-level valuation hierarchy for disclosures of fair value measurements, defined as follows:

Level 1 – inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 – inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the assets or liability, either directly or indirectly, for substantially the full term of the financial instruments.

Level 3 – inputs to the valuation methodology are unobservable and significant to the fair value and require significant judgment and estimation.

Financial assets and financial liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. While the Company believes that its valuation methods are appropriate, the Company recognizes that the use of different methodologies or assumptions to determine the fair value could result in a different estimate of fair value at the reporting date. The primary assumptions that would significantly affect the fair values are the probability weighting of the different settlement outcomes used.

The Company did not have any assets or liabilities measured at fair value as of March 31, 2025 and 2024, respectively. In the fourth quarter of the Company's fiscal year ended March 31, 2024 there was a transfer out of Level 3 for the warrant liability, for the settlement and reclassification to equity of the instrument, that occurred in the three months ended March 31, 2024. For additional information, see *Note 2 - Warrant Liability and Fair Value of Financial Instruments*.

The carrying value of short-term instruments, including cash, accounts payable, accrued expenses and convertible notes included in long-term debt, approximate fair value due to the relatively short period to maturity for these instruments.

Related Parties

The Company follows ASC 850, *Related Party Disclosures*, for the identification of related parties and disclosure of related party transactions. See further discussion in the Notes below on this matter.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax basis of reported assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. As of March 31, 2025 and March 31, 2024 the Company determined a full valuation allowance was required to offset its deferred tax assets as a result of recurring operating losses.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740-10 which prescribes a recognition threshold and measurement attribute for financial statement disclosure of tax positions taken, or expected to be taken, on its tax return. The Company evaluates and records any uncertain tax positions based on the amount that management deems is more likely than not to be sustained upon examination and ultimate settlement with the tax authorities in the tax jurisdictions in which it operates. As of March 31, 2025 and March 31, 2024 the Company had no uncertain tax positions.

Stock-based Compensation

Employee share-based compensation is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the requisite service period. For awards with a performance condition, compensation expense is recognized over the requisite service period if it is probable that the performance condition will be satisfied. For awards to non-employees, the Company recognizes compensation expense in the same manner as if the Company had paid cash for the goods or services. The Company estimates the fair value of options and equity classified warrants granted using an options pricing model. Expense is recognized within general and administrative and research and development expenses and forfeitures are recognized as they are incurred.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own ordinary shares and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations. The fair value of the warrants is estimated using a Black-Scholes pricing model or a Monte Carlo simulation.

The Company issued warrants to purchase shares of common stock (i) in connection with the Bridge Offering, (ii) as part of selling agent compensation in 2024, (iii) in connection with the Exclusive License Termination Agreement (the "Termination Agreement"), and (iv) as part of the Offering. Based on the guidance noted above, we determined that warrants issued in connection with the Termination Agreement should be accounted for as a liability and the remaining warrants issued meet the requirements for equity classification. Liability classified warrants are subject to remeasurement at each balance sheet date, while equity classified warrants are valued at inception only. As discussed in Note 2, the liability warrants subsequently met the requirements for equity classification.

Loss Per Common Share

Basic loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, which includes shares issuable for little to no consideration upon the exercise of certain equity-classified warrants. Diluted loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents. In periods when losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents, because their inclusion would be anti-dilutive. Generally, the Company's outstanding warrants are non-participating securities as they are not entitled to non-forfeitable rights to dividends or dividend equivalents during the vesting term and have no obligation to fund losses.

However, the Company's warrants described in Note 2 and the warrants issued in connection with the Offering, are participating securities as the holders receive the right to dividends, but they are not obligated to fund losses. In periods of loss, since no income is allocated to these securities, the Company's use of the "treasury stock method" derives the same result. The dilutive effect of convertible securities is calculated using the "if-converted method." Under the if-converted method, securities are assumed to be converted at the beginning of the period, and the resulting common shares are included in the denominator of the diluted calculation for the entire period being presented.

For the twelve months ended March 31, 2025 and 2024, dilutive securities that were not included in the calculations of the loss per common share because they would be anti-dilutive included the following:

	March 31,	
	2025	2024 (as revised)
Equity based warrants to purchase common shares	87,531	4,334
Convertible Notes - common shares (1)	-	33,250
Convertible Notes - equity-based warrants to purchase common shares	25,003	25,003
Stock options granted under Company's incentive plan	243,483	100,180
Series A Warrants	1,533,096	-
Representative Warrants	91,985	-
Total potentially dilutive securities	1,981,098	162,767

(1) Shares for the convertible note proceeds received

Research and Development Costs

Research and development costs are expensed as incurred.

Advertising

It is our policy to expense advertising costs as incurred. Advertising expenses are included within general and administrative expenses within the statement of operations. For the years ended March 31, 2025 and 2024, the Company recorded less than $0.1 million and $1.8 million, respectively.

Fair Value of Common Stock

Prior to establishing a public market for the Company’s common stock, the estimated fair value of the Company’s common stock was determined by the Company’s Board of Directors (the "Board") as of the date of each option grant, with input from management, considering the Company’s most recently available third-party valuations of common stock, recent sales of common stock to third parties, and the Company’s board of directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant.

JOBS Act Accounting Election

The Company qualifies as an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). The JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company’s financial statements with another public company which is neither an early-stage company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Segments

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in deciding how to allocate resources in assessing performance. Management has determined that the Company operates in one reportable segment, which is advancing the development of innovative technologies for sensing and treating disorders relating to the nervous system. The Company is initially focused on developing the technology for patients with pancreatic cancer, however, the Company believes the technology constitutes a platform with the potential to address several indications, including chronic pain management, hypertension, cardiovascular disease and a wide range of other nerve-related disorders. The Company's CODM is its Chief Executive Officer.

The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance based on net loss, which is reported on the Statements of Operations. The measure of segment assets is reported on the balance sheet as total assets.

To date, the Company has not generated any product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances its' technology through all stages of development and clinical trials and, ultimately, seek regulatory approval.

As such, the CODM primarily evaluates performance of the Company using various financial metrics, including the combined net income (loss) from operations, also shown on the Statements of Operations, forecasted cash expenditures and existing and forecasted cash balances. These financial metrics are used by the CODM to make key operating decisions, such as the assessment of segment performance and allocation of resources. The significant expense categories within net loss from operations that the CODM regularly reviews are expenses related to research and development, general and administrative, and depreciation and amortization. The significant expense categories and subcategories are reported on the Statements of Operations. Other expenses included in the Company’s net loss include change in fair value of warrant liabilities, other income (expense), interest income, net, and any additional non-operating expenses that are reported on the Statements of Operations.

Recent Accounting Pronouncements

In November 2024 and January 2025, FASB issued ASU 2024-03 and ASU 2025-01, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires disclosure in the notes to the financial statements of specified information about certain costs and expenses. The amendments to the standards are effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments should be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the new guidance to determine the impact it may have on its financial statements and related disclosures.

In December 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. This guidance will be effective for the annual periods beginning after the year ended December 31, 2024. The Company is currently assessing the impact of ASU 2023-09 on its disclosures.

In November 2023, the FASB issued ASU No. 2023-07, Improvements to Reportable Segment Disclosures (ASU 2023-07) which is intended to improve reportable segment disclosures primarily through enhanced disclosure of reportable segment expenses and requires that a public entity that has a single reportable segment provide all the disclosures required by ASU 2023-07 and all existing segment disclosures in Topic 280. The new guidance is required to be applied retrospectively to all prior periods presented in the financial statements and is effective for the Company for fiscal periods beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. The Company adopted ASU 2023-07 during the year ended March 31, 2025. There was no impact upon adoption of ASU 2023-07. The Company views its operations and manages its business in one operating segment.

There are no other effective pronouncements, or pronouncements issued but not yet effective, if adopted, that would have a material effect on the accompanying financial statements.

Correction of an Immaterial Error in the Prior Period Financial Statements

During the three months ended December 31, 2024, the Company determined that previously filed quarterly and annual financial statements had an immaterial earnings per share error resulting from the exclusion of certain unexercised equity based warrants to purchase common shares that had an exercise price of approximately $0.01 or less from the basic earnings per share calculations in accordance with *ASC 260-10-45-13*. As a result, the prior year earnings per share calculations have been revised for consistency with the current year presentation. The Company assessed the materiality of this change in presentation on prior period financial statements in accordance with *SEC Staff Accounting Bulletin No. 99*, "*Materiality*," (*ASC Topic 250, Accounting Changes and Error Corrections*). Based on this assessment, the Company concluded that this error correction in its *Statements of Operations* and *Note 1 – Description of the Business, Basis of Presentation and Summary of Significant Accounting Policies (Loss Per Common Share)* is not material to any previously presented financial statements based upon overall considerations of both quantitative and qualitative factors. The corrections had no impact in the comparative period Balance Sheet, Statements of Cash Flows, or Statement of Changes in Stockholders' Equity. Further, the immaterial correction did not result in a change in operating losses or net loss in the Statement of Operations and the effects of including unexercised warrants in the earnings per share calculation have an antidilutive effect reducing the net loss per share amount. Accordingly, the Company corrected the previously reported earnings per share calculation for the twelve months ended March 31, 2024 in this Annual Report on Form 10-K.

A summary of the impact of the Company's Reverse Stock Split and immaterial corrections reflecting the prior period impact to the Company's Statement of Operations and earnings per share are shown below:

	Twelve Months Ended March 31, 2024			
	Originally Filed	Adjusted for 1-for-20 Reverse Stock Split	Correction	As Revised
Net Loss (in thousands)	$ (15,426)	$ -	$ -	$ (15,426)
Loss per share - basic and diluted	$ (1.05)	$ (21.09)	$ 6.27	$ (14.82)
Weighted average shares outstanding - basic and diluted	14,626,282	731,372	309,348	1,040,720

A summary of the impact of the Company's Reverse Stock Split and immaterial corrections reflecting the prior period impact to the disclosure of dilutive securities that were not included in the calculations of the loss per common share because they would be anti-dilutive are shown below:

	Twelve Months Ended March 31, 2024			
	Originally Filed	Adjusted for 1-for-20 Reverse Stock Split	Correction	As Revised
Equity based warrants to purchase common shares	5,744,569	287,231	(282,897)	4,334
Convertible Notes - common shares	665,000	33,250	-	33,250
Convertible Notes - equity-based warrants to purchase common shares	500,000	25,003	-	25,003
Stock options granted under Company's incentive plan	2,003,600	100,180	-	100,180
Total potentially dilutive securities	**8,913,169**	**445,664**	**(282,897)**	**162,767**

Note 2 – Warrant Liability and Fair Value of Financial Instruments

Financial assets and financial liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. While the Company believes that its valuation methods are appropriate, the Company recognizes that the use of different methodologies or assumptions to determine the fair value could result in a different estimate of fair value at the reporting date. The primary assumptions that would significantly affect the fair values are the probability weighting of the different settlement outcomes used.

There were no outstanding instruments classified as Level 3 measurements as of March 31, 2025 or March 31, 2024.

There were not any transfers into or out of Level 3 as of March 31, 2025 and March 31, 2024.

The following table summarizes the activity of the Level 3 fair value measurements during the twelve months ended March 31, 2024 (in thousands):

	Warrant Liabilities
Balance as of March 31, 2023	$ —
Additions	4,556
Change in fair value measurements - warrants mark-to-market	3,444
Settlement and reclassification to equity	(8,000)
Balance as of March 31, 2024	$ —

The Company recognized the initial warrant expense as a component of operating expenses on the statement of operations under *warrant expense – termination agreement* for $4.6 million and the changes in the fair value under *warrant liability – mark-to-market* for $3.4 million. There were no changes to the valuation approaches or techniques used for Level 3 measurements.

Warrant Liabilities

As more fully detailed in *Note 6 – Related Party Transactions*, on July 7, 2023, the Company entered into an Exclusive License Termination Agreement (the "Termination Agreement") with a licensee in exchange for the issuance, upon the closing of the Company's IPO within one year of the agreement's execution, of a warrant (the "Warrant") to purchase shares of the Company for a variable number of shares.

The fair value of the warrant liability has been estimated using a discounted cash flow model under various scenarios and used the probability-weighted expected return method ("PWERM") comparing the probabilities of different outcomes. The outcomes considered included (i) the closing of a qualified financing as part of the Company's IPO at various points in time and (ii) the possibility of default whereby the licensee receives nothing. Key assumptions for the model were as follows for the initial measurement:

Discount rate at issuance (1)	20.00%
Probability (2)	70% - 10% - 20%
Payment (3)	$0 - $8,000,000
Expected term (in years)	0.48 - 0.98

(1) The initial discount rate was chosen based on private equity rates of return as described in the AICPA Practice Aid on Valuation of Privately-Held-Company Equity securities issued as compensation. For the recurring fair value measurement, the Company updated the discount rate based upon yield curves estimated to be similar in credit quality to the Company;

(2) Scenario probability as of issuance was based on timing expectations of management that a qualified offering occurring as of December 31, 2023 was estimated at 70%, respectively; a qualified offering occurring as of June 30, 2024 was estimated at 10%; and no qualified offering occurring was estimated at 20%;

(3) The warrant has a $0.02 strike price, however, the strike price is low relative to the stock price, making the warrant value close to the value of a stock unit. The agreement has a fixed payment value of $8.0 million, see Note 6 – Related Party Transactions.

On January 29, 2024, the Company issued 80,000 warrant shares pursuant to the Termination Agreement.

The completion of the Company's IPO fixed the number of warrant shares issuable and the Company re-classified the Warrant to additional-paid in capital as it met the requirements for equity classification. Upon reclassification, the Company valued the warrant at $8.0 million, which represented the fair value of the shares issued on that date.

Note 3 – Convertible Notes Payable

On September 9, 2023, the Company's Board authorized an offering up to $2.0 million in unsecured, non-interest bearing convertible promissory notes (the "Notes") and accompanying warrants (the "Bridge Financing Warrants") (collectively, the "Bridge Offering") that will mature on December 31, 2025. The Notes provided that, on the closing date of the IPO, the outstanding principal would be automatically converted into common stock at the conversion price of $40.00. Each dollar in principal amount of Notes purchased were accompanied by a five-year Bridge Financing Warrant to purchase 0.0125 shares of Common stock with an exercise price of $20.00 per share. The Company records the Bridge Financing Warrants as a discount to the Notes.

The Bridge Financing Warrants can be exercised from the date of Notes issuance through the five-year anniversary of the issuance of the Notes. The shares issuable pursuant to the Notes and Bridge Financing Warrants had a 180-day lock-up after the Company's IPO. Thereafter, the foregoing lock-up agreement ceased to apply to 25% of the purchased shares each month for a period of four months. The Note holders were not permitted to convert their Notes when the holders or any of their affiliates would beneficially own in excess of 4.99% of the Company's common stock after such conversion.

As of March 31, 2024, the Company received proceeds of $2.0 million of Notes executed from the Bridge Offering. Upon the closing of the IPO, certain notes were to be automatically converted according to their terms into the Company's common stock to the extent and provided that certain holders of these notes are not permitted to convert such notes to the extent that the holders or any of its affiliates would beneficially own in excess of 4.99% of the Company's common stock after such conversion. Due to this 4.99% limitation, principal representing $1.3 million, or 33,250 shares, of these notes remained outstanding. As discussed in Note 1, the remaining notes converted into common stock in accordance with their original terms on the IPO. During the year ended March 31, 2025, the remaining Notes were converted into 33,250 shares.

The Company's effective interest rate for the Notes was 15.3% due to the amortization of the discount stemming from the issuance of the Bridge Financing Warrants.

The following table presents a summary of activity for the Company's zero-coupon convertible notes payable (in thousands):

	Principal Amount	Amortized Debt Discount	Net Carrying Amount
Outstanding, March 31, 2024	$ 1,330	$ (328)	$ 1,002
Amortization of debt discount	—	175	175
Issuance of common stock for extinguishment of convertible debt	(1,330)	153	(1,177)
Outstanding, March 31, 2025	$ —	$ —	$ —

Warrants

The Company issued the Notes with detachable warrants for the purchase of shares of the Company's common stock. The Company utilized a Monte Carlo simulation model to determine the fair value of each Bridge Offering Warrant. During the year ended March 31, 2024, the Company issued warrants valued at $0.6 million. The key inputs to the Monte Carlo simulation used to determine the fair value of each warrant include, the Company's stock price fair value which was determined through a back solve calculation such that the stock price results in the average total value of the Notes and the Bridge Offering Warrants being equal to the cash proceeds received, volatility based on a selection of publicly held peer companies of 101.88%, expected term of 5 years, risk free rate of 4.40%, discount rate of 20.00% and a discount for lack of marketability of 15.77%.

During the year ended March 31, 2025, the Company recorded less than $0.2 million in interest expense related to the amortization of the debt discount.

The following table presents a summary of activity for the warrants issued in connection with the Company's Notes:

	Warrants	Weighted-Average Exercise Price Per Share	Remaining Life (In Years)	Aggregate Intrinsic Value*
Outstanding and exercisable, March 31, 2024	25,003	$ 20.00	4.48	$ 1,010,000
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited/Cancelled	—	—	—	—
Expired	—	—	—	—
Outstanding, March 31, 2025	25,003	$ 20.00	3.48	$ —
Exercisable, March 31, 2025	25,003	$ 20.00	3.48	$ —

*Aggregate Intrinsic Value = Excess of market value over the exercise price of all in-the-money warrants.

Note 4 – Equity

On November 29, 2023, the Company's Board of Directors and applicable shareholders approved to amend and restate the Company's certificate of incorporation and increased the authorized shares to 500,000,000 shares of common stock, with a par value of $.001 per share, and 10,000,000 shares of preferred stock, with a par value of $.001 per share. The specific rights of the preferred stock shall be determined by the Board of Directors.

Preferred Stock

As of March 31, 2025, the Company had no shares of preferred stock outstanding.

Restricted Stock

On February 15, 2024, the Company issued 1,750 restricted shares of common stock to the Company's marketing consultant at the closing price of $76.00 of the Company's common stock. The total value of these shares is $133,000. These shares vest monthly over a 12-month period beginning on the issue date.

	Year ended March 31,	
	2025	2024
Recognized in general and administrative expense	$ 116,375	$ 16,625
Total	$ 116,375	$ 16,625

For the year ended March 31, 2025, there was no unrecognized stock-based compensation expense related to unvested Restricted Stock.

A summary of activity regarding Restricted Stock issued is as follows:

	Number of Shares	Grant Date Fair Value Per Share
Outstanding, March 31, 2024	1,604	$ 76.00
Granted	—	$ —
Vested	(1,604)	$ 76.00
Outstanding, March 31, 2025	—	$ —

Common Stock

On April 6, 2023, the Board of Directors approved a private placement offering of up to 100,000 common shares at a price of $40.00 per share. During the year ended March 31, 2024, the Company sold 71,000 shares for cash proceeds of $2,840,000. The Company did not incur any costs that were direct and incremental to the private placement.

On September 9, 2023, the Board approved a Bridge Offering. See Note 3 *Convertible Notes Payable* for additional detail as these notes are convertible into common stock.

On February 28, 2025, the Company entered into an ATM Agreement. Pursuant to the terms of the Agreement, the Company may sell from time to time, the Company's Common Stock, par value $0.001 per share, with an initial aggregate sales price of up to $2.1 million. As of March 31, 2025, the Company sold 800 shares pursuant to the ATM Agreement for net proceeds of approximately $1,746.

Stock Plan and Stock Options

In June 2023, the Company adopted, and the Company's shareholders approved, the Autonomix Medical, Inc. 2023 Stock Plan (the "Plan"). The Plan is a stock-based compensation plan that provides for discretionary grants of stock options, stock awards and stock unit awards to key employees, non-employee directors, and consultants, subject to certain individual threshold limitations. The Plan provides for up to 200,000 shares to be issued. Shares that are surrendered because of forfeiture, expiration, termination, or cancellation are available for re-issuance. As of March 31, 2025, there were 75,633 shares remaining available in the Plan.

In August 2023, the Plan was amended to allow for an automatic increase of the available shares for issuance, whereby on the 1st of each fiscal year, beginning on April 1, 2024 and ending on (and including) April 1, 2033 in an amount equal to five percent (5%) of the total number of shares of Common Stock outstanding on the March 31st immediately preceding the applicable date. However, the Board may act prior to the automatic increase of a given year to provide that there will be no increase for such year, or that the increase for such year will be a lesser number of shares of Common Stock. On April 1, 2024, the Plan was increased by 47,116 shares and on April 1, 2025, the Plan was increased by 124,852 shares.

The following table summarizes the stock option activity for the year ended March 31, 2025.

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Life (In Years)	Aggregate Intrinsic Value*
Outstanding, March 31, 2024	100,180	$ 46.59	9.35	$ 1,680,672
Granted	143,303	23.02	—	—
Exercised	—	—	—	—
Forfeited/Cancelled	—	—	—	—
Expired	—	—	—	—
Outstanding, March 31, 2025	243,483	$ 32.72	8.92	$ -
Exercisable, March 31, 2025*	37,923	$ 44.35	8.20	$ -

*Aggregate Intrinsic Value = Excess of market value over the exercise price of all in-the-money stock.

During the year ended March 31, 2025, the Company granted certain individuals options to purchase 143,303 shares of common stock with contractual terms of ten years, and vesting periods of annually over four years. The options had an aggregate grant date fair value of $2.6 million that was calculated using the Black-Scholes option pricing model. Variables used in the Black-Scholes option pricing model included the following: (1) fair value of common stock on the measurement date ranging from $1.99 and $56.20 per share; (2) discount rate ranging from 4.17% to 4.39% based on the daily yield curve rates for U.S. Treasury obligations, (3) expected life of 6.25 years based on the simplified method (vesting plus contractual term divided by two), and (4) expected volatility ranging from 110% to 138% based on the historical volatility of comparable companies' stock.

All options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at March 31, 2025 was $4.3 million. During the year ended March 31, 2025, the Company recorded stock-based compensation - option expense of $1.5 million, of which $1.3 million was recorded in general and administrative expenses and $0.2 million was recorded in research and development expenses in the statements of operations. The unrecognized compensation expense at March 31, 2024 was $3.1 million. During the year ended March 31, 2024, the Company recorded stock-based compensation - option expense of $0.6 million, of which $0.5 million was recorded in general and administrative expenses and $0.1 million was recorded in research and development expenses in the statements of operations.

License Agreement

On July 10, 2024, we entered into a license agreement (the "Agreement") with RF Innovations, Inc. ("RFI"), a privately held medical technology company, to license products utilizing RFI's intellectual property related to its Apex 6 Radiofrequency Generator (the "Licensed Products"). The Apex 6 Generator is a United States Food and Drug Administration ("FDA") cleared ablation technology designed to lesion neural tissue for pain management in the peripheral nervous system. Pursuant to the Agreement, RFI granted us a perpetual non-exclusive worldwide royalty free fully paid license related to the Licensed Products, provided that the license did not include the right to sell certain products to customers for the treatment of spine pain. In connection with the Agreement, we issued RFI 12,500 unregistered shares of our common stock as consideration for the license. The Company determined that the fair value of the shares granted was $0.1 million, which represented its stock price on the date of the Agreement less a 25.6% discount for lack of marketability ("DLOM"). The Company concluded a discount for lack of marketability was appropriate as the shares are subject to an initial lock-up period of six-months until they are eligible for registration pursuant to SEC Rule 144 followed by restrictions that allow for a maximum of 10% of total shares to be sold within a 30-day period. The DLOM effectively reflects the value of an average strike put option relative to our stock price and was calculated based on the Finnerty average put model. The Company concluded that the licensed technology qualified as a research and development expense pursuant to ASC Topic 730, Research and Development, as the Company does not have an alternative future use for the technology and the Company does not have a plan to otherwise monetize the Licensed Products. The Company recognized $0.1 million in Research and Development expense in its condensed statement of income for the three and nine-months ended December 31, 2024. The Agreement provides RFI the right to terminate the license if we breach any representation, warranty or covenant contained in the Agreement, subject to any relevant cure periods, or if we are subject to a bankruptcy or insolvency event.

Offering Agreement

On November 22, 2024, the Company entered into the Offering, which consisted of: (i) 458,691 Common Units, each Common Unit consisting of one share of common stock, par value $0.001 per share, and one Series A Warrant to purchase one share of common stock; and (ii) 917,596 Pre-Funded Units, each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one share of common stock and one Series A Warrant. The purchase price of each Common Unit was $6.540, and the purchase price of each Pre-Funded Unit was $6.539. In addition, the Company granted the Underwriters a 45-day option to purchase additional 206,422 shares of common stock, and/or additional 206,422 Series A Warrants, solely to cover over-allotments, if any. The Offering closed on November 25, 2024. On November 22, 2024, the Underwriters partially exercised their over-allotment option with respect to 156,809 shares of Common Stock and 156,809 Series A Warrants. The Company received gross proceeds of $10.0 million, before deducting the placement agent's fees and other offering expenses payable by the Company. Under the terms of the Underwriting Agreement, the Underwriters received an underwriting discount of 8.0% to the public offering price for the Units. The Company also issued to the Representative's Warrants to purchase up to 91,985 shares of Common Stock.

The Pre-Funded Warrants have an exercise price of $0.001 per share, are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full, subject to a beneficial ownership limitation of 4.99%. The Series A Warrants have an exercise price of $6.540 per share and may be exercised at any time until the five-year anniversary of the date of issuance, subject to a beneficial ownership limitation of 4.99%. The Pre-Funded Warrants and Series A Warrants were issued pursuant a Warrant Agency Agreement between the Company and Equity Stock Transfer, LLC. The Series A Warrants and the Representative's Warrants, largely have the same terms and conditions, except the Representative's Warrants were not exercisable until May 21, 2025 and were subject to a 180-day lock-up prior to being transferable. The Series A Warrants and Representative's Warrants may, at the option of the holder be settled upon a change of control at the Black-Scholes value, as defined in the agreement. Upon a change of control the holder may receive cash, other assets or shares of the successor entity, depending on the specific nature of the change of control transaction and the settlement options afforded to the holders of Common Stock. The Company analyzed the Pre-Funded Warrants, the Series A Warrants, and the Representative's Warrants (collectively the "Offering Warrants") in accordance with ASC Topic 480, Distinguishing Liabilities from Equity and ASC Topic 815, Derivatives and Hedging. Management concluded that the Offering Warrants meet all the requirements for equity classification. Since the Offering Warrants meet the requirements for equity classification and the Offering represents an arms-length cash transaction, the Common Units and Pre-Funded Units were recorded in equity based on the proceeds received, net of issuance costs.

At issuance the Pre-Funded Warrants had a fair value of $6.3290 per share, which represented the common stock issuance price less the $0.001 exercise price. At issuance, the Series A Warrants and the Representative's Warrants had a fair value of $5.3597 and $5.2125 per share, respectively, which was determined using a Black-Scholes option pricing model. Variables used in the Black-Scholes option pricing model included the following: (1) fair value of common stock on the measurement date; (2) discount rate of 4.17% based on the daily yield curve rates for U.S. Treasury obligations, (3) the contractual term of the warrants and (4) expected volatility of 144.15% based on the historical volatility of comparable companies' stock. Due to the relative volume of Series A Warrants and Representative's Warrants issued compared with the Company's outstanding shares, the Company's stock price was adjusted for the effects of dilution.

In connection with the Offering, the Company incurred total offering costs of $1.5 million. This was comprised of $1.0 million in cash offering costs and $0.5 million for the fair value of the Representative's Warrant issued.

Equity-Based Stock Warrants

On January 26, 2024, the Company issued five-year warrants to the selling agent in the Company's IPO to purchase 2,988 shares of common stock at an exercise price of $125.00. Under the fair value method, the fair value of these warrants was estimated on the grant date using the Black-Scholes option pricing model. Variables used in the Black-Scholes warrant pricing model included the following: (1) fair value of common stock on the measurement date of $100.00 split-adjusted per share; (2) discount rate of 4.04% based on the daily yield curve rates for U.S. Treasury obligations; (3) expected life of 5 years and (4) expected volatility of 104% based on the historical volatility of comparable companies' stock. The costs associated with these shares were reclassified to additional paid-in capital upon completion of the Company's IPO on January 26, 2024.

The Company will periodically grant warrants to investors in connection with equity financing or to third-party service providers in exchange for services rendered. The following table summarizes the stock warrant activity for the year ended March 31, 2025:

	Warrants	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Life (In Years)	Aggregate Intrinsic Value*
Outstanding and exercisable, March 31, 2024	287,231	$ 1.64	4.80	$ 17,072,147
Granted	2,542,677	4.31	—	—
Exercised**	(892,432)	0.04	—	—
Forfeited/Cancelled	(2,602)	0.20	—	—
Expired	—	—	—	—
Outstanding, March 31, 2025	1,934,874	$ 5.89	4.09	$ 532,060
Exercisable, March 31, 2025	1,842,889	$ 5.67	4.06	$ 532,060

*Aggregate Intrinsic Value = Excess of market value over the exercise price of all in-the-money stock.
**197,098 exercised shares utilized the "cashless exercise" option and 695,334 exercised shares were paid in cash.

The unrecognized compensation expense at March 31, 2025 was $0. During the year ended March 31, 2025, the Company recorded stock-based compensation - warrant expense of less than $0.1 million. The unrecognized compensation expense at March 31, 2024 was less than $0.1 million.

During the year ended March 31, 2024, the Company recorded stock-based compensation - warrant expense of less than $0.1 million.

Under the fair value method, the fair value of each warrant was estimated on the grant date using the Black-Scholes option pricing model. Variables used in the Black-Scholes warrant pricing model included the following:

	Range	
	2025	2024
Fair value of common stock on the measurement date (per share)	—	$2.00 to $5.00
Discount rate based on the daily yield curve rates for U.S. Treasury obligations	—	4.04% to 4.54%
Expected life	—	3 to 5 years
Expected volatility based on the historical volatility of comparable companies' stock	—	104% to 119%

Note 5 – Commitments and Contingencies

Legal Proceedings

From time to time, we may be involved in claims that arise during the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we do not currently have any pending litigation to which we are a party or to which our property is subject that we believe to be material. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations.

Employment Agreements

The Company has agreements with key employees to provide certain benefits, including salary and other wage-related benefits, in the event of termination. In addition, the Company has adopted a severance policy for certain key members of executive management to provide certain benefits, including salary and other wage-related benefits, in the event of termination without cause. In total, these benefits would amount to a range of $1.1 million to $1.6 million using the rate of compensation in effect at March 31, 2025.

Brad Hauser - Chief Executive Officer

On June 17, 2024, we entered into an employment agreement with Brad Hauser pursuant to which Mr. Hauser agreed to serve as our chief executive officer and president for an initial three-year period, which may be extended on a year-to-year basis. Mr. Hauser's agreement provides for an initial annual base salary of $450,000 (subject to an annual review and increase at the discretion of our Compensation Committee) and a target annual bonus of 60% of his base salary. Pursuant to the agreement, Mr. Hauser was granted a ten-year option (the "Inducement Options") to purchase 45,000 shares of common stock at an exercise price equal to the closing price of our common stock on the date of the employment agreement. The option vests in four equal annual installments (or 11,250 shares each installment) on each of the succeeding four anniversary dates of the execution of the employment agreement, provided Mr. Hauser is employed by us on each vesting date. In the event of a "change of control" or the termination of the agreement by us without "cause" or by Mr. Hauser for "good reason," all of the unvested options shall immediately vest. The Inducement Options were granted outside of our 2023 Stock Plan as an inducement material to Mr. Hauser's entering into employment with us in accordance with Nasdaq Stock Market Listing Rule 5635(c)(4). Commencing with the year ending March 31, 2025, Mr. Hauser will be eligible to receive annual option grants as determined by the Compensation Committee of the Board of Directors, based on criteria established by the Compensation Committee. The number of shares underlying the target annual option grant will be equal to $1,000,000 divided by the Black-Scholes value per share of our common stock on the date of grant.

If Mr. Hauser's employment is terminated at our election without "cause," or by Mr. Hauser for "good reason," Mr. Hauser shall be entitled to receive severance payments equal to twelve months of Mr. Hauser's base salary and 100% of the target bonus for the year in which such termination occurs; provided that such amounts shall be increased by 50% if Mr. Hauser's agreement is terminated without "cause" or by Mr. Hauser for "good reason" within three months prior to or twelve months after a "change of control." In the event that any payments or benefits provided to Mr. Hauser would trigger the excise tax under Section 4999 of the Internal Revenue Code or any similar provision, the Company agreed to provide Mr. Hauser with a gross-up payment to ensure that, after payment of all taxes (including the excise tax, federal, state, and local income taxes, and employment taxes) imposed on the gross-up payment, Mr. Hauser receives a net amount equal to the payments or benefits Mr. Hauser would have received if the excise tax didn't apply.

Lori Bisson - Vice Chair (former Chief Executive Officer)

On June 17, 2024, we entered into an employment agreement with Lori Bisson pursuant to which Ms. Bisson agreed to serve as our Executive Vice Chair and Strategic Adviser to the Chief Executive Officer ("Vice Chair") for a two-year period. Ms. Bisson's agreement provides for an initial annual base salary of $150,000 (subject to an annual review and increase at the discretion of our Compensation Committee) and a target annual bonus of 50% of her base salary. Pursuant to the agreement, Ms. Bisson continued to vest in the option grants issued to Ms. Bisson in her role as chief executive officer and president in accordance with the vesting schedule set out in her initial employment agreement. In the event of a "change of control" or the termination of the agreement by us without "cause" or by Ms. Bisson for "good reason," all of the unvested options shall immediately vest. Ms. Bisson is entitled to receive any compensation, including incentive compensation, for the fiscal year ended March 31, 2024 that has not been paid as of the date of the agreement. Commencing with the year ending March 31, 2025, Ms. Bisson will be eligible to receive annual option grants as determined by the Compensation Committee of the Board of Directors, based on criteria established by the Compensation Committee. Ms. Bisson agreed to waive any severance payments due to her in connection with the termination of the prior employment agreement that we entered into with her on June 30, 2023.

Fractional Shares

See *Note 1 - Description of the Business, Basis of Presentation and Summary of Significant Accounting Policies* - "*Reverse Stock Split*" for additional information.

On November 1, 2024, the Company received notice from the Depository Trust and Clearing Corporation ("DTCC") on behalf of the brokerage firms that hold the shares of Company common stock held in "street name" that in connection with the rounding of fractional shares in connection with the Reverse Stock Split, the Company would need to issue 271,846 shares of common stock (the "Shares") for the rounding of shares. The Company does not believe the number of Shares being requested is correct based on the historical number of shareholders of its common stock and is aware of similar anomalies in recent months for other companies completing a Reverse Stock Split. As such, the Company has begun an inquiry into the calculations set forth in the request. During the pendency of this inquiry, the Company does not intend to issue any shares in connection with the fractional shares being requested and has concluded that an obligation should not be recorded in its financial statements. The Company is not currently subject to any pending litigation as a result of the fractional roundup shares.

Note 6 – Related Party Transactions

The Company utilizes a consulting firm that is owned by the Company's former Chief Financial Officer to provide accounting and financial reporting services and pays certain expenses on behalf of the Company. During the year ended March 31, 2025 and 2024, the Company incurred fees of less than $0.1 million, respectively, for these services, excluding officer compensation. As of March 31, 2025 and March 31, 2024, the Company owed the consulting firm $0 and less than $0.1 million, respectively, for services and expenses.

As of March 31, 2025, members of the Company's management/Board and an immediate family member of the Company's management (related party), collectively purchased $0.5 million ($0.4 million and $0.1 million, respectively) of the Bridge Offering.

On December 21, 2021, the Company entered into a perpetual, worldwide, exclusive license agreement (the "License" or "License Agreement") with a company controlled by a significant stockholder of the Company (the "Licensee"). The License allows the Licensee to use certain intellectual property and technology related to the diagnosis and treatment of cardiovascular conditions held by the Company. Upon 90 days following the completion of an IPO or special purpose acquisition company transaction, the Licensee may enter into sublicenses of the licensed intellectual property and technology.

On July 7, 2023, the Company and the Licensee entered into an Exclusive License Termination Agreement (the "Termination Agreement") in exchange for the issuance, upon the closing of the Company's IPO within one year of the agreement's execution, of a warrant to purchase shares of the Company for a variable number of shares. Upon the Company's closing of its IPO on January 29, 2024, 80,000 warrant shares were issued at $100.00 per share for a fixed value of $8.0 million. The warrants are exercisable at a price of $0.02 per share and may be exercised any time after the issuance date, subject to a beneficial ownership limitation, and expire five years from the original issuance. The warrants contain dividend rights commensurate with the holders of common stock. The warrants do not include any other stockholder rights or privileges prior to exercise.

The shares underlying the warrant will be subject to a lockup agreement for a period of six months after the closing of the IPO with respect to 12.5% of the shares issued and twelve months after the closing of the IPO for the remainder of the shares. In connection with the Termination Agreement, the Company agreed to register the resale of the shares of common stock. One of the Company's directors holds a 20% interest in the company receiving the warrant.

Note 7 – Income Taxes

The Company files U.S. federal and various U.S. state income tax returns. Due to the Company's losses, there was no income tax expense for the years ended March 31, 2025 and 2024 (in thousands):

	March 31, 2025		March 31, 2024	
	Amount	%	Amount	%
Tax benefit at the U.S. federal statutory rate	$ (2,396)	21.00%	$ (3,239)	21.00%
Tax rate change	—	—	—	—
Permanent differences	5	(0.05)%	1,697	(11.01)%
Return to provision	(44)	0.39%	(69)	0.45%
Change in state rate	234	(2.05)%	(190)	1.23%
State tax (net of federal benefit)	(63)	0.55%	(192)	1.24%
Valuation allowance	2,264	(19.84)%	1,993	(12.91)%
Effective income tax rate	$ —	—%	$ —	—%

The effective income tax rate varied from the statutory rate in 2025 primarily due to permanent differences and the increase in the valuation allowance. The effective income tax rate varied from the statutory rate in 2024 primarily as a result of the increase in the valuation allowance.

Deferred tax assets and liabilities consist of the following (in thousands):

	March 31, 2025	March 31, 2024
Assets related to:		
Capitalized R&D costs	$ 1,380	$ 602
Net operating losses	761	2,643
Accruals and reserves	3,438	72
Stock-based compensation	450	142
Total deferred tax assets	6,029	3,459
Valuation allowance for deferred tax assets	(5,723)	(3,459)
Net deferred tax assets	306	—
Liabilities related to:		
Section 481A method change	(306)	—
Net deferred tax liabilities	(306)	—
Net deferred tax	$ —	$ —

At March 31, 2025, the Company had U.S. federal net operating loss ("NOL") carry forwards of $3.6 million. Approximately $0.9 million of the U.S. federal NOLs will start expiring in 2037. Additionally, the Company generated a U.S. federal NOL carry-forward of approximately $2.7 million post-2017 to 2024. Under the new Tax Act, post-2017 federal NOL carry forwards do not expire, but can only offset 80% of taxable income in the year the loss carry forward is used.

Sections 382 and 383 of the Internal Revenue Code limit the annual use of NOL carry-forwards and tax credit carry forwards, respectively, following an ownership change. NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (Section 382) (or comparable provisions of state law) if certain changes in ownership were to occur. Determination of ownership change, or limitation hasn't been calculated; however, the Company will perform the NOL limitation analysis under Section 382 before any NOLs are expected to be utilized.

The Company has recorded a full valuation allowance against its net total deferred tax assets as of March 31, 2025 and 2024 because management determined that it is not more-likely-than not that those assets will be realized. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of deferred assets will not be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. During the year ended March 31, 2025, the valuation allowance increased by $2.3 million mainly due to additional capitalized R&D and Start-up Costs.

The Company is subject to income taxes in the U.S. federal jurisdiction and various state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. As of March 31, 2025, all of the tax years remained open to examination by the federal and state taxing authorities, for three or four years from the tax year in which net operating losses or tax credits are utilized completely.

As of March 31, 2025, the Company has no uncertain tax positions.

Note 8 – Subsequent Events

As of May 28, 2025, the Company has sold 289,144 shares pursuant to the ATM Agreement for net proceeds of approximately $0.6 million.

On April 17, 2025, we granted a new employee a ten-year option (the "Inducement Options") to purchase 5,000 shares of common stock at an exercise price equal to the closing price of our common stock on the date of the employment. The option vests in four equal annual installments (or 1,250 shares each installment) on each of the succeeding four anniversary dates of the execution of the date of employment, provided the employee is employed by us on each vesting date.

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

Our management, including our Chief Executive Officer ("CEO"), who serves as our principal executive officer, and our Chief Financial Officer ("CFO"), who serves as our principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our CEO and our CFO concluded that as a result of the material weaknesses in our internal control over financial reporting discussed below, our disclosure controls and procedures were not effective at ensuring that information required to be disclosed in the reports we file or submit under the Exchange Act 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 our management, including our CEO and CFO, or persons performing similar functions, as appropriate to allow timely decisions regarding disclosure.

Attestation Report of the Registered Public Accounting Firm

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal controls over financial reporting for as long as we are an "emerging growth company" pursuant to the provisions of the Jumpstart Our Business Startups Act.

Management's Report on Internal Control Over Financial Reporting

Our CEO and our CFO are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management conducted an assessment of the effectiveness of our internal control over financial reporting as of March 31, 2025. In making this assessment, management used the criteria described in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based upon such assessment and due to both the limited staffing of the Company at its early stage of development and the existence of the material weaknesses in our internal control over financial reporting described below, our CEO and CFO have concluded that, as of March 31, 2025, our disclosure controls and procedures were not effective.

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Our management, including our CEO and CFO, concluded that our internal control over financial reporting was, and continues to be, ineffective as of March 31, 2025 due to material weaknesses in our internal controls arising from a lack of segregation of duties; general technology controls; and financial statement reporting. It should be noted that any system of controls, however well designed and operated, can provide only reasonable and not absolute assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of certain events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

Due to our size and the limited number of qualified personnel available, our segregation of certain duties, financial statement reporting and general technology controls are areas we have focused on, and continue, to put our focus. The proper review of these matters may not always be possible and may not be economically feasible. However, to the extent possible, these are the main areas of our focus. Management evaluated the impact of our failure to maintain effective segregation of duties, financial statement reporting and general technology controls on our assessment of our internal control over financial reporting and has concluded that the control deficiencies represent a material weakness. We have hired new executive officers and management with significant financial and accounting experience in both private and public companies. During the twelve months ended March 31, 2025, an additional experienced staff was hired in the accounting and finance department. Experienced personnel will be hired in the accounting and finance department and appropriate consultants will be upgraded as soon as it becomes economically feasible and sustainable. In addition, management has added additional mitigating controls with regards to cash disbursements; changes were made in our authorization processes to improve segregation of duties; and we performed additional analysis and other post-closing procedures to ensure our financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, we believe that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

Changes in Internal Control over Financial Reporting

We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working remotely. We are continually monitoring and assessing the situation on our internal controls to minimize the impact on their design and operating effectiveness.

Other than as described above, there has been no change in our internal control over financial reporting during our most recent calendar quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During the twelve months ended March 31, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by Part III, Item 10 is incorporated herein by reference to our definitive proxy statement relating to the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Our Board of Directors has adopted a written Code of Business Conduct and Ethics applicable to all officers, directors and employees, which is available on our website (www.autonomix.com) under "Investors" within the "Corporate Governance" section. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of this Code and by posting such information on the website address and location specified above.

Item 11. Executive Compensation

The information required by Part III, Item 11 is incorporated herein by reference to our definitive proxy statement relating to the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by Part III, Item 12 is incorporated herein by reference to our definitive proxy statement relating to the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by Part III, Item 13 is incorporated herein by reference to our definitive proxy statement relating to the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services

The information required by Part III, Item 14 is incorporated herein by reference to our definitive proxy statement relating to the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

The independent registered public accounting firm is FORVIS MAZARS, LLP (PCAOB Firm ID No. 686) located in Atlanta, Georgia.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed or furnished as part of this Form 10-K:

1. Financial Statements

   Reference is made to the Index to Financial Statements under Item 8, Part II hereof.

2. Financial Statement Schedules

   The Financial Statement Schedules have been omitted either because they are not required or because the information has been included in the financial statements or the notes thereto included in this Annual Report on Form 10-K.

3. Exhibits

Exhibit Index

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation of Autonomix Medical, Inc. (incorporated by reference from exhibit 2.1 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Autonomix Medical, Inc., filed with the Secretary of State of the State of Delaware (incorporated by reference from exhibit 3.1 of the Form 8-K filed October 28, 2024)
3.3	Amended and Restated Bylaws of Autonomix Medical, Inc. (incorporated by reference from exhibit 2.2 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
4.1	Form of Warrant Agreement issued in SAFE offering (incorporated by reference from exhibit 3.1 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
4.2	Form of Selling Agent Warrant (incorporated by reference from exhibit 3.2 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
4.3	Form of Pre-Funded Warrant issued in November 2024 offering (incorporated by reference from exhibit 4.1 of the Form 8-K filed November 25, 2024)
4.4	Form of Series A Warrant issued in November 2024 offering (incorporated by reference from exhibit 4.2 of the Form 8-K filed November 25, 2024)
4.5	Form of Representative’s Warrant issued in November 2024 offering (incorporated by reference from exhibit 4.4 of the Form 8-K filed November 25, 2024)
4.6	Warrant Agency Agreement, dated November 22, 2024, with Equity Stock Transfer, LLC (incorporated by reference from exhibit 4.3 of the Form 8-K filed November 25, 2024)
4.7*	Description of the Company's Securities
10.1**	Employment Letter dated January 4, 2022 between the Company and Robert Schwartz (incorporated by reference from exhibit 6.1 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)

10.2**	Amended and Restated Consulting Agreement effective January 4, 2022 between the Company and Landy Toth (incorporated by reference from exhibit 6.2 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
10.3**	Employment Agreement between the Company and Lori Bisson dated June 30, 2023 (incorporated by reference from exhibit 6.3 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
10.4**	Employment Agreement between the Company and Trent Smith dated July 24, 2023 (incorporated by reference from exhibit 6.4 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
10.5**	Autonomix Medical, Inc. 2023 Stock Plan, as amended and restated (incorporated by reference from exhibit 6.5 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
10.6	Form of Indemnification Agreement with Executive Officers and Directors of the Company (incorporated by reference from exhibit 6.6 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
10.7	Form of Lock-Up Agreement to be entered into between the Company and its officers and directors (incorporated by reference from exhibit 6.7 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
10.8+	Exclusive License Agreement dated December 21, 2021 between Autonomix Medical, Inc. and Impulse Medical, Inc. (incorporated by reference from exhibit 6.8 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
10.9	Exclusive License Termination Agreement dated July 7, 2023 between Autonomix Medical, Inc. and Impulse Medical, Inc. (incorporated by reference from exhibit 6.9 of the Form 1-A POS, file number 024-12296, filed January 19, 2024)
10.10**	Employment Agreement between Brad Hauser and Autonomix Medical, Inc. dated June 17, 2024. (incorporated by reference from exhibit 10.1 of the Form 8-K filed June 17, 2024)
10.11**	Employment Agreement between Lori Bisson and Autonomix Medical, Inc. dated June 17, 2024. (incorporated by reference from exhibit 10.2 of the Form 8-K filed June 17, 2024)
10.12	License Agreement between Autonomix Medical, Inc. and RF Innovations, Inc. (incorporated by reference from exhibit 10.1 of the Form 8-K filed July 15, 2024)
10.13**	Non-Employee Director Compensation Plan (incorporated by reference from exhibit 10.2 of the Form 10-Q filed November 8, 2024)
10.14	Underwriting Agreement, dated November 22, 2024, with Ladenburg Thalmann & Co. Inc. (incorporated by reference from exhibit 1.1 of the Form 8-K filed November 25, 2024)
10.15	At Market Issuance Sales Agreement, dated February 28, 2025, by and between Autonomix Medical, Inc. and Ladenburg Thalmann & Co. Inc. (incorporated by reference from exhibit 1.1 of the Form 8-K filed February 28, 2025)
19*	Autonomix Medical, Inc. Insider Trading Policy
23.1*	Consent of Forvis Mazars, LLP
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended

32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97	Autonomix Medical, Inc. Restatement Recoupment Policy (incorporated by reference from exhibit 97 of the Form 10-K filed May 31, 2024)
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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* Filed herewith.

** Denotes a management contract or compensatory plan or arrangement.

\+ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

Item 16. 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AUTONOMIX MEDICAL, INC.

Date: May 29, 2025 By: /s/ BRAD HAUSER

Brad Hauser
Chief Executive Officer, President and Director
(Principal Executive Officer)

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 in the capacities and on the dates indicated.

Date: May 29, 2025 By: /s/ BRAD HAUSER

Brad Hauser
Chief Executive Officer, President and Director
(Principal Executive Officer)

Date: May 29, 2025 /s/ TRENT SMITH

Trent Smith
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: May 29, 2025 /s/ WALTER KLEMP

Walter Klemp
Executive Chair of the Board of Directors

/s/ LORI BISSON

Date: May 29, 2025 **Vice Chair of the Board of Directors**

Date: May 29, 2025 /s/ JONATHAN FOSTER

Jonathan Foster
Director

Date: May 29, 2025 /s/ DAVID ROBINS

David Robins
Director

Date: May 29, 2025 /s/ CHRISTOPHER CAPELLI, MD

Christopher Capelli
Director

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