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 December 31, 2024

OR

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

For the Transition Period From to
Commission file number: 001-38677

Catheter Precision, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**38-3661826**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1670 Highway 160 West, Suite 205 Fort Mill, South Carolina	**29708**
(Address of principal executive offices)	**(Zip Code)**

(973) 691-2000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of the exchange on which registered**
Common Stock, $0.0001 par value	**VTAK**	**NYSE American**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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.

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 Exchange Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of common stock on June 30, 2024 as reported by the NYSE American on such date was approximately $3.9 million. Shares of the registrant's common stock held by each executive officer, director and other persons who may be deemed an affiliate of the registrant have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 17, 2025, the registrant had 9,268,632 shares of common stock, par value $0.0001, outstanding.

Documents Incorporated by Reference

Portions of the proxy statement for the 2025 Annual Meeting of Stockholders of Catheter Precision, Inc. are incorporated by reference into Part III, Item 13 of this report, or will be included in an amendment to this report if the proxy statement is not filed on or before April 30, 2025.

CATHETER PRECISION, INC.

TABLE OF CONTENTS

		Page
Forward Looking Statement Disclaimer		2
Risk Factor Summary		3
	Part I	
Item 1.	Business	4
Item 1A.	Risk Factors	21
Item 1B.	Unresolved Staff Comments	50
Item 1C.	Cybersecurity	50
Item 2.	Properties	51
Item 3.	Legal Proceedings	51
Item 4.	Mine Safety Disclosures	51
	Part II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	52
Item 6.	[Reserved]	52
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	53
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	63
Item 8.	Financial Statements and Supplementary Data	63
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	63
Item 9A.	Controls and Procedures	63
Item 9B.	Other Information	65
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	65
	Part III	
Item 10.	Directors, Executive Officers and Corporate Governance	65
Item 11.	Executive Compensation	67
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	71
Item 13.	Certain Relationships and Related Transactions, and Director Independence	73
Item 14.	Principal Accounting Fees and Services	74
	Part IV	
Item 15.	Exhibit and Financial Statement Schedules	75
Item 16.	Form 10-K Summary	79
	Signatures	80

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available. This section should be read in conjunction with our audited financial statements and related notes included in Part II, Item 8 of this report. The statements contained in this Annual Report on Form 10-K that are not historical facts are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended.

Forward- looking statements can be identified by words such as "believe," "anticipate," "may," "might," "can," "could," "continue," "depends," "expect," "expand," "forecast," "intend," "predict," "plan," "rely," "should," "will," "may," "seek," or the negative of these terms and other similar expressions, although not all forward-looking statements contain these words. Specifically, forward-looking statements in this report may include statements relating to: the future financial performance of our business; changes in the market for our services; expansion plans and opportunities; our future growth; our ability to implement our corporate strategy, and the impact of such strategy on our future operations and financial and operational results; anticipated growth in the markets in which we operate, additions to a our workforce and anticipated future product approvals. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements.

These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled "Risk Factors" included in Part I, Item 1A and elsewhere in this report, including in the Risk Factor Summary below. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Annual Report on Form 10-K by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

Risk Factor Summary (This Summary is not intended to and does not describe all of the risk factors discussed at Item 1A below that may impact the Company. We urge investors to review the detailed descriptions of risk factors contained in Item 1A.)

Risks Related to Our Financial Position and Need for Additional Capital

- We will be required to raise additional funds to finance our operations and continue as a going concern; We may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.
- Our business has a history of losses, will incur additional losses, and may never achieve profitability.

Risks Related to Our Internal Controls

- We have identified material weaknesses in our internal control over financial reporting. These material weaknesses could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.
- Compliance with Sarbanes-Oxley Act Section 404 could have a material adverse impact on our business.

Risks Related to Our Business and Products

- We will not be able to reach profitability unless we are able to achieve our product expansion and growth goals; our VIVO launch plans require significant investment in infrastructure and sales representatives.
- Our research and development and commercialization efforts may depend on entering into agreements with corporate collaborators.
- We have entered into joint marketing agreements with respect to our products, and may enter into additional joint marketing agreements that will reduce our revenues from product sales.
- Royalty agreements with respect to LockeT, the surgical vessel closing pressure device, will reduce any future profits from this product.
- If we experience significant disruptions in our information technology systems, our business may be adversely affected.
- Litigation and other legal proceedings may adversely affect our business.
- If we make acquisitions or divestitures, we could encounter difficulties that harm our business.
- Failure to attract and retain sufficient qualified personnel could also impede our growth.
- Our revenues may depend on our customers' receipt of adequate reimbursement from private insurers and government sponsored healthcare programs.
- We may be unable to compete successfully with companies in our highly competitive industry, many of whom have substantially greater resources than we do.
- Our future operating results depend upon our ability to obtain components in sufficient quantities on commercially reasonable terms or according to schedules, prices, quality and volumes that are acceptable to us, and suppliers may fail to deliver components, or we may be unable to manage these components effectively or obtain these components on such terms.
- If hospitals, physicians and patients do not accept our current and future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any.

- The recent coronavirus outbreak ("COVID-19") adversely affected our financial condition and results of operations, and we cannot provide any certainty as to whether there will be future impacts from COVID-19 or another pandemic.
- A variety of risks associated with marketing our products internationally could materially adversely affect our business.
- The impact of the military conflicts in Ukraine and Israel, and the actions that have been and could be taken by other countries, including new and stricter sanctions and actions taken in response to such sanctions, have affected, and may continue to affect, our business and results of operations, including our supply chain.
- If the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory approval for or commercialize our product candidates.
- We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements.
- Our ability to use our net operating loss carry forwards may be limited.
- We may have to make milestone payments under the Settlement Agreement we entered into with the Department of Justice ("DOJ").

Risks Related to Government Regulation and our Industry

- We are subject to pervasive and continuing regulation by the FDA and other regulatory agencies. Our products may be subject to additional recalls, revocations or suspensions after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business.
- Changes in trade policies among the U.S. and other countries, in particular the imposition of new or higher tariffs, could place pressure on our average selling prices as our customers seek to offset the impact of increased tariffs on their own products. Increased tariffs or the imposition of other barriers to international trade could have a material adverse effect on our revenues and operating results.
- Product clearances and approvals can often be denied or significantly delayed.
- Although we have obtained regulatory clearance for our VIVO and LockeT products in the U.S. and certain non-U.S. jurisdictions, our business plans include expanding uses for our products, which will require additional clearances; and even after clearance is obtained, our products remain subject to extensive regulatory scrutiny.
- If we or our suppliers fail to comply with the FDA's Quality System Regulation, or QSR, or any applicable state equivalent, our operations could be interrupted, and our potential product sales and operating results could suffer.
- Our products may be subject to additional recalls, revocations or suspensions after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business.
- If any of our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.
- Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets.

Risks Related to our Intellectual Property

- If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our existing products and any products we may develop, and our technology may be adversely affected.

Risks Related to Ownership of Our Common Stock Including Volatility, Anti-takeover Provisions, the Impact of Future Sales and Potential Dilution

PART I

ITEM 1. BUSINESS

Overview

The registrant (together with our consolidated operating subsidiary, the "Company" or "Catheter") was incorporated under the name "Ra Medical Systems, Inc." as a Delaware corporation in July 2018. A predecessor had been incorporated in California in September of 2002, but was reincorporated in 2018 in connection with our initial public offering. The Company was initially formed to develop, commercialize and market an excimer laser-based platform for use in the treatment of vascular and dermatological immune-mediated inflammatory diseases, including the DABRA product line.

On January 9, 2023, the Company merged with Catheter Precision, Inc., or "Old Catheter", a privately-held Delaware corporation (the "Merger"), and the business of Old Catheter became a wholly owned subsidiary of the Company, which today is our only operating subsidiary. Following the Merger, we discontinued the Company's legacy lines of business and the use of any of its DABRA-related assets. For further information about these historical lines of business, see "Item 1. Business" of the Company's Form 10-K for the fiscal year ended December 31, 2021. Since the Merger, we have shifted the focus of our operations to Old Catheter's product lines. Accordingly, our current activities primarily relate to Old Catheter's historical business which comprises the design, manufacture and sale of new and innovative medical technologies focused in the field of cardiac electrophysiology, or "EP."

Our two primary products include the VIVO System and LockeT. The VIVO System, which is an anacronym for View into Ventricular Onset System("VIVO" or "VIVO System") is a non-invasive imaging system that offers 3D cardiac mapping to help with localizing the sites of origin of idiopathic ventricular arrhythmias in patients with structurally normal hearts prior to EP procedures.

Our newest product, LockeT, is a suture retention device indicated for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure. LockeT is intended to temporarily secure sutures and aid clinicians in locating and removing sutures efficiently.

On January 24, 2025, we acquired PeriKard, LLC., a development stage company developing a kit of tools to enable physicians to more easily gain access to the pericardial space of the heart. It is intended that the kit will have both a better needle system and a better drainage system than current alternatives. The pericardium is the thin, fluid filled, sac that surrounds the heart. The pericardium is made up of an outer layer of tissue that holds the heart in place within the chest, protects it from inflammation, and acts as a barrier to infection. It also prevents the heart from stretching out and filling with too much blood which could constrict the heart and impede normal heart function in which case, access to the pericardium is needed to drain the excess fluid. Access is also desirable for ablation to treat arrhythmias outside the heart wall. PeriKard is currently in the product development phase. Additional future royalty cash payments may be due to the seller equal to 10% of aggregate future net sales activity of PeiKard's pericardial access kits, to the extent the product is successfully commercialized, for five years from the acquisition's closing date.

Our product portfolio also includes the Amigo® Remote Catheter System, or Amigo, a robotic arm that serves as a catheter control device. Prior to 2018, Old Catheter marketed Amigo. We own the intellectual property related to Amigo, and this product is under consideration for future research and development of a generation 2 product.

We continue to evaluate potential product acquisitions from time to time that might prove complementary to our current portfolio.

Electrophysiology Market Overview

EP is one of healthcare's largest sectors and rapidly growing. The EP market includes well known medical devices such as pacemakers, electrocardiogram, or ECG, systems and cardiac catheters, but also laboratory equipment such as intracardiac mapping systems and fluoroscopy systems (similar to x-ray in real time). The EP market includes large medical device companies such as Medtronic, Plc., Abbott Laboratories, Biosense-Webster (J&J) and Boston Scientific Corp.

Population growth, increasing rates of heart disease and the rising cost of healthcare are driving growth in the EP markets. In September 2024, the Heart Failure Society of America ("HFSA") reported in the Journal of Cardiac Health that approximately 6.7 million Americans over the age of 20 currently live with heart failure, forecast to rise to 8.7 million by 2030. The proportion of younger patients (aged 35-64) is rising faster than that of older patients driven in part by increasing obesity and hypertension rates amount younger patients, and the overall lifetime risk of heart failure for Americans has risen to 24%.

Within the EP market, we focus our products that address the catheter ablation market. The catheter ablation market was $3.5 billion in 2022 and is estimated by Global Market Insights to grow to $14.5 billion in 2032. This market includes medical devices used for atrial and ventricular ablation procedures.

Within the last 10 years, ventricular ablation has become a fast-growing treatment option due to updated treatment guidelines, improved technology and raising incidence rates. However, the exact number of ventricular ablations performed is not well documented. The ventricular ablation market is estimated by Global Market Insights to grow at a rate of 14.5% CAGR through 2032. Over a ten-year period, one study in Australia demonstrated a growth of 18% for ventricular tachycardia. Of note, this surpassed the growth rate of atrial fibrillation (12.7%) which has historically been the largest incidence of cardiac arrhythmias. The Heart Rhythm Society, or HRS, Expert Consensus Statement on Catheter Ablation of Ventricular Arrhythmias, published in May 2019 recommends catheter ablation in preference to anti arrhythmic drugs or in the situation where anti arrhythmic therapy has failed or is not tolerated. The guidelines also recommend ablation for reducing recurrent ventricular tachycardia, or VT, and implantable cardioverter-defibrillator shocks.

Existing Treatments and Methods for Catheter Ablations

Traditionally, the first line of treatment for cardiac arrhythmias is medication. However, this is often not a permanent fix and many patients eventually need a catheter ablation. In September 2024, the New England Journal of Medicine published clinical trial results which compared the number of adverse events in patients treated with catheter ablation versus patients treated with drug therapy. The trial found that patients treated with catheter ablation had suffered 50% fewer adverse events at the median follow-up period of 4.3 years than patients treated with drug therapy.

Catheter Ablation Procedure Overview

An electrophysiologist stands next to the patient's bed near the patient's groin. A catheter or catheters are inserted into the femoral vein (located at the groin) and navigated into the right side of the heart. Depending on the type of arrhythmia, the catheter is inserted into the atrium or the ventricle. Once inserted, a diagnostic catheter is used in conjunction with an invasive (traditional) mapping system to create a map of the patient's heart. This allows the physician to see the individual patient's cardiac structures and size. Once the map is created, the physician begins to "pace map." This process requires the physician to move the catheter from spot to spot to determine the electrical conduction at different areas to determine if the tissue in that area is responsible for the arrhythmia. Once the area is located, the physician will provide a form of energy (radiofrequency, cryo, etc.) to ablate the tissue in that spot.

Treatment Challenges for Ventricular Arrhythmias

Treatment of ventricular arrhythmias with cardiac ablations is a relatively new treatment option. As a result, we believe that the patient population is underserved, the condition is not as well understood, and the available techniques and technologies are limited when compared to the atrial ablation options.

Ablation locations within the ventricle are very difficult to identify. Often, patients are highly symptomatic (dizzy, breathing difficulties, etc.) but the arrhythmia is infrequent. When this happens, it is hard to predict when the patient will be having an "active" arrhythmia. Because of this, the physician may not be able to identify the location even when using medication to induce the arrhythmia. Without confirmation during invasive mapping, the patient is removed from the electrophysiology lab without the ablation procedure being performed and the patient is required to return at a later date and try again for a successful outcome.

Even when a patient has frequent ventricular arrhythmias, the process of pace-mapping often takes 4 – 5 hours to identify the location for ablation, which can increase the likelihood of patient complications due to the extended time under anesthesia.

Lastly, many patients with untreated ventricular arrhythmias cannot tolerate anesthesia well, thus invasive mapping may not be an option for them.

Treatment Challenges for Atrial Arrhythmias

Catheter ablation for atrial arrhythmias is more standardized and "advanced" than for ventricular ablations, thus less pace mapping is required. Instead, a procedure called Pulmonary Vein Isolation ("**PVI**") is performed for atrial fibrillation, and a single line is ablated for atrial flutter. In pulmonary vein isolation, tiny scars are created in the left upper chamber of the heart in the area where the four lung (pulmonary) veins connect.

Despite steady improvement in the tools available to perform effective procedures, there is clear study evidence that catheter based atrial fibrillation treatment technology can become more effective. According to a study entitled "*Long Term Outcomes of Catheter Ablation of Atrial Fibrillation: A Systematic Review and Meta- Analysis*" *published in the Journal of the American Heart Association on March 18, 2013,* which looked at multiple individual studies covering over 6,000 patients, "single procedure freedom from atrial fibrillation at long term follow up was 53.1%." The same study found "with multiple procedures performed, the long-term success rate was 79.8%." Ineffective treatment may result in patients undergoing two or more EP procedures to achieve relief from atrial fibrillation at an estimated cost in the range of $20,000 or more per procedure.

Specific reasons have not been proven for the lower success rate of initial ablation procedures. However, there is growing evidence that better results occur if the treating EP physician is able to make better lesions by maintaining stable contact force of the catheter against the heart wall, thereby reliably delivering the energy required to eliminate the abnormal rhythms. Variation in catheter contact force occurs as the physician attempts to manually position and hold the catheter tip in a stable position during cases lasting 2 to 3 hours in order to perform typically over 100 ablations of the cardiac anatomy.

Large multi-national medical device companies, such as Medtronic, Inc., Boston Scientific Corp., Abbott Laboratories, St. Jude Medical, Inc. and the Biosense Webster division of Johnson & Johnson, among others, continue to invest heavily to develop and introduce new devices and technologies to improve patient outcomes. Included among these are force-sensing catheters, including the Biosense SmartTouch *TM* catheter, which provide a continuous readout of the contact force between the catheter and the heart wall. Our Vivo System is focused on the controlled delivery of these catheter technologies to enhance both the performance of ablation procedures and the ease and safety for the physicians who perform them.

Our Products

VIVO™ System

Our lead product, VIVO, is an FDA-cleared and CE marked product that utilizes non-invasive inputs to locate the origin of ventricular arrhythmias. VIVO has been used in more than 1,000 procedures in leading U.S. and European hospitals.

VIVO is a non-invasive imaging system that offers 3D cardiac mapping to help with localizing the sites of origin of idiopathic ventricular arrhythmias in patients with structurally normal hearts prior to electrophysiology procedures. The VIVO system has achieved a CE Mark allowing it to be sold in the European Union and has been placed at several hospitals in Europe. FDA 510(k) Clearance in the United States was received in June 2019.

The VIVO software is provided on an off-the-shelf laptop, and the system includes a 3D camera. In addition, the system can only be used with a disposable component, the VIVO Positioning Patches, which are required for each procedure.

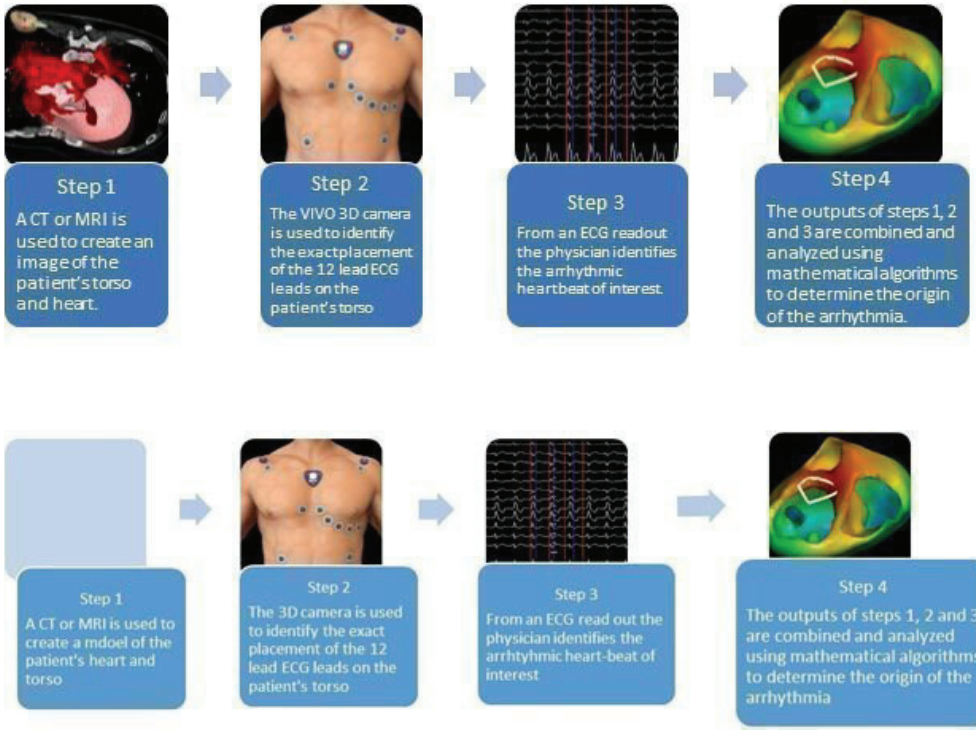






The VIVO software contains proprietary algorithms that are based on standard EP principles. However, the accuracy of the algorithms is improved because it does not use generalized assumptions and instead uses patient specific information. VIVO uses standard clinical inputs such as a CT or MRI and a 12 lead ECG, both of which are routinely gathered for most EP procedures, allowing VIVO to seamlessly integrate into the workflow. A 3D photograph is obtained of the patient's torso after the ECG leads are in place and all of these clinical inputs are combined to generate a 3D map of the patient's heart with a location of the earliest onset of the ventricular arrhythmia.

VIVO Workflow



VIVO Clinical Use and Studies

To date, VIVO has been used in more than 1,000 procedures, by more than 30 physicians in 11 countries. Initial clinical work was completed with the first-generation software, which resulted in FDA 510(k) Clearance in June 2019.

The U.S. multi-center study enrolled 51 patients from 5 centers. Of note, the Principal Investigator and center to have the highest enrollment was Johns Hopkins University in Baltimore, Maryland. This study was conducted to evaluate the accuracy of VIVO as compared to invasive mapping systems (current prevailing method for determining arrhythmia origins). VIVO met all study endpoints and correctly matched the predicted arrhythmia origin in 44/44 patients (100%; primary endpoint) and correctly matched paced sites in 225/226 locations (99.56%; secondary endpoint). In some instances, this study showed that VIVO has better predictability for arrhythmia origin than a physician's manual review of a 12 lead ECG.

While conducting the initial clinical study for FDA submission, we developed generation 2 in parallel with a goal to have this version complete and ready to submit upon 510(k) clearance of generation 1. We successfully achieved this goal and received CE Mark and FDA 510(k) Clearance for generation 2 in 2020.

Additional clinical work has occurred with generation 2. Until recently, this data has been single center, physician-initiated research and has resulted in peer reviewed clinical science at electrophysiology conferences and in journals.

Three physicians, at different centers in the UK conducted a feasibility study for Stereotactic Ablative Radiotherapy, or SABR, and published their data on nine patients. SABR is an ablation technique utilizing non-invasive methods akin to proton therapy for cancer treatment. To do a complete non-invasive ablation, accurately predicting the ablation location non-invasively is key to procedural success, and VIVO was utilized for this purpose. Non-invasive ablation is a new technique and requires additional data, but it is showing promise and has generated excitement within the EP community. If accepted for wide-spread treatment, this would allow for previously un-ablatable patients to receive lifesaving treatments.

In October 2021 the first patient was enrolled in the VIVO EU Registry. This registry aims to gather data about how VIVO is used in real-world settings, outside of a rigorous clinical study. The registry enrolled 125 patients across Europe and the UK and collected information about different workflows and applications for VIVO. Enrollment of 125 patients was completed in June 2023. The study required a 12-month follow-up and data collection was completed in late 2024.This data serves multiple purposes including fulfilling European regulatory requirements for on-going data collection, publication of multi-center data, and future development of studies and improvements to the VIVO technology.

The EU registry data demonstrated that approximately 60% of physicians used VIVO pre-procedurally to improve procedural workflow and that VIVO is 94.33% accurate. This data is planned for publication submission in early Q2 2025.

The physician-initiated study at Coventry Hospital in the UK completed enrollment and follow-up of 50 patients in Q4 2024. This study focused on outcomes of re-entrant ventricular tachycardia procedures when using VIVO pre-procedurally. These patients have hearts that are not structurally normal and have scarred tissue present in the ventricle. This data will be used for publication and to support an FDA submission to expand the current labeling of the existing product in Q2 2025.

The Coventry data shows that the VIVO non-invasive mapping system was able to accurately map the ventricular tachycardia sight of origin in scar development dependent ventricular tachycardia and identify the relevant myocardial scar. Procedural success was seen in 90% of patients at mean follow up of 7.3 ± 4.7 months.

LockeT

LockeT, a suture retention device, is a sterile, Class I product that was registered with the FDA in February 2023, at which time we began initial shipments to

distributors. In May 2023, Catheter submitted LockeT for CE Mark approval. CE Mark approval is expected in the first half of 2025, at which time initial international shipments to distributors will begin. LockeT is indicated for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure and is intended to temporarily secure sutures, aid clinicians in locating and removing sutures efficiently and promote hemostasis.







Clinical studies for LockeT began during 2023. The five phases of the current studies are planned to show the product's effectiveness and benefits, including faster wound closure, earlier ambulation, potentially leading to faster hospital discharge, and lower costs for the healthcare provider and/or insurance payor. This data is intended to aid our marketing efforts and expand our indications for use with the FDA. See *License and Other Agreements* below.

The Phase I - First in Man Feasibility Study was completed in 2023 and showed that the device works for its intended purpose and that there were no safety events, and gathered initial data to support Phase II submission to Institutional Review Board (IRB). This data has been presented as an abstract at several conferences including Western Atrial Fibrillation Symposium in February 2024 and American Heart Association in March 2024. This data was also accepted and published in August 2024 in the Journal of Cardiovascular Electrophysiology.

Phase II completed enrollment of 97 patients in late 2024. This phase compared manual compression (standard of care) to LockeT. This data has been drafted into a manuscript and is currently undergoing revisions and journal submission is planned for the first half of 2025. The journal for submission has not yet been determined.

Phase III was submitted to the IRB in December 2024. The study was approved by the IRB in January 2025. This study is collecting retrospective data, and as such, data collection has already been completed. The manuscript is currently in draft form and under review for planned journal submission in the first half of 2025. The aim of this study is to evaluate the safety profile of LockeT as compared to another vascular closure device when closing large bore access sites for left atrial appendage occlusion procedures.

Phase IV was submitted to the IRB in December 2024. The study was approved by the IRB in January 2025. This study aims to evaluate the effectiveness of LockeT, a novel external compression device, for large-bore venous vascular access site hemostasis following electrophysiologic pulsed field ablation procedures. This study is planned to begin enrollment by April 2025 and take 6 months to complete. Thus, the anticipated completion date is October 2025.

Phase V was submitted to IRB in February 2025. The goal of this study is to compare the safety and effectiveness of LockeT for small bore vascular closure compared to Vascade, a vascular closure device. It is anticipated that approval from the IRB will be provided by April 1, 2025, at which point enrollment will commence. Study duration is expected to be 9 months, with enrollment conclusion by end of Q4 2025.

Our Solutions

Adoption of our VIVO System by electrophysiologists is expected to enhance their ability to diagnose and treat cardiac arrhythmias.

Non- invasive mapping prior to the ablation procedure provides a solution for patients that could not be ablated previously. First, many patients with VT do not tolerate anesthesia well. By providing a non-invasive solution to determine the ablation location, physicians are better able to understand where the arrhythmia originates and how easily one can access the ablation location, minimizing the amount of time that the patient may need to be anesthetized, and allowing many patients the ability to have an ablation that otherwise could not. Second, many patients are highly symptomatic, but do not have PVCs often. In these situations, the patients are often brought in for ablation procedures only to have no arrhythmia and sent home time and time again. In these instances, the physicians can monitor the patient prior to hospitalization and obtain information about the arrythmia. In this way, the patient can still proceed to an ablation procedure without having PVCs on the day of surgery.

Non- invasive mapping also enables planning prior to the start of the procedure. This enables the physicians to better understand where they are targeting, which enables them to make advanced decisions about where they are navigating the catheter and which catheter(s) they are using, reducing both procedure time and cost.

Surgery patients who are offered the LockeT device are expected to benefit from faster wound closure, more comfort than manual compression and earlier ambulation, potentially leading to early hospital discharge and lower costs for the healthcare provider and/or insurance payor.

Our Strategy

Our goal is to become a leading developer and marketer of electrophysiology products which provide patients, hospitals, and physicians with novel technologies and solutions to improve procedural outcomes and the lives of patients with cardiac arrhythmia. We intend to establish VIVO as an integral tool for cardiac electrophysiologists to reduce procedure time during ablation treatment of ventricular arrhythmias, patient complications and increasing procedural success. We further intend to establish LockeT as a standard for wound closure, shortening time to achieve hemostasis while improving patient comfort.

Customers

Our primary customers are hospitals providing cardiac electrophysiology lab procedures. We believe there are 2,000 to 3,000 EP labs in the U.S. and a similar number of labs outside of the U.S. performing approximately 600,000 ablation procedures annually. During fiscal 2024, we had two individual customers that represented approximately 37% and 15% of our total revenues, respectively, and three customers (including the two just described) that in the aggregate represented approximately 62% of our total revenues.

Sales and Marketing

During 2024 we hired a new Chief Commercial Officer, two regional directors, eight territory managers and four clinical support specialists, replacing our entire sales team. Our new salespeople average 10 years of electrophysiology sales experience. Our sales team sells both VIVO and LockeT. The sales team qualifies appropriate prospective customers, and with support from our direct clinical specialists they conduct product demonstrations, and support customer training and case usage. In Europe, our products are sold through distributors, supported by one full-time contracted sales consultant.

In the future, we intend to market our products in the U.S. and certain international markets using a combination of a direct sales force and independent distributors. This may require us to make a significant investment building our U.S. commercial infrastructure and sales force and in recruiting and training our sales representatives and clinical specialists for U.S. commercialization of VIVO and LockeT. This is a lengthy process that requires recruiting appropriate sales representatives, establishing a commercial infrastructure in the United States, and training our sales representatives, and will require significant ongoing investment by us. Following initial training, our sales representatives typically require lead time in the field to grow their network of accounts, coordinate their sales efforts with each hospital's capital budgeting and acquisition cycle and produce sales results. Successfully recruiting and training a sufficient number of productive sales representatives is required to achieve growth at the rate we desire.

We previously entered into a joint marketing agreement with Stereotaxis, Inc. The parties agreed to terminate the agreement in December 2024.

Outside the U.S., we will continue to foster additional key partner relationships with distributors who will market, sell and support our products.

In addition, we believe there are opportunities to offer additional complementary products through our sales and marketing channels that would enhance the productivity of our sales force and provide additional scale to revenue, better covering fixed operating costs.

Manufacturing and Availability of Raw Materials

VIVO manufacturing, inventory and product fulfillment is housed in our approximate 2,000 square feet facility in Fort Mill, South Carolina. This facility currently has one full-time employee who oversees manufacturing, quality objectives, and order fulfillment. The VIVO system includes VIVO software, loaded onto an off-the-shelf laptop, which we equip with a 3D camera. We purchase laptops and cameras that have been manufactured by third parties. Disposable VIVO Positioning Patches are also required for use of the system, and the manufacture of the patches is outsourced. In January 2025, we hired an in-house full-time software engineer for research and development activities related to VIVO. This includes updates to the existing VIVO version and development and product release of VIVO 3. LockeT manufacturing, inventory and product fulfillment has been subcontracted to the company that provided research and development of the product.

Competition

The medical device industry is highly competitive, subject to rapid change and is significantly affected by new product introductions and other activities of industry participants. We face potential competition from major medical device companies worldwide, many of which have longer, more established operating histories, and significantly greater financial, technical, marketing, sales, distribution, and other resources. Our overall competitive position is dependent upon a number of factors, including product performance and reliability, manufacturing cost, and customer support. Our primary competitors in the cardiac electrophysiology space include known medical devices such as pacemakers, electrocardiogram, or ECG, systems and cardiac catheters, but also laboratory equipment such as intracardiac mapping systems and fluoroscopy systems (similar to x-ray in real time). The EP market includes large medical device companies such as Medtronic, Plc., Abbott Laboratories, Biosense-Webster (J&J) and Boston Scientific Corp. LockeT's direct competitors include Abbott's Perclose device, Haemonetic's VASCADE device and Inari Medical's FlowStasis device.

Research and Development

The major focus of our research and development team is to leverage our existing technology platform for new applications and improvements to our existing applications, including multiple engineering efforts to improve our current products. Future research and development efforts will involve continued enhancements to and cost reductions of VIVO and LockeT, and commercialization opportunities for the acquired PeriKard technology. We will also explore the development of other products that can be derived from our core technology platform and intellectual property. Our research and development team works together with our commercial team to set development priorities based on communicated customer needs. The feedback received from our customers is reviewed and evaluated for incorporation into new products.

With the hiring of an in-house full-time software engineer, we have begun the development of a generation 3 of VIVO. If successful, this version will have expanded indications to include ischemic heart disease and improve usability by the hospital staff. It would also contain more automaticity, potentially reducing our need for clinical support.

Resources Material to Our Business

Patents and Proprietary Technology

Patents

We have a number of patents covering our intellectual property, both in the U.S., as well in a number of international countries. We consider the U.S. to be the most important market for our products, and hence, the most important country for the filing of patents. Any foreign filings are merely replicates of the U.S. filings. For the U.S., our key patents include:

- VIVO – We have two U.S. patents granted on the original VIVO concept, which have been licensed from a third party. We consider the primary component to be the ideas around utilizing a 3D camera to identify the exact location of the body surface electrodes. These two patents expire in 2038. An additional two applications have been granted, which disclosed ideas around merging of the heart models to other heart images and expire in 2038 and 2040. An additional three applications were published, all filed in 2021, covering the idea of determining the thickness of the wall of the ventricle, covering the concept of the rendering of a heart model and likely outcomes of an EP procedure. An additional application was filed in September 2023 and is not yet published.

- LockeT – Suture Retention Device - We have four published U.S. patent applications. These cover the basic concept, methods of use and the design of the conceived device.

License and Other Agreements

PEACS, NV Software and Technology License Agreement

On May 1, 2016, we entered into a certain Software and Technology License Agreement with PEACS, NV, a Netherlands company, or the License Agreement, for the exclusive worldwide license of the underlying technology to the VIVO product, including intellectual property rights and patent applications pertaining thereto. The license was for use of the technology for the field of use defined as “the localization of the origin of cardiac activation for the electrophysiology treatment and/or detection of cardiac arrhythmias.” The License Agreement called for us to pay for the prosecution and maintenance of patents to protect the technology.

In May 2021, the License Agreement was modified to modify the field of use to specifically exclude the use of clinical applications for the implanting of atrial or ventricular pacemakers, including bi-ventricular pacemakers. The terms of the License Agreement are incorporated herein by reference to Exhibits 10.32 and 10.32.1 hereto.

LockeT Royalty Agreement

In February 2022, we agreed to an assignment and royalty agreement, or the Royalty Agreement, for the LockeT device. Pursuant to the Royalty Agreement, we agreed to pay a royalty fee of 5% on net sales up to $1 million. Thereafter, if a patent for the LockeT device is obtained from the U.S. Patent and Trademark Office, we will pay a royalty fee of 2% of net sales up to a total of $10 million in royalties. In addition, at the time of the Merger, additional royalty rights with respect to LockeT device were granted to certain holders, or the Noteholders, of Old Catheter's outstanding convertible promissory notes, including our Chief Executive Officer, David Jenkins, and certain of his affiliates, in exchange for forgiveness of the interest that had accrued under those notes but remained unpaid, pursuant to the terms of certain Debt Settlement Agreements. The Debt Settlement Agreements provided for the Noteholders to receive, in the aggregate, approximately 12% of the net sales, if any, of the LockeT device, commencing upon the first commercial sale through December 31, 2035.

Trademarks

We own or have rights to trademarks that we use in connection with the operation of our business. We own or have rights to trademarks for Catheter Precision, LockeT and Ra Medical Systems and their logos, as well as other trademarks such as AMIGO.

Trade Secrets

We also have relied upon trade secrets, know-how and technological innovation, and may in the future rely upon licensing opportunities to develop and maintain our competitive position. We have protected our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information.

Government Regulations

Governmental authorities in the U.S. (at the federal, state, and local levels) and abroad extensively regulate, among other things, the research and development, testing, manufacture, quality control, clinical research, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of products such as those we market and are developing. See *Item 1.A. Risk Factors—Risks Related to Government Regulation.*

United States Medical Device Regulation

In the U.S., medical devices are subject to extensive regulation by the Food and Drug Administration ("FDA"), pursuant to the Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, and certain other federal and state statutes and regulations. The laws and regulations govern, among other things, the design, manufacture, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as FDA refusal to approve pending pre-market approval ("PMA"), applications or premarket notification submissions (commonly referred to as "510(k)s)," issuance of warning letters or untitled letters, product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

The FDCA classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class II devices provide intermediate levels of risk. They are subject to general controls and must also comply with special controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by the FDA before they are marketed. LockeT is a sterile, Class I product and was registered with the FDA in February of 2023. It does not require FDA marketing authorization. VIVO is an FDA-cleared Class II product. We are currently evaluating the regulatory path for any potential PeriKard products.

Establishments that manufacture devices are required to register their establishments with the FDA and provide the FDA with a list of the devices that they handle at their facilities.

The FDA conducts market surveillance and periodic visits, both announced and unannounced, to inspect or re-inspect equipment, facilities, laboratories and processes to confirm regulatory compliance. These inspections may include the manufacturing facilities of subcontractors. Following an inspection, the FDA may issue a report, known as a Form 483, listing instances where the manufacturer has failed to comply with applicable regulations and/or procedures or, if observed violations are severe and urgent, a warning letter. If the manufacturer does not adequately respond to a Form 483 or warning letter, the FDA (with assistance from the Justice Department in certain cases) make take enforcement action against the manufacturer or impose other sanctions or consequences, which may include:

- injunctions or consent decrees;
- civil monetary penalties;
- recall, detention or seizure of our products;
- operating restrictions, partial or total shutdown of production facilities;
- refusal of or delay in granting requests for 510(k) clearance, de novo classification, or premarket approval of new products or modified products;
- withdrawing 510(k) clearances, de novo classifications, or premarket approvals that are already granted;
- refusal to grant export approval or export certificates or devices; and
- criminal prosecution.

Pre-Market Authorization and Notification

While some Class I and some Class II devices can be marketed without prior FDA authorization, most medical devices can be legally sold within the U.S. only if the FDA has: (i) approved a PMA application prior to marketing, generally applicable to most Class III devices; (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class I and II devices; or (iii) authorized the device to be marketed through the de novo process, generally applicable for novel Class I or II devices. Some devices that have been classified as Class III are regulated pursuant to the 510(k) requirements because the FDA has not yet called for PMAs for these devices.

510(k) Notification

Product marketing in the U.S. for most Class II and limited Class I devices typically follows a 510(k) pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a legally marketed device, referred to as the predicate device. A predicate device may be a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of PMA applications, or a product previously granted de novo authorization. The manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or it is shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

There are three types of 510(k)s: traditional; special, for certain device modifications; and abbreviated, for devices that conform to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review. The FDA intends to process special 510(k)s within 30 days of receipt and abbreviated 510(k)s within 90 days of receipt. Though the FDA has a goal to clear a traditional 510(k) within 90 days of receipt, the clearance pathway for traditional 510(k)s can take substantially longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer’s decision not to seek a new 510(k) clearance for the modified device, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained.

VIVO was cleared by the FDA via a traditional 510(k) with supporting clinical data. This data was collected via a clinical study enrolling 51 subjects and took approximately 12 months to gather. In order to expand the indications for use of the current VIVO product with the FDA to include ischemic hearts, data collection via the Coventry study to support a new 510(k) submission will be required. It is expected that future generations of VIVO will require similar data collection and 510(k) submission to receive separate FDA clearance.

Because the LockeT device is a Class I product, it did not require clinical data or a formal submission process. After completing validation testing and compiling a Device History File, LockeT was added to our listing of registered devices. The regulatory pathway for future LockeT devices will depend on the intended use and desired labeling claims and the requirements for clinical data.

De Novo Classification

Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f) (1) of the FDCA, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDCA. This provision allows the FDA to classify a low- to moderate-risk device not previously classified into Class I or II through the de novo classification pathway. The FDA evaluates the safety and effectiveness of devices submitted for review under the de novo classification pathway, and devices determined to be Class II through this pathway can serve as predicate devices for future 510(k) applicants. The de novo classification pathway can require clinical data and is generally more burdensome than the 510(k) pathway and less burdensome than the PMA pathway.

Pre-Market Approval

A product not eligible for 510(k) clearance or de novo classification must follow the PMA pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction.

Results from adequate and well-controlled clinical trials are required to establish the safety and effectiveness of a Class III PMA device for each indication for which FDA approval is sought. After completion of the required clinical testing, a PMA including the results of all preclinical, clinical, and other testing, and information relating to the product's marketing history, design, labeling, manufacture, and controls, is prepared and submitted to the FDA.

The PMA process is generally more expensive, rigorous, lengthy, and uncertain than the 510(k) premarket notification process and de novo classification process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with Quality System Regulations, or QSR, requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The FDA's review of a PMA application typically takes one to three years but may last longer. The FDA will often convene an independent advisory panel to review the submission. If the FDA's evaluation of the PMA application is favorable, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval and/or placement of restrictions on the sale of the device until the conditions are satisfied.

Even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

Clinical Trials

A clinical trial is almost always required to support a PMA application and de novo classification and is sometimes required for a premarket notification. For significant risk devices, the FDA regulations require that human clinical investigations conducted in the U.S. be approved under an Investigational Device Exemption ("IDE"), which must become effective before clinical testing may commence. A nonsignificant risk device does not require FDA approval of an IDE. In some cases, one or more smaller IDE studies may precede a pivotal clinical trial intended to demonstrate the safety and efficacy of the investigational device. A 30-day waiting period after the submission of each IDE is required prior to the commencement of clinical testing in humans. If the FDA disapproves the IDE within this 30-day period, the clinical trial proposed in the IDE may not begin. In addition, even if the 30-day waiting period expires without objection by the FDA, the FDA can impose a clinical hold if safety issues arise.

An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. The FDA typically grants IDE approval for a specified number of patients to be treated at specified study centers. During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain patient informed consent, follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. Prior to granting PMA, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard intended to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Pivotal clinical trials supporting premarket applications for devices are typically conducted at geographically diverse clinical trial sites and are designed to permit the FDA to evaluate the overall benefit-risk relationship of the device and to provide adequate information for the labeling of the device when considering whether a device satisfies the statutory standard for commercialization. Clinical trials, for significant and nonsignificant risk devices, must be approved by an institutional review board, or IRB—an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of the human research subject.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with the FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial it has approved to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions or sanctions.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing. Investigational devices may only be distributed for use in an investigation and must bear a label with the statement: "CAUTION-Investigational device. Limited by Federal law to investigational use."

Post-Market Requirements

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR requirements, labeling regulations, the medical device reporting regulations (which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and reports of corrections and removals regulations (which require manufacturers to report recalls or removals and field corrections to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA). Failure to properly identify reportable events or to file timely reports, as well as failure to address observations to FDA's satisfaction, can subject us to warning letters, recalls, or other sanctions and penalties.

Advertising, marketing and promotional activities for devices are also subject to FDA oversight and must comply with the statutory standards of the FDCA, and the FDA's implementing regulations. The FDA's oversight authority review of marketing and promotional activities encompasses, but is not limited to direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA also regulates industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context.

Manufacturers of medical devices are permitted to promote products solely for the uses and indications set forth in the approved or cleared product labeling. A number of enforcement actions have been taken against manufacturers that promote products for "off-label" uses (i.e., uses that are not described in the approved or cleared labeling), including actions alleging that claims submitted to government healthcare programs for reimbursement of products that were promoted for "off-label" uses are fraudulent in violation of the Federal False Claims Act or other federal and state statutes and that the submission of those claims was caused by off-label promotion. The failure to comply with prohibitions on "off-label" promotion can result in significant monetary penalties, revocation or suspension of a company's business license, suspension of sales of certain products, product recalls, civil or criminal sanctions, exclusion from participating in federal healthcare programs, or other enforcement actions. In the United States, allegations of such wrongful conduct could also result in a corporate integrity agreement with the U.S. government that imposes significant administrative obligations and costs, as has occurred in the past with respect to our legacy products that we no longer market.

The Federal Trade Commission, or FTC, also oversees the advertising and promotion of our products (other than labeling) pursuant to its broad authority to police deceptive advertising for goods or services within the U.S. The FDA and FTC work together to regulate different aspects of activities by medical product manufacturers, consistent with the inter-agency Memorandum of Understanding. Under the Federal Trade Commission Act, or FTCA, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. In the context of performance claims for products such as our devices and services, compliance with the FTCA includes ensuring that there is scientific data to substantiate the claims being made, that the advertising is neither false nor misleading, and that any user testimonials or endorsements we or our agents disseminate related to the devices or services comply with disclosure and other regulatory requirements.

Violations of the FDCA or FTCA relating to the inappropriate promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, including state consumer protection laws.

For a PMA or Class II 510(k) or de novo devices, the FDA also may require post-marketing testing, surveillance, or other measures to monitor the effects of an approved or cleared product. The FDA may place conditions on a PMA-approved device that could restrict the distribution or use of the product. In addition, quality control, manufacture, packaging, and labeling procedures must continue to conform to QSRs and other applicable regulatory requirements after approval and clearance, and manufacturers are subject to periodic inspections by the FDA. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with QSRs. If the FDA believes we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements and patients are being subjected to serious risks, the agency can shut down our manufacturing operations, require recalls of our medical device products, refuse to approve new marketing applications, initiate legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees.

European Economic Area (EEA) Regulation

The EEA recognizes a single medical device approval (the CE Mark) which allows for distribution of an approved product throughout the EEA without additional general applications in each country. Individual EEA members, however, reserve the right to require additional labeling or information to address particular patient safety issues prior to allowing marketing. Third parties called "Notified Bodies" award the CE Mark. These Notified Bodies are approved and subject to review by the "Competent Authorities" of their respective countries. Our Notified Bodies perform periodic on-site inspections to independently review our compliance with systems and regulatory requirements. A number of countries outside of the EEA accept the CE Mark in lieu of marketing submissions as an addendum to that country's application process. We have a CE Mark for the VIVO System. Beginning July 1, 2023, the United Kingdom requires its own medical device approval (UKCA). VIVO is currently registered with UK's Medicines and Healthcare products Regulatory Agency to market the VIVO system in the UK. Since July 1, 2023, VIVO bears the UKCA symbol as required by the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) ("MDR") to continue UK distributions. MDR requirements now include on-going collection of clinical data to include in annual reports to ensure state-of-the-art technology and safety requirements are met. We are currently collecting data via a multi-center (and country) European Registry. This registry concluded enrollment in June 2023. The required 12-month follow-up and data collection was completed in late 2024.

LockeT is currently undergoing MDR review and approval via the Notified Body. CE Mark is anticipated in the first half of 2025.

Other Healthcare Laws

Our business operations and current and future arrangements with healthcare professionals, consultants, customers and patients, expose us to broadly applicable state, federal, and foreign fraud and abuse and other healthcare laws and regulations. These laws constrain the business and financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products. Such laws include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;

- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;

- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the health care fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;

- in addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH Act, and its implementing regulations, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Physician Payments Sunshine Act, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), non-physician healthcare professionals (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives) and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise report or restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery laws in other jurisdictions, generally prohibit businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. The scope of the FCPA includes interactions with certain healthcare professionals in many countries.

There is no assurance that our internal control policies and procedures will protect us from acts committed by our employees or agents. If we are found to be liable for FCPA or other violations (either due to our own acts or our inadvertence, or due to the acts or inadvertence of others), we could suffer from civil and criminal penalties or other sanctions, including contract cancellations or debarment, and loss of reputation, any of which could have a material adverse impact on our business, financial condition, and results of operations.

Environmental Regulation

We are subject to federal, state and local regulations governing the storage, use and disposal of waste materials and products. Although we believe that our safety procedures for storing, handling and disposing of these materials and products comply with the standards prescribed by law and regulation, we cannot eliminate the risk of accidental contamination or injury from those hazardous materials. Federal regulations promulgated by the Occupational Safety and Health Administration impose additional requirements on us, including those protecting employees from exposure to elements such as blood-borne pathogens. We cannot predict the frequency of compliance, monitoring, or enforcement actions to which we may be subject, which events and actions could adversely affect our operations.

Employees

As of March 6, 2025, we had a total of 22 employees, including 22 full-time employees, which include finance and administrative, research and development, sales and marketing and clinical professionals. We also have retained a total of 3 people as independent contractors. We are planning to increase our sales force in support of product launches but currently have no other plans to increase our staff.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, before making an investment decision. The risks and uncertainties described below may not be the only ones we face. If any of the risks actually occur, our business, financial condition, operating results, cash flow and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

We will be required to raise additional funds to finance our operations and continue as a going concern; We may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.

Our operations to date have consumed substantial amounts of cash and our business, including the business of Old Catheter conducted prior to its being acquired by the Company, sustained negative cash flows from operations for the last several years. In addition, our auditors' report on our financial statements included in this Form 10-K contains an explanatory paragraph about the substantial doubt to continue as a going concern. As of March 14, 2025, we have approximately $787 thousand in cash and cash equivalents, which, together with our anticipated cash from operations, is not adequate to meet our working capital needs through the remainder of 2025, and our business is currently not profitable. During 2024 we raised approximately $7.2 million in net proceeds from securities transactions, but operating costs and other negative cash flows have substantially depleted our cash. As a result, we will require additional future capital infusions including public or private financing, strategic partnerships or other arrangements with organizations that have capabilities and/or products that are complementary to our own capabilities and/or products, in order to execute our strategic vision. However, there can be no assurances that we can complete any financings, strategic alliances or collaborative development agreements, and the terms of such arrangements may not be advantageous to us. In addition, any additional equity financing will be dilutive to our current stockholders, and debt financing, if available, may involve restrictive covenants. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize. Our failure to raise capital when needed could materially harm our business, financial condition, and results of operations. See "—We have entered into joint marketing agreements with respect to our products, and may enter into additional join marketing agreements, that will reduce our revenues from product sales," and "—Royalty agreements with respect to LockeT, the surgical vessel closing pressure device, will reduce any future revenues from this product."

Our business has a history of losses and will incur additional losses, and we may never achieve profitability.

Our current business primarily derives revenues from the View into Ventricular Onset System or VIVO™ System ("VIVO" or "VIVO System") and our LockeT product. VIVO is FDA cleared, and CE marked, having received FDA 510(k) clearance in June 2019. Old Catheter began a limited commercial launch of VIVO in the third quarter of 2021, and we began a full-scale launch in 2023 in conjunction with the expansion of a direct sales force in the U.S. Our current business strategies include a plan to expand uses for VIVO, which will require additional clearances. LockeT, a suture retention device, is a sterile, Class I product that was registered with the FDA in February 2023, at which time we began initial shipments to distributors. In May 2023, Catheter submitted LockeT for CE Mark approval. CE Mark approval is expected in the first half of 2025, at which time initial international shipments to distributors will begin. While we do generate revenue, we are currently operating at a loss, and there is no guarantee that we will be able to grow revenues enough to offset our costs and achieve profitability. To date, we have not been profitable, and our accumulated deficit was approximately $292 million at December 31, 2024. Historically, aside from Merger costs, our losses have resulted principally from costs incurred in research and development, and from general and administrative costs associated with our operations. During the 2024 we raised approximately $7.2 million in net proceeds from securities transactions, but operating costs and negative cash flows have substantially depleted our cash. However, in order to continue the commercialization of our assets consistent with our vision, we will need to conduct substantial additional research, development and clinical trials. Our business strategy also includes expanding uses for our products which will require us to seek additional regulatory clearances in the United States and abroad, and we also must continue to expand our patents in order to obtain meaningful patent protection for and establish freedom to commercialize our product candidates. We must also complete further clinical trials and seek regulatory approvals for any new product candidates we discover, license or acquire. We cannot be sure whether and when we will obtain required regulatory approvals, or successfully research, develop, commercialize, manufacture and market any other product candidates. We expect that these activities, together with future general and administrative activities, will result in significant expenses for the foreseeable future. We may never achieve profitability. Our current cash flows are not sufficient to fund our current operations, and we believe that we will need to complete additional financings within the next three to six months.

Risks Related to Our Internal Controls

We have identified material weaknesses in our internal control over financial reporting. These material weaknesses could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our disclosure controls and to disclose any material changes to our internal controls identified through such evaluation. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. As described elsewhere in this Form 10-K and in our Quarterly Reports on Form 10-Q filed during 2024, we have identified material weaknesses in our internal control over financial reporting related to (1) the lack of segregation of duties, (2) the lack of designed and operating review controls with respect to oversight of the financial reporting process, and (3) review of work performed by service providers with regards to (i) management's provision of inputs for valuations to a third-party service provider and (ii) the Section 382 calculation in the tax provision in that the Company's provision did not reference the correct dates when determining ownership changes resulting in material changes in the amount of expiring net operating losses available to be utilized. As a result of these material weaknesses, our management has concluded that our disclosure controls were not effective as of March 31, 2024, June 30, 2024, September 30, 2024, and December 31, 2024. For a discussion of management's consideration of the material weaknesses described above, see below "Part II, Item 9A. Controls and Procedures: of this Annual Report on Form 10-K, and "Part I, Item 4. Controls and Procedures" included in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024.

As described below at "Part II, Item 9A. Controls and Procedures" of this Annual Report on Form 10-K and "Part I, Item 4. Controls and Procedures" included in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, we have concluded that our disclosure controls were not effective as of March 31, 2024, June 30, 2024, September 30, 2024, and December 31, 2024 because material weaknesses existed in our internal control over financial reporting. We have formulated and are implementing a plan to remediate the material weaknesses described therein; however, if we are unable to remediate our material weaknesses in a timely manner or we identify additional material weaknesses, we may be unable to provide required financial information in a timely or reliable manner and we may incorrectly report financial information. Likewise, if our financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. In such a case, there could be a material adverse effect on our business. The existence of material weaknesses or significant deficiencies in internal control over financial reporting could adversely affect our reputation or investor perceptions of us, which could have a negative effect on the trading price of our stock. In addition, we may incur additional costs to remediate the material weaknesses in our internal control over financial reporting.

We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weaknesses identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls or otherwise.

There may be additional undetected material weaknesses in our internal control over financial reporting, as a result of which we may not detect financial statement errors on a timely basis. Further, to the extent we identify additional material weaknesses, we will not be able to fully assess whether corrective measures will remediate the material weakness in our internal control over financial reporting until we have completed our implementation efforts and sufficient time passes in order to evaluate their effectiveness. In addition, if we identify additional errors that result in material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. Moreover, in the future we may engage in additional business transactions, such as acquisitions, reorganizations or implementation of new information systems, any of which could negatively affect our internal control over financial reporting and result in material weaknesses.

If we identify additional material weaknesses in our internal control over financial reporting or if we continue to be unable to assert that our internal control over financial reporting is effective, we may again be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock could be negatively affected. As a result of any internal control failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation or divert financial and management resources from our core business, and which would have a material adverse effect on our business, financial condition and results of operations.

Compliance with Section 404 of the Sarbanes-Oxley Act could have a material adverse impact on our business.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. As a "smaller reporting company" that is a non-accelerated filer, we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be a non-accelerated filer. When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 to us in a timely manner, or if we or our independent registered public accounting firm identifies additional deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Risks Related to Our Business and Products

We will not be able to reach profitability unless we are able to achieve our product expansion and growth goals.

Our goal to achieve profitability is dependent upon establishing VIVO as an integral tool used by cardiac electrophysiologists during ablation treatment of ventricular arrhythmias, as well as upon developing and marketing new products, such as LockeT, the wound closure device, and our PeriKard products, and the successful build out of our U.S. commercial infrastructure and sales force. During fiscal 2024, over 70% of our revenues were derived from four customers, two of whom represented over half of our revenues. In today's healthcare environment, the process for new technologies to be adopted and penetrate market share has become more complex, with the need to win over multiple stakeholders within clinical, administrative and support teams in hospitals, and increasingly we must target the administrators in integrated delivery networks. To accomplish this, we will need to:

- Develop initial users that demonstrate clinical and economic benefits and support studies which provide evidence of tangible benefits to prospective customers, such as procedural success, no or minimal patient complications and reduced procedure times.
- Collaborate with clinical thought leaders to establish clinical techniques, evolve our product features and demonstrate enhanced capabilities to broaden the appeal of VIVO and LockeT.
- Acquire data and expand our FDA clearance to market our products for additional procedure types. In Europe, VIVO is cleared for pre-procedural planning in all types of hearts and procedures, including ischemic hearts. In the U.S., we will need to seek clearance for ischemic hearts to broaden the indications for use of our products, which can expand clinical demand. Data from the Coventry study focused on reentrant ventricular tachycardia will be used to support a clinical submission with existing version of VIVO.
- Enhance the design, user utility and clinical capability of VIVO and LockeT through further product development and collaboration with clinical users.
- Seek to engage collaboration with larger market participants and their larger sales force coverage to integrate the prospecting, sale and support of our products in conjunction with other products used in electrophysiology procedures.
- Opportunistically identify acquisitions to enhance our enterprise scale, sales synergy and fixed cost coverage.
- Seek to obtain permanent CPT codes for reimbursement from Medicare to broaden the appeal of using VIVO in the physician's clinic. The process takes five to seven years to complete. To date, we have met with reimbursement specialists and are working to determine the best strategy.
- Develop new products, including potentially our PeriKard products.

In addition, our sales and marketing strategy for VIVO requires us to hire additional clinical support and sales representatives who are experienced in the EP field. We must also make a significant investment building our U.S. commercial infrastructure and sales force, a lengthy process requiring ongoing investment and a certain amount of lead time to produce the growth rate we desire.

If we are unable to accomplish one or more of the foregoing, we may be unable to achieve our product expansion and growth goals and may be unable to achieve profitability.

Our research and development and commercialization efforts may depend on entering into agreements with corporate collaborators.

We may need to seek out additional collaborations in order to commercialize our products. We will continue to seek research collaborations, co-development and marketing agreements, and licensing deals for our products in development; however, there is no guarantee that we will be successful in our efforts. Any collaborator with whom we may enter into such collaboration agreements may not support fully our research and commercial interests since our programs may compete for time, attention and resources with such collaborator's internal programs. Therefore, these future collaborators may not commit sufficient resources to our programs to move them forward effectively, or the programs may not advance as rapidly as they might if we had retained complete control of all research, development, regulatory and commercialization decisions.

Economic uncertainty or downturns, and related tariffs, particularly as they impact particular industries, could adversely affect our business and results of operations.

In recent years, the U.S. and other significant markets have experienced inflationary pressures and cyclical downturns, and worldwide economic conditions remain uncertain. Economic uncertainty and associated macroeconomic conditions make it extremely difficult for our partners, suppliers, and us to accurately forecast and plan future business activities and could cause our customers to slow spending on our offerings and could limit the ability of hospitals to purchase sufficient quantities of our products. Inflationary pressures may lead to increases in the cost of our products, freight, overhead costs or wage rates and may adversely affect our operating results. Sustained inflationary pressures may have an adverse effect on our ability to produce and market our products cost effectively.

A significant downturn in the domestic or global economy may cause our customers to pause, delay, or cancel spending on our products or seek to lower their costs by exploring alternative providers or our competitors. To the extent purchases of our products are perceived by customers and potential customers as discretionary, our revenue may be disproportionately affected by delays or reductions in general healthcare spending. Also, competitors may respond to challenging market conditions by lowering prices and attempting to lure away our customers.

the current, volatile, political environment affecting tariffs and economic policies adopted by the U.S. and foreign governments can pose a significant risk to our business by increasing costs of raw materials, disrupting supply chains and making it harder to obtain supplies, and limiting product availability, which can lead to higher prices for our customers as well as reduced for the Company.

We cannot predict the timing, strength, or duration of any economic disruption or any subsequent recovery generally, or in any particular industry. If the conditions in the general economy and the markets in which we operate worsen from present levels, our business, financial condition, and results of operations could be materially adversely affected.

Artificial intelligence-based platforms may present new risks and challenges to our business.

Artificial Intelligence, or AI, technologies may exacerbate existing risks, including risks associated with data privacy, cybersecurity, IP, healthcare fraud and abuse, drug development and manufacturing, and risks to patients or human subjects in clinical trials. AI also introduces new risks, due to the autonomous nature of the technology, which, in some cases, may be deployed to perform tasks, inform decisions, automate decisions, and make predictions, sometimes using unverified or false information. AI may amplify biased and discriminatory decision making, perform unreliably and malfunction, generate insights which are difficult to interpret and explain, and cause direct harm to individuals or groups.

Regulators are proposing, adopting, and implementing new AI laws and regulations. We may be required to change our business practices and policies as a result of such laws and regulations and may incur substantial compliance-related costs. Regulators are also using existing laws and regulations to take enforcement actions related to the deployment of AI in ways that result in non-compliance with current laws and regulations. If we fail to comply with AI laws and regulations, we may be subject to sanctions, fines, and reputational damage, orders to stop certain processing of personal data, orders to delete certain data or destroy AI algorithms derived from data collection, legal action on behalf of impacted individuals or other enforcement or other actions. If we or our vendors using AI technologies fail to take steps to protect our confidential data, trade secrets, IP and personal data, we may be subject to legal, regulatory, financial, and reputational risks.

AI technologies present significant opportunities and risks to our business. Harnessing AI's transformative potential may enable us to speed up the discovery and development of new products and new uses for existing products, optimize our manufacturing processes, and drive efficiencies. Our failure to use AI technologies in a way that maintains trust, quality and control in our business activities and to capitalize on opportunities presented by AI may also place us at a competitive disadvantage. Failure to address AI risks will reduce our ability to deliver strategic objectives. Also, investments in AI may not realize the benefits that were anticipated.

We have previously entered into joint marketing agreements with respect to our products and may enter into additional joint marketing agreements that will reduce our revenues from product sales.

We have previously entered into joint marketing agreements that materially reduced the revenues that we received from VIVO products, and although all such agreements have been terminated, we may enter into similar agreements in the future with respect to any or all of our products, and any similar agreements entered into in the future may also materially reduce our per unit product revenues.

Royalty agreements with respect to LockeT, our surgical vessel closing pressure device, will reduce any future profits from this product.

In February 2022, Old Catheter agreed to an assignment and royalty agreement for the Surgical Vessel Closing Pressure Device ("LockeT"). Pursuant to the agreement, Old Catheter agreed to pay a royalty fee of 5% on net sales of up to $1 million. Thereafter, if a patent for the Surgical Vessel Closing Pressure Device is obtained from the U.S. Patent and Trademark Office, Old Catheter will pay a royalty fee of 2% of net sales up to a total of $10 million in royalties. In addition, at the time of our merger with Old Catheter, additional royalty rights with respect to LockeT were granted to certain holders (the "Noteholders") of Old Catheter's outstanding convertible promissory notes in exchange for forgiveness of the interest that had accrued under those notes but remained unpaid, pursuant to the terms of certain Debt Settlement Agreements. The agreements provide for the Noteholders to receive, in the aggregate, approximately 12% of the net sales, if any, of the Surgical Vessel Closing Pressure Device, commencing upon the first commercial sale through December 31, 2035. As a result, even if the Surgical Vessel Closing Pressure Device is successfully developed and marketed, our revenues from this device will be reduced by the amount of these royalties.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, as well as for accounting, financial reporting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures and user errors, among other malfunctions. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks. Technological interruptions could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers, or could disrupt our customers' ability to use our products for treatments. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition, and results of operations. Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount, subject to deductibles, and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition, and results of operations.

The rate of technological innovation of our products might not keep pace with the rest of the market.

The rate of innovation for the market in which our products compete is fast-paced and requires significant resources and innovation. If other products and technologies are developed that compete with, or may compete with, our products, it could be difficult for us to maintain our current competitive status. Likewise, the innovation and development cycle of competitors may impact our research and development efforts and ultimately, commercial adoption of viable research and development efforts. In addition, if we are not able to continue to commit sufficient resources to ensure that our products are compatible with other products within the electrophysiology lab, this could have a negative impact on our revenues.

Litigation and other legal proceedings may adversely affect our business.

From time to time we are involved in and may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class actions, and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. For example, we have previously been a party to securities class action and shareholder derivative litigation and other litigation. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition, and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

We must indemnify or advance reasonable legal expenses for officers and directors, including, in certain circumstances, former employees and directors, in their defense against legal proceedings, unless certain conditions apply. A prolonged uninsured expense and indemnification obligation could have a material adverse effect on our business, financial condition, and results of operations.

If we make acquisitions or divestitures, we could encounter difficulties that harm our business.

We may acquire companies, products or technologies that we believe to be complementary to the present or future direction of our business, or that may be of a strategic nature with a focus on a new direction. If we engage in such acquisitions, we may have difficulty integrating the acquired personnel, financials, operations, products or technologies. Acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees, increase our expenses, subject us to liabilities, and increase our risk of litigation, all of which could harm our business. If we use cash to acquire companies, products or technologies, it may divert resources otherwise available for other purposes. If we use our common stock to acquire companies, products or technologies, our stockholders may experience substantial dilution. In addition, development of acquired products and technologies may require significant investments of cash and management time, which could materially adversely affect the development of our existing products and technology.

Failure to attract and retain sufficient qualified personnel could also impede our growth.

We do not maintain "key man" insurance policies on the lives of any of our employees, including our Executive Chairman and Chief Executive Officer, David A. Jenkins. Mr. Jenkins is critical to our current business development, and we would not be able to easily replace him. Our success also depends on our ability to retain our other current key employees and continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations. We face intense competition for executive-level talent from a variety of sources, including from current and potential competitors in the medical device and healthcare industries, and there is no guarantee that we can locate suitable replacements when they are needed.

Our revenues may depend on our customers' receipt of adequate reimbursement from private insurers and government sponsored healthcare programs.

Political, economic, and regulatory influences continue to change the healthcare industry in the United States. The ability of hospitals to pay fees for our products will partially depend on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from private health coverage insurers and other similar organizations. We may have difficulty gaining market acceptance for the products we sell if third-party payers do not provide adequate coverage and reimbursement to hospitals and/or other relevant healthcare providers.

Major third-party payers of hospitals, such as private healthcare insurers, periodically revise their payment methodologies based, in part, upon changes in government sponsored healthcare programs. We cannot predict these periodic revisions with certainty, and such revisions may result in stricter standards for reimbursement of hospital charges for certain specified products, potentially adversely impacting our business, results of operations, and financial condition when we start receiving reimbursement from third party payers.

The sales of our products and services will depend in part on the availability of reimbursement by third-party payers, such as government health administration authorities, private health insurers and other organizations. Third-party payers often challenge the price and cost-effectiveness of medical treatments and services. Governmental approval of health care products does not guarantee that these third-party payers will pay for the products. Even if third-party payers do accept our products and services, the amounts they pay may not be adequate to enable us to make a profit. Legislation and regulations affecting the pricing of therapies may change before our products and services are approved for marketing, and any such changes could further limit reimbursement, if any.

We may be unable to compete successfully with companies in our highly competitive industry, many of whom have substantially greater resources than we do.

The healthcare industry is highly competitive. There are numerous approved products for treating the indications for which we have received clearance or approval and those that we may pursue in the future. Many of these cleared or approved products are well-established and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may encourage the use of competitors' products. In addition, many companies are developing products, and we cannot predict what the standard of care will be in the future.

Our primary competitors in the cardiac electrophysiology, or EP, space include known medical devices such as pacemakers, electrocardiogram, or ECG systems and cardiac catheters, but also laboratory equipment such as intracardiac mapping systems and fluoroscopy systems (similar to x-ray in real time). The EP market includes large medical device companies such as Medtronic, Plc., Abbott Laboratories, Biosense-Webster (J&J) and Boston Scientific Corp.

Many of our competitors have substantially greater financial, manufacturing, commercial, and technical resources than we do. There has been consolidation in the industry, and we expect that to continue. Larger competitors may have substantially larger sales and marketing operations than we do. This may allow those competitors to spend more time with current and potential customers and to focus on a larger number of current and potential customers, which gives them a significant advantage over our sales and marketing team and our international distributors in making sales. In addition, we are often selling to customers who already utilize our competitors' products and who have established relationships with our competitors' sales representatives and familiarity with our competitors' products.

Larger competitors may also have broader product lines, which enables them to offer customers bundled purchase contracts and quantity discounts. These competitors may have more experience than we have in research and development, marketing, manufacturing, preclinical testing, conducting clinical trials, obtaining FDA and non-U.S. regulatory clearances or approvals and marketing cleared or approved products. Our competitors may discover technologies and techniques, or enter into partnerships and collaborations, to develop competing products that are more effective or less costly than our products or the products we may develop. This may render our technology or products obsolete or noncompetitive. Our competitors may also be better equipped than we are to respond to competitive pressures. If we are unable to compete successfully in our industry, it would have a material adverse effect on our business, financial condition, and results of operations.

Our future operating results depend upon our ability to obtain components in sufficient quantities on commercially reasonable terms or according to schedules, prices, quality and volumes that are acceptable to us, and suppliers may fail to deliver components, or we may be unable to manage these components effectively or obtain these components on such terms.

We have historically obtained certain components globally, some of which were uniquely customized, from limited sources. This subjected us to significant supply and pricing risks and exposed us to multiple potential sources of component shortages. Many components, including those that are available from multiple sources, are at times subject to industry-wide shortages and significant commodity pricing fluctuations that could materially adversely affect our financial condition and operating results. We may source alternative parts to mitigate the challenges caused by these shortages, but there is no guarantee we may be able to continually do so as we scale production to meet our growth targets. The unavailability of any component or supplier could result in production delays, idle manufacturing facilities, product design changes and loss of access to important technology and tools for producing and supporting our products, as well as impacting our production capacity. Our suppliers may not be willing or able to sustainably meet our timelines or our cost, quality and volume needs, or to do so may cost us more, which may require us to replace them with other sources. If our supply of components for a new or existing product continues to be delayed or constrained for any reason, including if an outsourcing partner delayed shipments of completed products to us or additional time is required to obtain sufficient quantities from the original source, or if we have to identify and obtain sufficient quantities from an alternative source, then our financial condition and operating results could be materially adversely affected. In addition, the continued availability of these components at acceptable prices, or at all, can be affected for any number of reasons, including if suppliers decide to concentrate on the production of common components or components for other customers instead of components customized to meet our requirements. While we have entered into agreements for the supply of certain components, there can be no assurance that we will be able to extend or renew these agreements on similar terms, or at all. Some of our components are purchased off the shelf and therefore we have no contractual certainties regarding their availability or pricing. Component suppliers may suffer from poor financial conditions, which can lead to business failure for the supplier or consolidation within a particular industry, further limiting our ability to obtain sufficient quantities of components on commercially reasonable terms. While we believe that we will be able to secure components as needed, and where necessary locate additional or alternate sources or develop our own replacements for relevant components, there is no assurance that we will be able to do so quickly or at all.

Additionally, we may be unable to obtain components on attractive terms and where applicable to achieve through negotiations with relevant suppliers cost reductions and/or avoid unfavorable changes to terms, source less expensive suppliers for certain parts and redesign certain parts to make them less expensive to produce. Any of these occurrences may harm our business, prospects, financial condition and operating results.

If hospitals, physicians and patients do not accept our current and future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any.

Even when any of our product candidates obtain regulatory approval, they may not gain market acceptance among hospitals, physicians, patients, and third-party payers. Physicians may decide not to use our products for a variety of reasons including:

- timing of market introduction of competitive products;
- demonstration of clinical safety and efficacy compared to other products;
- cost-effectiveness;
- limited or no coverage by third-party payers;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- restrictions in the label of the device;
- other potential advantages of alternative treatment methods; and
- ineffective marketing and distribution support of our products.

If any of our product candidates are approved but fail to achieve market acceptance or such market is smaller than anticipated, we may not be able to generate significant revenue and our business would suffer.

The recent coronavirus, or COVID-19, outbreak adversely affected our financial condition and results of operations, and we cannot provide any certainty as to whether there will be future impacts from COVID-19 or another pandemic.

The COVID-19 outbreak adversely affected our financial condition and results of operations. The impact of the outbreak of COVID-19 on the businesses and the economy in the United States and the rest of the world was significant. The extent to which the COVID-19 outbreak will continue to impact business and the economy is highly uncertain and cannot be predicted, and there can be no guarantee that a future pandemic will not have similar or worse impacts. Accordingly, we cannot predict the extent to which our financial condition and results of operation will be affected.

A variety of risks associated with marketing our products internationally could materially adversely affect our business.

In addition to selling our products in the U.S., we sell products outside of the U.S. We are subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- differing reimbursement regimes in foreign countries, including price controls and lower payment;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;

- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities abroad;
- the impact of the current situation relating to trade with China and tariffs and other trade barriers that may be implemented by governmental authorities with respect to China and other countries;
- the impact of public health epidemics on the global economy; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations, which would have a material adverse effect on our business, financial condition, and results of operations.

The impact of the ongoing Russia-Ukraine and Israel-Gaza military conflicts, and other actions that have been and could be taken by other countries, including new and stricter sanctions and actions taken in response to such sanctions, have affected, and may continue to affect, our business and results of operations, including our supply chain.

On February 24, 2022, Russian forces launched significant military action against Ukraine, and sustained conflict and disruption in the region has occurred. The impact to Ukraine, as well as actions taken by other countries, including new and stricter sanctions imposed by Canada, the United Kingdom, the European Union, the U.S. and other countries and companies and organizations against officials, individuals, regions and industries in Russia and Ukraine, and actions taken by Russia in response to such sanctions, and each country's potential response to such sanctions, tensions and military actions could have a material adverse effect on our operations. Any such material adverse effect from the conflict and enhanced sanctions activity may disrupt our supply chains and affect the delivery of our products and services or impair our ability to complete financial or banking transactions. We may suffer similar adverse effects from the Israel-Gaza conflict which has been ongoing since October 2023.

We also cannot predict the impact of any heightened geopolitical instability or the results that may follow, including reductions in consumer confidence, heightened inflation, cyber disruptions or attacks, higher natural gas costs, higher manufacturing costs and higher supply chain costs. The impact of armed conflicts such as those described above could cause our results to differ materially from the outlook presented in this Annual Report.

If the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory approval for or commercialize our product candidates.

We may use independent clinical investigators and other third-party service providers to conduct and/or oversee the clinical trials of our product candidates.

FDA requires us and our clinical investigators to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate, and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our product candidates or result in enforcement actions against us.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements.

We are exposed to potential product liability risks inherent in the design, manufacturing, and marketing of our products. These matters are subject to many uncertainties, and outcomes are not predictable. In addition, we may incur significant legal expenses regardless of whether we are found to be liable.

While we maintain product liability insurance, there can be no assurance that such coverage is sufficient to cover all product liabilities that we may incur. We are not currently subject to any product liability proceedings, and we have no reserves for product liability disbursements. However, we may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the usage and delivery of our products. Should we incur product-related liabilities exceeding our insurance coverage, we would be required to use available cash or raise additional cash to cover such liabilities.

Our ability to use our net operating loss carryforwards may be limited.

As of December 31, 2024, we had net operating loss carryforwards, or NOLs, available of approximately $147 million for federal income tax purposes and $111.7 million for state income tax purposes. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. These NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or IRC, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership by 5% stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. We completed an IRC Section 382 analysis regarding the limitation of net operating losses through December 31, 2024, and determined that ownership changes occurred in during 2023 and 2024. Accordingly, utilization of our NOLs is subject to an annual limitation for federal tax purposes under IRC Section 382. Due to the changes in control, we estimated that $46.2 million of the $104.3 million federal NOLs are effectively eliminated, according to IRC Section 382. In addition, $61.2 million of our $63.8 million in state NOLs were also eliminated. As a result of these eliminations, our ability to utilize the federal and state NOLs were reduced to $58.2 million and $2.6 million, respectively.

Risks Related to Governmental Regulation and our Industry

We are subject to pervasive and continuing regulation by the FDA and other regulatory agencies.

Our medical device operations are subject to pervasive and continuing FDA regulatory requirements.

Medical devices regulated by the FDA are subject to "general controls" which include:

- registration with the FDA; listing commercially distributed products with the FDA;
- complying with applicable cGMPs under the Quality System Regulations, or QSR;
- filing reports with the FDA and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation;
- assuring that device labeling complies with device labeling requirements;
- reporting recalls and certain device field removals and corrections to the FDA; and
- obtaining premarket notification 510(k) clearance for devices prior to marketing.

Some devices known as "510(k)-exempt" devices can be marketed without prior marketing clearance or approval from the FDA. In addition to the "general controls," Class II medical devices are also subject to "special controls," including, in many cases, adherence to a particular guidance document and compliance with the performance standard. As a Class II, 510(k)-cleared device, our VIVO product is subject to both general and special controls. Instead of obtaining 510(k) clearance, most Class III devices are subject to premarket approval, or PMA. We do not believe any of our current products are Class III devices, but future products could be, which would subject them to the PMA process.

Many medical devices are also regulated by the FDA as "electronic products." In general, manufacturers and marketers of "electronic products" are subject to certain FDA regulatory requirements intended to ensure the radiological safety of the products. These requirements include, but are not limited to, filing certain reports with the FDA about the products and defects/safety issues related to the products as well as complying with radiological performance standards.

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, or MDR, requirements, including the reporting of adverse events and malfunctions related to our products. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales. 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 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 clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which may have a material adverse effect on our business, financial condition, and results of operations.

The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving marketing, business practices, and product quality management. For example, on December 28, 2020, we entered into a Settlement Agreement with the DOJ to resolve a civil False Claims Act investigation and related civil action, and in connection with the Settlement Agreement, we also have reached agreements that resolve previously disclosed related investigations conducted by certain state attorneys general. Under the Settlement Agreement, and the agreements with the participating states, we were required to make an initial payment of $2.5 million, of which we paid $2.4 million in December 2020 and $0.1 million in April 2021. We also were required to make a payment of $5.0 million as a result of the January 2023 merger with Old Catheter in January 2023, which we made in February 2023.

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, the U.S. Physician Payment Sunshine Act, now known as Open Payments, requires us to report to the Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. On December 28, 2020, we entered into the Settlement Agreement with the DOJ relating to claims under the civil False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices, which we are no longer marketing, for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute. Effective January 2022, we are also required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives. Failure to comply with these legal and regulatory requirements could impact our business, and we have spent and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition, and results of operations for years after any resolution of these investigations and any resulting claims are resolved.

Product clearances and approvals can often be denied or significantly delayed.

Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510(k) clearance, is authorized through the de novo classification process, or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510(k) clearance must be supported by preclinical and clinical data. Our ability to enroll patients in clinical trials could be impacted by a resurgence of the COVID-19 outbreak or another pandemic, as many patients would be likely to elect or would likely be asked to delay procedures at such a time.

The PMA process typically is more costly, lengthy and stringent than the 510(k) process. Unlike a 510(k) review which determines "substantial equivalence," a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and human clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the U.S. and similar agencies in other countries.

We may be required to obtain PMAs, PMA supplements or additional 510(k) premarket clearances to market modifications to our existing products, and our current business strategy contemplates expanding uses of our products to include uses that will require additional clearances. The FDA requires device manufacturers to make and document a determination of whether a device modification requires approval or clearance; however, the FDA can review a manufacturer's decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. If the FDA requires us to obtain PMAs, PMA supplements or premarket clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties.

The FDA may not approve future PMA applications or supplements or clear our 510(k) applications on a timely basis or at all. For example, the a new pandemic outbreak could affect the FDA's ability to review applications or supplements. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

International regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non-U.S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non-U.S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations.

Although we have obtained regulatory clearance for our VIVO and LockeT products in the U.S. and certain non-U.S. jurisdictions, our business plans include expanding uses for our products, which will require additional clearances; and even after clearance is obtained, our products will remain subject to extensive regulatory scrutiny.

Although our VIVO and LockeT products have received regulatory clearance in the U.S. and certain non-U.S. jurisdictions, they are subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, effectiveness, and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable non-U.S. regulatory authorities. In addition, our business plans include expanding uses for our products, which will require additional clearances.

Any regulatory clearances or approvals that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted or to the conditions of approval or contain requirements for potentially costly post-marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to ensure compliance. The FDA and other agencies, including the DOJ, closely regulate and monitor the post-clearance or post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling.

Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's cleared or approved labeling. As such, we may not promote our products for indications or uses for which they do not have clearance or approval. However, physicians can use their independent and professional judgment and use our products for off-label purposes, as FDA regulations do not restrict a physician's choice of treatment with the practice of medicine. Prior to making certain changes to a cleared product, including certain changes to product labeling, the holder of a cleared 510(k) application may be required to submit a new premarket application and obtain clearance or approval.

If a regulatory agency discovers previously unknown problems with our products, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of our products, such regulatory agencies or enforcement authority may impose restrictions on that product or us, including requiring withdrawal of the product from the market. In addition to this type of penalty for failing to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- subject us to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication, or correspondence;
- issue warning or untitled letters that would result in adverse publicity or may require corrective advertising;
- impose civil or criminal penalties;
- suspend or withdraw regulatory clearances or approvals;
- refuse to clear or approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our sub-assembly suppliers' facilities;
- seize or detain products; or
- require a product recall.

In addition, violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. As disclosed previously, we settled a DOJ civil False Claims Act investigation concerning, among other things, whether we marketed and promoted our DABRA devices for unapproved uses that were not covered by federal healthcare programs. We are no longer marketing DABRA devices.

Any government adverse finding, regulatory sanction or investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition, and results of operations.

Our products may be subject to additional recalls, revocations or suspensions after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business.

The FDA and similar foreign governmental authorities have the authority to order the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions, or other adverse events, such as serious injuries or deaths, or quality-related issues such as manufacturing errors or design or labeling defects.

For example, prior to our acquisition of Old Catheter and switch in focus to developing and marketing its products, we conducted four recalls related to our previously marketed DABRA product. We no longer market DABRA, but any government-mandated recall or additional voluntary recall by us of VIVO, LockeT or another product we market in the future could occur as a result of component failures, manufacturing errors, design or labeling defects or other issues. These voluntary recalls and any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business.

In addition, the FDA conducted an unannounced facility inspection in December 2019 in connection with our previously marketed DABRA product. The FDA issued us a Form 483 that included observations related to our previously marketed DABRA product, that schedules for the adjustment, cleaning, and other maintenance of equipment had not been adequately established, a device master record index was not current, and document control procedures had not been fully established. We responded to the FDA with the corrective measures we were taking and to address the issues identified in the Form 483 and based on this information, the FDA issued to us an Establishment Inspection Report, or EIR, closing out the inspection. All actions were completed, and the final Form 483 report was sent to the FDA on September 25, 2020. We are no longer operating this facility, but the FDA could conduct inspections of our current facilities.

Depending on the corrective action we take to address a product's deficiencies or defects, the FDA may require, or we may voluntarily decide, that we will need to seek and obtain new approvals or clearances for a device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including adverse inspection findings, FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred. After a May 2018 inspection related to our previously marketed DABRA product, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints related to our previously marketed DABRA product that we received rose to a level required to be reported to the FDA. At that time, in response, we informed the FDA that we had modified our complaint review procedures and we completed a retrospective evaluation and did not find any complaints which required a submission to the FDA. We have not requested, and the FDA has not issued, an EIR related to this inspection. We no longer market DABRA.

The failure by us to properly identify reportable events or to file timely reports with the FDA can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

If we or our suppliers fail to comply with the FDA's Quality System Regulation, or QSR, or any applicable state equivalent, our operations could be interrupted, and our potential product sales and operating results could suffer.

We and our suppliers are required to comply with the FDA's QSR, which delineates, among other things, the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, complaint handling, records requirements, servicing requirements, and statistical techniques potentially applicable to the production of our medical devices. We and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we market products overseas. The FDA enforces the QSR through periodic and announced or unannounced inspections of manufacturing facilities. We anticipate that we and certain of our third-party suppliers will be subject to future inspections. If our facility or manufacturing processes or our suppliers' facilities or manufacturing processes are found to be in non-compliance or fail to take satisfactory corrective action in response to adverse QSR inspectional findings, the FDA could take legal or regulatory enforcement actions against us and/or our products, including but not limited to the cessation of sales or the initiation of a recall of distributed products, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Current regulations depend heavily on administrative interpretation. If the FDA does not believe that we are in compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and/or our products. We are also subject to periodic inspections by the FDA, other governmental regulatory agencies, as well as certain third-party regulatory groups. Future interpretations made by the FDA or other regulatory bodies made during the course of these inspections may vary from current interpretations and may adversely affect our business and prospects. The FDA's and other comparable non-U.S. regulatory agencies' statutes, regulations, or policies may change, and additional government regulation or statutes may be enacted, which could increase post-approval regulatory requirements, or delay, suspend, or prevent marketing of any cleared or approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

The medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If our operations and activities are found to be in violation of any FDA laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and other legal and/or agency enforcement actions. Any penalties, damages, fines, or curtailment or restructuring of our operations or activities could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of FDA laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend ourselves against that action and its underlying allegations, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Where there is a dispute with a federal or state governmental agency that cannot be resolved to the mutual satisfaction of all relevant parties, we may determine that the costs, both real and contingent, are not justified by the commercial returns to us from maintaining the dispute or the product.

Various claims, design features or performance characteristics of our medical devices, that we regarded as permitted by the FDA without new marketing clearance or approval, may be challenged by the FDA or state or foreign regulators. The FDA or state or foreign regulatory authorities may find that certain claims, design features or performance characteristics, in order to be made or included in the products, are required to be supported by further clinical studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable.

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

Under the FDA medical device reporting regulations, or MDR 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 events required to be reported to the FDA within the required timeframes, or at all, the 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 our time and capital, distract management from operating our business, and may harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets.

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increasing costs of healthcare and, more generally, to reform the U.S. healthcare system.

Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products on the market. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition, and results of operations.

For example, in the U.S., in March 2010, the Patient Protection and Affordable Care Act, or PPACA, was passed. The PPACA was intended to make significant changes to the way healthcare is financed by both federal and state governments and private insurers, with direct impacts to the medical device industry. Among other provisions, the PPACA imposed, with limited exceptions, a deductible excise tax of 2.3% on sales of medical devices by entities that manufacture or import certain medical devices offered for sale in the U.S. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law in December 2015, included a two-year moratorium on the medical device excise tax. A second two-year moratorium on the medical device excise tax was signed into law in January 2018 as part of the Extension of Continuing Appropriations Act, 2018 (Pub. L. 115-120), extending the moratorium through December 31, 2019. On December 20, 2019, President Trump signed into law a permanent repeal of the medical device tax under the PPACA, but there is no guarantee that Congress or the President will not reverse course in the future. If such an excise tax on sales of any of our products in the U.S. is enacted, it could have a material adverse effect on our business, financial condition, and results of operations.

In addition, the PPACA and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs. Under the Trump Administration, there were ongoing efforts to modify or repeal all or part of PPACA or take executive action that affects its implementation. Tax reform legislation was passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so-called “individual mandate”). Such actions or similar actions could have a negative effect on the utilization of our products.

On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld a lower court’s determination in Texas v. Azar, 4:18-cv-00167, that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether PPACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law. In June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the PPACA. Thus, the PPACA remains in effect in its current form. Further, legislative and regulatory changes under the PPACA remain possible. It is unclear how future litigation and healthcare measures promulgated by the Trump administration or future administrations will impact the implementation of the PPACA and our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the PPACA could be time-consuming and expensive, resulting in a material adverse effect on our business.

Other healthcare reform legislative changes have also been proposed and adopted in the U.S. since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013, which, due to subsequent legislative amendments, will stay in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020, through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of the sequester. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed, and enacted, federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. As a result of reform of the U.S. healthcare system, changes in reimbursement policies or healthcare cost containment initiatives may limit or restrict coverage and reimbursement for procedures using our products and cause our revenue to decline. Additionally, individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, Medicare, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase, and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue, attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services and could have a material adverse effect on our business, financial condition, and results of operations.

Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive coverage and reimbursement practices of third-party payors could decrease the demand for our products and the number of procedures performed using our devices, which could have an adverse effect on our business.

The ability of our customers to obtain reimbursement for procedures that are performed using our products from government and private third-party payors is critical to our success. The availability of coverage and reimbursement for procedures performed using our products affects which products customers purchase and the prices they are able to pay to us.

Reimbursement can vary based on geographical location, type of provider/customer, and third-party payor and can significantly influence the acceptance of new products and services. Third-party payors may view some procedures performed using our products as experimental and may not provide coverage. Third-party payors may not cover and reimburse our customers for certain procedures performed using our products in whole or in part in the future, or payment rates may decline and not be adequate, or both. Further, coverage and reimbursement by third-party payors to our customers is also related to billing codes to describe procedures performed using our products. Hospitals and physicians use several billing codes to bill for such procedures. Obtaining Category I CPT codes for VIVO will be important to our future success. However, even if these codes are obtained, third-party payors may not recognize CPT codes available for use by our customers. Further, CPT codes may change over time, undermining our customer's ability to continue to use those codes, and reimbursement may be interrupted. Furthermore, some payors may not accept these new or revised codes for payment.

Reimbursement rates are unpredictable, and we cannot project how our business may be affected by future legislative and regulatory developments. Future legislation or regulation, or changing payment methodologies, may have a material adverse effect on our business, financial condition, and results of operations, and reimbursement may not be adequate for all customers. From time to time, typically on an annual basis, payment amounts are updated and revised by third-party payors. To be successful, our business model requires it to be possible for the cost of our products to generally be recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed. For that reason, even after we achieve CPT codes for our products, these annual updates, especially lower payments, could continue to directly impact the demand for our products. For example, in July 2013, the Centers for Medicare and Medicaid Services, or CMS, proposed reimbursement changes that would have decreased reimbursement for procedures in an outpatient-based facility, such as a catheterization lab. Although CMS chose not to implement those changes in 2013, we cannot assure you that CMS will not take similar actions in the future.

After we develop new products or seek to market our products for new approved or cleared indications, there tends to be limited demand for the product unless government and private third-party payors provide adequate coverage and reimbursement to our customers. However, obtaining codes and reimbursement for new products requires an extended, multi-year effort.

Even after reimbursement approval and coverage by government and private payors is obtained, providers submitting reimbursement claims for new products or existing products with new approved or cleared indications may face delay in payment if there is confusion by providers or payors regarding the appropriate codes to use in seeking reimbursement. Such delays may create an unfavorable impression within the marketplace regarding the level of reimbursement or coverage available for our products.

Demand for our products or new approved indications for our existing products may fluctuate over time if federal or state legislative or administrative policy changes affect coverage or reimbursement levels for our products or the services related to our products. In the U.S., there have been, and we expect there will continue to be legislative and regulatory proposals to change the healthcare system, such as the potential repeal of the PPACA, some of which could significantly affect our business. It is uncertain what impact the current U.S. presidential administration or future administrations will have on healthcare spending. If enacted and implemented, any measures to restrict healthcare spending could result in decreased revenue from the sale of our products and decreased potential returns from our research and development initiatives. Other legislative or administrative reforms to the U.S. or international reimbursement systems in a manner that significantly reduces reimbursement for procedures performed using our products or denies coverage for those procedures could have a material adverse effect on our business, financial condition, and results of operations.

We are regulated by federal Anti-Kickback Statutes.

The Federal Anti-Kickback Statute is a provision of the Social Security Act of 1972 that prohibits as a felony offense the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (1) the referral of a patient for items or services for which payment may be made in whole or part under Medicare, Medicaid, or other federal healthcare programs, (2) the furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid, or other federal healthcare programs or (3) the purchase, lease, or order or arranging or recommending the purchasing, leasing or ordering of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The Patient Protection and Affordable Care Act, or PPACA, amended section 1128B of the Social Security Act to make it clear that a person need not have actual knowledge of the statute, or specific intent to violate the statute, as a predicate for a violation. The OIG, which has the authority to impose administrative sanctions for violation of the statute, has adopted as its standard for review a judicial interpretation which concludes that the statute prohibits any arrangement where even one purpose of the remuneration is to induce or reward referrals. A violation of the Anti-Kickback Statute is a felony punishable by imprisonment, criminal fines of up to $25,000, civil fines of up to $50,000 per violation, and three times the amount of the unlawful remuneration. A violation also can result in exclusion from Medicare, Medicaid or other federal healthcare programs. In addition, pursuant to the changes to the PPACA, a claim that includes items or services resulting from a violation of the Anti-Kickback Statute is a false claim for purposes of the False Claims Act. We cannot assure that the applicable regulatory authorities will not determine that some of our arrangements with hospitals or physicians violate the federal Anti-Kickback Statute or other applicable laws. An adverse determination could subject us to different liabilities, including criminal penalties, civil monetary penalties and exclusion from participation in Medicare, Medicaid or other health care programs, any of which could have a material adverse effect on our business, financial condition or results of operations.

We are regulated by the federal Stark Law.

The federal Stark Law, 42 U.S.C. 1395nn, also known as the physician self-referral law, generally prohibits a physician from referring Medicare and Medicaid patients to an entity (including hospitals) providing 'designated health services,' if the physician or a member of the physician's immediate family has a 'financial relationship' with the entity, unless a specific exception applies. Designated health services include, among other services, inpatient hospital services, outpatient prescription drug services, clinical laboratory services, certain imaging services (e.g., MRI, CT, ultrasound), and other services that our affiliated hospitals may order for their patients. The prohibition applies regardless of the reasons for the financial relationship and the referral. Like the Anti-Kickback Statute, the Stark Law contains statutory and regulatory exceptions intended to protect certain types of transactions and arrangements. Unlike safe harbors under the Anti-Kickback Statute with which compliance is voluntary, an arrangement must comply with every requirement of a Stark Law exception or the arrangement is in violation of the Stark Law.

Because the Stark Law and implementing regulations continue to evolve and are detailed and complex, while we attempt to structure our relationships to meet an exception to the Stark Law, there can be no assurance that the arrangements entered into by us with affiliated hospitals will be found to be in compliance with the Stark Law, as it ultimately may be implemented or interpreted. The penalties for violating the Stark Law can include the denial of payment for services ordered in violation of the statute, mandatory refunds of any sums paid for such services, and civil penalties of up to $15,000 for each violation, double damages, and possible exclusion from future participation in the governmental healthcare programs. A person who engages in a scheme to circumvent the Stark Law's prohibitions may be fined up to $100,000 for each applicable arrangement or scheme.

Some states have enacted statutes and regulations against self-referral arrangements similar to the federal Stark Law, but which may be applicable to the referral of patients regardless of their payer source and which may apply to different types of services. These state laws may contain statutory and regulatory exceptions that are different from those of the federal law and that may vary from state to state. An adverse determination under these state laws and/or the federal Stark Law could subject us to different liabilities, including criminal penalties, civil monetary penalties and exclusion from participation in Medicare, Medicaid or other health care programs, any of which could have a material adverse effect on our business, financial condition or results of operations.

We must comply with Health Information Privacy and Security Standards.

HIPAA and regulations thereunder contain detailed requirements concerning the use and disclosure of individually identifiable patient health information by various healthcare providers, such as medical groups. HIPAA covered entities must implement certain administrative, physical, and technical security standards to protect the integrity, confidentiality and availability of certain electronic health information received, maintained, or transmitted. HIPAA also implemented standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including billing and claim collection activities. Violations of the HIPAA privacy and security rules may result in civil and criminal penalties, including a tiered system of civil money penalties that range from $100 to $50,000 per violation, with a cap of $1.5 million per year for identical violations. A HIPAA covered entity must also promptly notify affected individuals where a breach affects more than 500 individuals and report breaches affecting fewer than 500 individuals annually. State attorneys general may bring civil actions on behalf of state residents for violations of the HIPAA privacy and security rules, obtain damages on behalf of state residents, and enjoin further violations.

Many states also have laws that protect the privacy and security of confidential, personal information, which may be similar to or even more stringent than HIPAA. Some of these state laws may impose fines and penalties on violators and may afford private rights of action to individuals who believe their personal information has been misused. We expect increased federal and state privacy and security enforcement efforts.

If a breach of our measures protecting personal data covered by HIPAA, as amended by the HITECH Act, occurs, we may incur significant liabilities.

HIPAA, as amended by the HITECH Act, and the regulations that have been issued under it, imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information. The requirements and restrictions apply to "covered entities" (which include health care providers and insurers) as well as to their business associates that receive protected health information from them in order to provide services to or perform certain activities on their behalf. The statute and regulations also impose notification obligations on covered entities and their business associates in the event of a breach of the privacy or security of protected health information. We occasionally receive protected health information from our customers in the course of our business. As such, we believe that we are business associates and therefore subject to HIPAA's requirements and restrictions with respect to handling such protected health information and have executed business associate agreements with certain customers.

It is possible the data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country and state to state and may vary based on whether testing is performed in the U.S. or in the local country. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Further, compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business. If we fail to comply or are deemed to have failed to comply with applicable privacy protection laws and regulations such failure could result in government enforcement actions and create liability for us, which could include substantial civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

A cyber security incident could cause a violation of HIPAA and/or state consumer privacy laws, breach of customer and patient privacy, or other negative impacts.

We rely extensively on our information technology (or IT) systems to manage scheduling and financial data, communicate with hospitals and their patients, vendors, and other third parties, and summarize and analyze operating results. In addition, we have made significant investments in technology, including the engagement of a third-party IT provider. A cyber-attack that bypasses our IT security systems could cause an IT security breach, a loss of protected health information, or other data subject to privacy laws, a loss of proprietary business information, or a material disruption of our IT business systems. This in turn could have a material adverse impact on our business and result of operations. In addition, our future results of operations, as well as our reputation, could be adversely impacted by theft, destruction, loss, or misappropriation of public health information, other confidential data, or proprietary business information.

Computer malware, viruses, and hacking and phishing attacks by third parties have become more prevalent in our industry and may occur on our systems in the future. Because techniques used to obtain unauthorized access to or sabotage systems change frequently and generally are not recognized until successfully launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. As cyber-security threats develop and grow, it may be necessary to make significant further investments to protect data and infrastructure. If an actual or perceived breach of our security occurs, (i) we could suffer severe reputational damage adversely affecting customer or investor confidence, (ii) the market perception of the effectiveness of our security measures could be harmed, (iii) we could lose potential sales and existing customers, our ability to deliver our services or operate our business may be impaired, (iv) we may be subject to litigation or regulatory investigations or orders, and (v) we may incur significant liabilities. Our insurance coverage may not be adequate to cover the potentially significant losses that may result from security breaches.

We must comply with environmental and Occupational Safety and Health Administration Regulations.

We are subject to federal, state and local regulations governing the storage, use and disposal of waste materials and products. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our business, financial condition, and results of operations. Future changes to environmental and health and safety laws could cause us to incur additional expenses or restrict our operations, which could have a material adverse effect on our business, financial condition, and results of operations. Although we believe that our safety procedures for storing, handling and disposing of these materials and products comply with the standards prescribed by law and regulation, we cannot eliminate the risk of accidental contamination or injury from those hazardous materials. In the event of an accident, we could be held liable for any damages that result and any liability could exceed the limits or fall outside the coverage of our insurance coverage, which we may not be able to maintain on acceptable terms, or at all. We could incur significant costs and attention of our management could be diverted to comply with current or future environmental laws and regulations. Federal regulations promulgated by the Occupational Safety and Health Administration impose additional requirements on us, including those protecting employees from exposure to elements such as blood-borne pathogens. We cannot predict the frequency of compliance, monitoring, or enforcement actions to which we may be subject as those regulations are being implemented, which could adversely affect our operations.

We must comply with a range of other Federal and State Healthcare Laws.

We are also subject to other federal and state healthcare laws that could have a material adverse effect on our business, financial condition or results of operations. The Health Care Fraud Statute prohibits any person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, which can be either a government or private payer plan. Violation of this statute, even in the absence of actual knowledge of or specific intent to violate the statute, may be charged as a felony offense and may result in fines, imprisonment, or both. The Health Care False Statement Statute prohibits, in any matter involving a federal health care program, anyone from knowingly and willfully falsifying, concealing or covering up, by any trick, scheme or device, a material fact, or making any materially false, fictitious or fraudulent statement or representation, or making or using any materially false writing or document knowing that it contains a materially false or fraudulent statement. A violation of this statute may be charged as a felony offense and may result in fines, imprisonment or both. Under the Civil Monetary Penalties Law of the Social Security Act, a person (including an organization) is prohibited from knowingly presenting or causing to be presented to any United States officer, employee, agent, or department, or any state agency, a claim for payment for medical or other items or services where the person knows or should know (a) the items or services were not provided as described in the coding of the claim, (b) the claim is a false or fraudulent claim, (c) the claim is for a service furnished by an unlicensed physician, (d) the claim is for medical or other items or service furnished by a person or an entity that is in a period of exclusion from the program, or (e) the items or services are medically unnecessary items or services. Violations of the law may result in penalties of up to $10,000 per claim, treble damages, and exclusion from federal healthcare programs.

In addition, the OIG may impose civil monetary penalties against any physician who knowingly accepts payment from a hospital (as well as against the hospital making the payment) as an inducement to reduce or limit medically necessary services provided to Medicare or Medicaid program beneficiaries. Further, except as permitted under the Civil Monetary Penalties Law, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider of Medicare or Medicaid payable items or services may be liable for civil monetary penalties of up to $10,000 for each wrongful act.

In addition to the state laws previously described, we may also be subject to other state fraud and abuse statutes and regulations if we expand our operations nationally. Many states have adopted a form of anti-kickback law, self-referral prohibition, and false claims and insurance fraud prohibition. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Generally, state laws reach to all healthcare services and not just those covered under a governmental healthcare program. A determination of liability under any of these laws could result in fines and penalties and restrictions on our ability to operate in these states. We cannot assure you that our arrangements or business practices will not be subject to government scrutiny or be found to violate applicable fraud and abuse laws.

Governmental export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our products may be subject to U.S. export controls. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely materially and adversely affect our business, financial condition, and results of operations.

Changes in trade policies among the U.S. and other countries, in particular the imposition of new or higher tariffs, could place pressure on our average selling prices as our customers seek to offset the impact of increased tariffs on their own products. Increased tariffs or the imposition of other barriers to international trade could have a material adverse effect on our revenues and operating results.

In addition to current and proposed economic sanctions on Russia, which may increase or continue for an indefinite period of time as a result of Russia's invasion of Ukraine, the U.S. has imposed or proposed new or higher tariffs on certain products exported by a number of U.S. trading partners, including China, Europe, Canada, and Mexico. In response, many of those trading partners, including China, have imposed or proposed new or higher tariffs on American products. Continuing changes in government trade policies create a heightened risk of further increased tariffs that impose barriers to international trade.

Tariffs on our customers' products may adversely affect our gross profit margins in the future due to the potential for increased pressure on our selling prices by customers seeking to offset the impact of tariffs on their own products. We believe that increases in tariffs on imported goods or the failure to resolve current international trade disputes could have a material adverse effect on our business and operating results.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our existing products and any products we may develop, and our technology may be adversely affected.

As with other medical device companies, our ability to maintain and solidify a proprietary position for our products will depend upon our success in obtaining effective patent claims that cover such products, their manufacturing processes and their intended methods of use, and enforcing those claims once granted. Furthermore, in some cases, we may not be able to obtain issued claims covering VIVO or LockeT, as well as other technologies that are important to our business, which are sufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to VIVO, LockeT or any new devices that we market could have a material adverse effect on our business, financial condition, and results of operations.

Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our issued patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain whether we were the first to make the inventions claimed in any of our pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, and the like, although we are unaware of any such defects that we believe are of material importance. If we or any future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, if any patents are issued in the future, they may not provide us with any competitive advantages or may be successfully challenged by third parties. Agreement terms that address non-competition are difficult to enforce in many jurisdictions and may not be enforceable in any particular case. To the extent that our intellectual property and other proprietary rights are not adequately protected, third parties might gain access to our proprietary information, develop and market products or services similar to ours, or use trademarks similar to ours, each of which could materially harm our business. Existing U.S. federal and state intellectual property laws offer only limited protection. Moreover, the laws of other countries in which we now, or may in the future, conduct operations or contracts for services may afford little or no effective protection of our intellectual property. The failure to adequately protect our intellectual property and other proprietary rights could materially damage our business.

The strength of patent rights involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. The patent applications that we own may fail to result in issued patents in the U.S. or foreign countries with claims that cover our products or services. Even if patents do successfully issue from the patent applications that we own, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products and services. Furthermore, even if they are unchallenged, our patents may not adequately protect our products and services, provide exclusivity for our products and services, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our products and services is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products and services.

Patents have a limited lifespan. In the U.S., the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and services, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products and services under patent protection would be reduced.

In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our products and services that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent products.

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

Third parties may attempt to commercialize competitive products or services in foreign countries where we do not have any patents or patent applications where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting, and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Consequently, we may not be able to prevent third parties from utilizing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the U.S. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Third parties may assert that we are infringing their intellectual property rights, and any defense of such assertions may be unsuccessful and expensive, even if we are successful.

Successfully commercializing our products depends in part on not infringing patents held by third parties. It is possible that one or more of our products, including those that we have developed in conjunction with third parties, infringe existing patents. We may also be liable for patent infringement by third parties whose products we use or combine with our own and for which we have no right to indemnification. In addition, because patent applications are maintained under conditions of confidentiality and can take many years to issue, there may be applications now pending of which we are unaware and which may later result in issued patents that our products infringe. Determining whether a product infringes a patent involves complex legal and factual issues and may not become clear until finally determined by a court in litigation. Our competitors may assert that our products infringe patents held by them. Moreover, as the number of competitors in our market grows, the possibility of a patent infringement claim against us increases. If we were unsuccessful in obtaining a license or redesigning our products, we could be subject to litigation. If we lose in this kind of litigation, a court could require us to pay substantial damages or prohibit us from using technologies essential to our products covered by third-party patents. An inability to use technologies essential to our products would have a material adverse effect on our financial condition, results of operations and cash flow and could undermine our ability to continue our current business operations.

Expensive intellectual property litigation is frequent in the medical device industry and may cause to incur substantial expenses to defend.

Infringement actions, validity challenges and other intellectual property claims and proceedings, whether with or without merit, can be expensive and time-consuming and would divert management’s attention from our business. We have incurred, and expect to continue to incur substantial costs in obtaining patents and may have to incur substantial costs defending our proprietary rights. Incurring such costs could have a material adverse effect on our financial condition, results of operations and cash flow.

Risks Related to Ownership of Our Common Stock

The price of our stock has been and may continue to be volatile, which could result in substantial losses for investors. Further, an active, liquid and orderly trading market for our common stock may not be sustained and we do not know what the market price of our common stock will be, and as a result it may be difficult for you to sell your shares of our common stock.

Prior to our listing on the New York Stock Exchange in September 2018, there was no public market for shares of our common stock. Although our common stock is now listed on the NYSE American, the market for our shares has demonstrated varying levels of trading activity. Furthermore, an active trading market for our shares may not be sustained in the future. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration, which could have a material adverse effect on our business, financial condition, and results of operations. In addition, the trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this *Risk Factors* section and elsewhere in this Annual Report, these factors include:

- our failure to increase the sales of our products;
- the failure by our customers to obtain adequate reimbursements or reimbursement levels that would be sufficient to support product sales to our customers and pricing of our products to support revenue projections;
- unanticipated serious safety concerns related to the use of our products;
- changes in our organization;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our future growth;
- the size and growth of our target markets;
- actual or anticipated variations in quarterly operating results;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including shareholder litigation, government actions or litigation related to intellectual property;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage, by securities analysts;
- any delay in any regulatory filings for our future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such products;
- adverse regulatory decisions, including failure to receive regulatory approval of our future products, failure to maintain regulatory approval for our existing products or failure to obtain regulatory approval for additional indications for our existing products;
- changes in laws or regulations applicable to our products;
- adverse developments concerning our suppliers or distributors;
- our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- our inability to establish and maintain collaborations if needed;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of large blocks of our common stock including sales by our executive officers and directors;
- trading volume of our common stock;

- limited “public float” in the hands of a small number of persons whose sales or lack of sales of our common stock could result in positive or negative pricing pressure on the market price for our common stock;
- additions or departures of key scientific or management personnel;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including recent fluctuations following proposed and enacted tariffs by the US government. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations.

We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a smaller reporting company, as defined by SEC rules. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced financial statement requirements, and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

Future sales and issuances of a substantial number of shares of our common stock or rights to purchase common stock by our stockholders in the public market could result in additional dilution of the percentage ownership of our stockholders and cause our stock price to fall.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of March 17, 2025, we had 9,268,632 outstanding shares of our common stock and outstanding options to purchase up to 2,222,434 shares of our common stock, as well as 2,157,000 shares subject to pre-funded warrants, and 15,960,613 shares subject to outstanding warrants that are currently out of the money. At our special meeting of stockholders held on March 21, 2023, our stockholders approved the conversion of 1,993.581 shares of our Series X Preferred Stock into 1,993,581 shares of our common stock. The remaining 12,656 shares of Series X Preferred Stock may be convertible into 1,265,601 shares of our common stock on or after July 9, 2024, in the event that we meet the initial listing standards of the NYSE American or another securities exchange or have been delisted from the NYSE American.

In July 2023, we adopted the 2023 Equity Incentive Plan, or the 2023 Plan. As of March 6, 2025, 796,615 shares were available for issuance as new awards under the 2023 Plan, options to purchase 1,681,000 shares were outstanding, and 66,667 shares of restricted stock awards had been authorized for future issuance. The 2023 Equity Incentive Plan provides for quarterly increases in the number of shares authorized for issuance under the Plan based on a percentage of the increase in the number of shares outstanding during the quarter. We assumed options to purchase 75,367 shares in connection with the merger with Old Catheter, and as of March 6, 2025, 16,427 of these options remained outstanding. We issued to officers of the Company non-plan options to purchase 525,000 shares, which were outstanding as of March 6, 2025. If these additional shares of common stock are issued and sold, or if it is perceived that they will be sold, in the public market, this could result in additional dilution and the trading price of our common stock could decline.

Further, additional capital may be needed in the future to continue our planned operations, including commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors or our current management and may adversely affect the market price of our common stock.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- that our board of directors is divided into three classes serving staggered three-year terms, such that not all members of the board is elected at one time, which could delay the ability of stockholders to change the membership of a majority of our board of directors;

- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders;

- a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer or president (in the absence of a chief executive officer) or a majority vote of our board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our certificate of incorporation relating to the issuance of preferred stock and management of our business or our bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt;

- the ability of our board of directors, by majority vote, to amend our bylaws, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend our bylaws to facilitate an unsolicited takeover attempt; and

- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our certificate of incorporation and bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the U.S. are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our certificate of incorporation further provides that the federal district courts of the U.S. are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to the continued listing requirements of the NYSE American. If we are unable to comply with such requirements, our common stock would be delisted from the NYSE American, which would limit investors' ability to effect transactions in our common stock and subject us to additional trading restrictions.

Shares of our common stock are currently listed on the NYSE American. In order to maintain our listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders' equity, minimum public float, and a minimum number of public stockholders. In addition to these objective standards, the NYSE American may delist the securities of any issuer if, in its opinion, the issuer's financial condition and/or operating results appear unsatisfactory; if it appears that the extent of public distribution or the aggregate market value of the security has become so reduced as to make continued listing on the NYSE American inadvisable; if the issuer sells or disposes of principal operating assets or ceases to be an operating company; if an issuer fails to comply with the NYSE American's listing requirements; if an issuer's common stock sells at what the NYSE American considers a "low selling price" (generally trading below $0.20 per share for an extended period of time); or if any other event occurs or any condition exists which makes continued listing on the NYSE American, in its opinion, inadvisable. On August 31, 2022, we received a deficiency letter from the NYSE American indicating that we were not in compliance with Section 1003(f)(v) of the NYSE American Company Guide, because shares of our common stock have been selling for a low price per share for a substantial period time. We have since regained compliance with this Section, but there can be no guarantee that our stock price will not fall below the required levels again. We also received similar letters related to our late Form 10-Q filings during 2023, but we have since filed all late Forms and have remedied those deficiencies.

If the NYSE American delists our shares of common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect our common stock would qualify to be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage;
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." Because our shares of common stock are listed on the NYSE American, our shares of common stock qualify as covered securities under such statute. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. If we were no longer listed on the NYSE American, our securities would not be covered securities and we would be subject to regulation in each state in which we offer our securities.

We have not paid dividends in the past and have no immediate plans to pay dividends.

We plan to reinvest all of our earnings, to the extent we have earnings, in order to market our products and to cover operating costs and to otherwise become and remain competitive. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

The Company approaches cybersecurity as an enterprise-wide risk and uses external resources to assess risk and manage its IT and 24x7 cybersecurity operations, including managed service providers who assist in the support of key business systems. The Company may also periodically engage external consultants to assist with cybersecurity incident management, particularly where advanced or specialized expertise may be required. If a material cybersecurity breach occurs, the incident will be reviewed by management to determine whether further escalation is appropriate. The Executive Chairman of the Board and Chief Executive Officer and the Chief Financial Officer have primary responsibility for this review and assessment. Any incident assessed as potentially being or becoming material will immediately be escalated for further assessment and reported to designated members of our executive team, and if deemed necessary or appropriate, the Board of Directors. The Board Audit Committee is responsible for reviewing and discussing the adequacy and effectiveness of the Company's information security policies and the procedures and controls regarding information systems. In addition, we plan to consult with outside counsel as appropriate, including on materiality analyses and disclosure matters, and to assist in making the final materiality determination regarding disclosure and other compliance decisions. We also plan to keep our independent public accounting firm informed of such incidents as appropriate.

The Company maintains a cyber liability insurance policy that is designed to cover certain expenses, business losses, business interruption, and fines and penalties associated with a data breach or other similar incident. Cyber liability insurance also provides coverage in the event of a ransomware attack.

To date, the Company has not had a cybersecurity event that materially impacted or is reasonably likely to materially affect its business strategy, results of operations, financial condition, or the security of its proprietary data.

ITEM 2. PROPERTIES

Our manufacturing, inventory and order fulfillment activities for VIVO are performed in our approximate 2,000 square foot headquarters facility in Fort Mill, South Carolina under a lease that expires in November 2025. We conduct administrative and accounting activities in an approximate 1,100 square foot facility in Augusta, New Jersey under a lease that expires in December 2025. Administrative activities are also conducted in an approximate 1,200 square foot facility in Park City, Utah under a lease that expires in April 2026.

We believe that our existing facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

ITEM 3. LEGAL PROCEEDINGS

In the normal course of business, we are at times subject to pending and threatened legal actions. In management's opinion, any potential loss resulting from the resolution of these matters will not have a material effect on our results of operations, financial position or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II — FINANCIAL INFORMATION

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock is traded on the NYSE American under the symbol "VTAK". Prior to August 17, 2023 the Company's common stock was traded on the NYSE American under the symbol "RMED".

On March 17, 2025, the last reported sales price of our common stock was $0.41 and, according to our transfer agent, as of March 17, 2025, there were 79 record holders of our common stock. The actual number of stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust or by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions, the terms of any future credit agreements and other factors that our board of directors may deem relevant.

ITEM 6. [Reserved]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K for the period ended December 31, 2024 (this "Annual Report"). The following discussion and analysis of our financial condition and results of operations contain forward-looking statements that involve a number of risks, uncertainties and assumptions. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, those set forth in Item 1A. Risk Factors of this Annual Report, many of which are outside of our control. All forward-looking statements included in this Annual Report are based on information available to us as of the time we file and, except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements.

Overview

On January 9, 2023, the Company merged with the former Catheter Precision, Inc. ("Old Catheter"), a privately held Delaware corporation (the "Merger"), which became a wholly owned subsidiary of the Company. Following the Merger, we discontinued the Company's legacy lines of business and the use of any of its DABRA-related assets. We shifted the focus of our operations to Old Catheter's product lines. Accordingly, our current activities primarily relate to Old Catheter's historical business, which comprises the design, manufacture and sale of new and innovative medical technologies focused in the field of cardiac electrophysiology (EP).

One of our two primary products is the View into Ventricular Onset ("VIVO" or "VIVO System"), which is a non-invasive imaging system that offers 3D cardiac mapping to help with localizing the sites of origin of idiopathic ventricular arrhythmias in patients with structurally normal hearts prior to EP procedures.

Our newest product, LockeT® ("LockeT"), is a suture retention device indicated for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure. LockeT is intended to temporarily secure sutures and aid clinicians in locating and removing sutures efficiently.

Our business strategy is to become a leading medical device company in the field of cardiac electrophysiology, and we are dedicated to developing and delivering electrophysiology products to provide patients, hospitals, and physicians with novel technologies and solutions to improve the lives of patients with cardiac arrhythmias. We aim to establish VIVO as an integral tool used by cardiac electrophysiologists during ablation treatment of ventricular arrhythmias by reducing procedure time and patient complications and increasing procedural success.

We have received FDA clearance to market and promote the VIVO System in the U.S. as a pre-procedure planning tool for patients with structurally normal hearts undergoing ablation treatment for idiopathic ventricular arrhythmias. VIVO allows for the acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician. We began a limited commercial launch of VIVO in 2021 and to date, VIVO has been utilized in more than 1,000 procedures in the U.S. and EU by over 30 physicians, with no reported device-related complications.

We have been cleared to label the VIVO System with the CE Mark in the EU and certain other countries. The CE Mark designation, which affirms the product's conformity with European health, safety, and environmental protection standards, allows us to market that product in countries that are members of the EU and the European Free Trade Association. Catheter has commenced limited sales of the VIVO System in Europe and the UK through independent distributors. Catheter's international distributors are supported by two EU-based full-time consultants.

In addition, our newest product is LockeT, a suture retention device indicated for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure. LockeT is intended to temporarily secure sutures and aid clinicians in locating and removing sutures efficiently. LockeT is a sterile Class I product that was registered with the FDA in February 2023, at which time we began initial shipments to distributors. In May 2024, we recognized our first sale of LockeT. In May 2023, Catheter submitted LockeT for CE Mark approval. CE Mark approval is expected in first half of 2026, at which time initial international shipments to distributors will begin. In September 2024, we received notification of the issuance of our first LockeT patent in the country of China and we also completed a Middle East distribution agreement for LockeT.

Clinical studies for LockeT began during the year ended December 31, 2023. The current studies are planned to show the product's effectiveness and benefits, including faster wound closure, earlier ambulation, potentially leading to early hospital discharge, and lower costs for the healthcare provider and/or insurance payor. These clinical studies are intended to provide crucial data for marketing and to expand our indications for use with the FDA. For more information about our clinical studies, refer to Item 1, Business.

Recent Developments

October 2024 Warrant Inducement Offer

On October 25, 2024, the Company executed the Warrant Inducement Offer Letters with certain holders of the Company's existing warrants. Pursuant to the terms and conditions of the Warrant Inducement Offer Letters, the holders immediately exercised an aggregate of (i) 33,160.8 Series E Warrants, (ii) 499,909.34 Series F Warrants, (iii) 499,909.34 Series G Warrants, (iv) 1,990,000 Series H Warrants, and (v) 2,325,000 Series I Warrants (collectively, the "2024 Existing Warrants") to purchase 5,347,981 shares of the Company's common stock at a reduced exercise price of $0.70 per share of common stock. In consideration for the immediate exercise of the 2024 Existing Warrants for cash, the Company agreed to issue unregistered new Series K Common Stock Purchase Warrants ("Series K Warrants") to purchase up to 10,695,962 shares of common stock. The Series K Warrants have an exercise price of $0.70 per share of common stock, are not exercisable until stockholders' approval is obtained ("Stockholder Approval"), and have a term of 5.5 years following Stockholder Approval.

In addition to the Series K Warrants, the Company also issued 320,879 Placement Agent Warrants to the Placement Agent as part of their compensation. The Placement Agent Warrants have the same terms as the Series K Warrants, except that the exercise price is $1.085 per share and the warrants are exercisable six months after the date of issuance.

Pursuant to the terms of the Warrant Inducement Offer Letters, in the event that the exercise of the 2024 Existing Warrants would cause a holder to exceed the beneficial ownership limitations included therein, the Company issued the number of shares of common stock that would not cause a holder to exceed such beneficial ownership limitations and held the remaining balance of shares of common stock in abeyance. Accordingly, the Company held an aggregate of 3,096,000 shares of common stock in abeyance (the "Abeyance Shares") as of December 31, 2024. The Abeyance Shares are evidenced through the holder's existing warrants and will be held by the Company until the holder sends notice that the remaining balance of shares of common stock may be issued without surpassing the beneficial ownership limitations. Until such time, the Abeyance Shares are evidenced through the holder's existing warrants and deemed to be prepaid.

The Company received aggregate gross proceeds of $3.7 million in cash, prior to deducting placement agent fees and offering expenses of $0.4 million, resulting in net proceeds of $3.3 million. The Company further recorded a deemed dividend of $5.2 million in connection with the modification of the 2024 Existing Warrants as well as the issuance of the Series K Warrants.

September 2024 Public Offering

On August 30, 2024, the Company entered into an underwriting agreement to issue and sell in a public offering (i) 347,277 Common Stock Units, priced at a public offering price of $1.00 per unit, with each unit consisting of (a) one share of Common Stock, (b) one warrant to purchase one share of Common Stock at an exercise price of $1.00 per share that expires on the six month anniversary of the date of issuance (a "Series H Warrant"), (c) one warrant to purchase one share of Common Stock at an exercise price of $1.00 per share that expires on the eighteenth month anniversary of the date of issuance (a "Series I Warrant"), and (d) one warrant to purchase one share of Common Stock at an exercise price of $1.00 per share that expires on the five year anniversary of the date of issuance (a "Series J Warrant"), and (ii) 2,773,000 Pre-Funded Warrant Units, priced at a public offering price of $0.9999 per unit, with each unit consisting of (a) one pre-funded warrant to purchase one share of Common Stock at an exercise price of $0.0001 per share that has no expiration date (a "Pre-Funded Warrant"), (b) one Series H Warrant, (c) one Series I Warrant, and (d) one Series J Warrant.

In addition to the securities described above, the Company granted the underwriter a 45-day Overallotment Option to purchase up to (i) 468,041 additional shares of Common Stock, (ii) 468,041 additional Series H Warrants, (iii) 468,041 additional Series I Warrants, and/or (iv) 468,041 additional Series J Warrants, solely to cover over-allotments. On August 30, 2024, the underwriter partially exercised the Overallotment Option to purchase an additional 458,623 shares of Common Stock, 458,623 Series H Warrants, 458,623 Series I Warrants, and 458,623 Series J Warrants.

In the aggregate, the Company issued and sold (i) 805,900 Common Stock Units, (ii) 2,773,000 Pre-Funded Warrant Units, and (iii) 214,734 Representative Warrants that were issued as part of the underwriter's compensation. The Representative Warrants have an exercise price of $1.55, are not exercisable until March 1, 2025, and expire on August 29, 2029. The public offering closed on September 3, 2024. The net proceeds to the Company, after deducting the underwriting discount, commissions, management fee and offering expenses payable by the Company, were approximately $2.6 million.

The net proceeds from the financing transactions summarized above have been used to advance the development and commercialization of our novel electrophysiology technologies and solutions and to support general corporate purposes.

Components of our results of operations for the years ended December 31, 2024 and 2023

Revenues

Prior to the Merger, product revenues consisted of sales of catheters for use with the DABRA laser in our atherectomy clinical trials. After the Merger, we shifted the focus of our operations to Old Catheter's product lines, such that our legacy DABRA laser is no longer in use. Accordingly, our current activities primarily relate to Old Catheter's historical business which comprises the design, manufacture and sale of new and innovative medical technologies focused in the field of cardiac electrophysiology.

We had two primary products in 2024: the VIVO System and the LockeT device. We did not recognize any revenues from LockeT during 2023.

We invoice the customer for the VIVO System and related software upgrade services after physical possession and control of the VIVO System has been transferred. Subsequent renewals for software upgrade services are invoiced at inception of the renewed term. The timing of payment for the corresponding invoices depends on the credit terms identified in each contract. We recognize revenues for VIVO System at the point in time that the product is delivered to the customer. We recognize revenues for software upgrade services evenly over time over the term of the contract. We did not recognize any revenues for software upgrade services during 2024 and 2023.

We recognize sales of LockeT at the point in time that the product is delivered to the customer.

We are a business that has operations within multiple countries. During the years ended December 31, 2024 and 2023, approximately 34% and 25% of our sales were derived from customers outside the United States, respectively.

Cost of revenues

Cost of revenues for product sales consists primarily of costs of components, labor costs, and manufacturing overhead incurred to produce our products and support production.

Selling, general and administrative expenses

Selling, general and administrative ("SG&A") expenses consist of employee-related costs, including salaries, benefits and stock-based compensation expenses. Other SG&A expenses include amortization of intangible assets, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses and facility-related expenses.

Research and development expenses

Research and development ("R&D") expenses are expensed as incurred and include the following: research grants paid to other parties; product development; cost of clinical studies to support new products and product enhancements, including expanded indications; supplies used for internal R&D and clinical activities; and cost of outside consultants who assist with technology development and clinical affairs.

Results of operations for the years ended December 31, 2024 and 2023

The following table sets forth the results of the Company's operations for the periods presented (in thousands):

	For the Year Ended December 31,		
	2024	**2023**	**Change**
Revenue	$ 420	$ 442	$ (22)
Cost of revenues	42	30	12
Selling, general and administrative expenses	11,349	17,122	(5,773)
Research and development expenses	272	475	(203)
Loss on impairment of goodwill	—	60,934	(60,934)
Change in fair value of royalties payable	(2,239)	7,208	(9,447)
Other income (expense), net (1)	(20)	339	(359)
Income tax provision	3,141	—	3,141

(1) Constitutes the operating activities within other income (expense), net in the consolidated statements of operations, except for the change in fair value of royalties payable that is presented separately in the table above.

Revenues

The decrease in revenues of approximately $22 thousand for the year ended December 31, 2024 as compared to the prior year was due to lower product sales of the VIVO System that was partially offset by our first sales of LockeT in 2024. VIVO System product sales decreased by $214 thousand from $442 thousand for the year ended December 31, 2023 to $228 thousand for the year ended December 31, 2024. LockeT sales increased by $191 thousand from $0 for the year ended December 31, 2023 to $191 thousand for the year ended December 31, 2024. The decrease in VIVO System product sales primarily relates to two customer accounts that accounted for 53% of VIVO System sales in 2023 and placed large, one-time orders for disposable VIVO patches in 2023. In October 2024, one of the two customer accounts placed an order for disposable VIVO patches totaling $30 thousand. The order for disposable VIVO patches was fulfilled and recognized as revenues during the year ended December 31, 2024.

Cost of revenues

The increase in cost of revenues of approximately $12 thousand for the year ended December 31, 2024 as compared to the prior year was due to order fulfillment charges that are now being incurred for LockeT, partially offset by lower cost of revenues for the VIVO Positioning Patches. During 2023, the VIVO manufacturing process was changed from 3D printing components of the VIVO Positioning Patches to the use of a more cost-effective specialized mold. This new process also allows for larger build quantities, which in turn further reduced production costs and led to a reduction in the manufacturing cost of VIVO Positioning Patches of approximately 40%. Accordingly, the VIVO Positioning Patches manufactured under the new process and sold in 2024 had lower costs per unit than those manufactured under the old process and sold in 2023.

Selling, general and administrative expenses

The decrease in selling, general and administrative expenses of approximately $5.8 million for the year ended December 31, 2024 as compared to the prior year was primarily due to a decrease in legal fees of $2.0 million and a decrease in professional accounting fees of $1.4 million that were primarily incurred in connection with the Merger in 2023. Furthermore, the decrease in selling, general and administrative expenses was impacted by a decrease in stock-based compensation expense of $1.2 million, which primarily related to the one-time, stock compensation expense incurred for Old Catheter stock options that were assumed in connection with the Merger in 2023. In addition, there was a decrease in salaries and benefits of $0.5 million, resulting from a $2.1 million decrease in costs related to the Company's former Chief Executive Officer’s and Chief Financial Officer's compensation, partially offset by a $1.6 million increase in salaries and benefits due to an increased departmental headcount. The remaining balance of the decrease in selling, general and administrative expenses of $0.7 million relates to other consulting services as a result of internalizing certain services, investor relations and SEC fees due to fewer stockholder meetings in 2024 relative to 2023, and insurance expense due to lower insurance premiums in 2024 relative to 2023.

Research and development expenses

The decrease in research and development expenses of approximately $0.2 million for the year ended December 31, 2024 as compared to the prior year was primarily due to a decrease in product development costs of $0.1 million, and a decrease in regulatory affairs related expenditures of $0.1 million. The net decreases were primarily the result of the discontinuation of the historical products of the Company that were previously under development.

Loss on impairment of goodwill

We test for goodwill impairment at the reporting level annually in the fourth quarter or more frequently if a change in circumstances or the occurrence of events indicates that potential impairment exists. As a result of the Merger with Old Catheter, the Company recognized $60.9 million of goodwill. Due to a sustained decrease in our share price during 2023, we concluded that a triggering event occurred indicating that potential impairment existed that required us to assess if goodwill was impaired during 2023. In accordance with ASC 350, *Intangibles - Goodwill and Other*, we performed a quantitative goodwill impairment test, which resulted in the carrying amount of the reporting unit exceeding its fair value, indicating that the goodwill of the reporting unit was impaired. We utilized a combination of an income and market-based approach to assess the fair value of the reporting unit during 2023. The income approach considered the discounted cash flow model, considering projected future cash flows (including timing and profitability), discount rate reflecting the risk inherent in future cash flows, perpetual growth rate, and projected future economic and market conditions while the guideline public company market-based approach considered marketplace earnings multiples from within a peer public company group.

We recorded the impairment charge of $60.9 million for the year ended December 31, 2023 within loss on impairment of goodwill in the consolidated statement of operations. There was no remaining goodwill balance as of December 31, 2023.

Change in fair value of royalties payable

As of the date of the Merger, the royalties payable was calculated using a discounted cash flow method utilizing a discount rate of 24.1%. At each reporting period, the fair value of the royalties payable is calculated using the discounted cash flow method. The discount rate was 22.5% and 28.0% as of December 31, 2024 and 2023, respectively. The change in fair value of the royalties payable for the year ended December 31, 2024 as compared to the prior year was a decrease of $9.4 million, which is primarily driven by the change in forecasted royalty payments and discount rates used to estimate the fair value of royalties payable.

Other income, net

The decrease in other income (expense), net of approximately $0.4 million for the year ended December 31, 2024, respectively, as compared to the prior year was primarily due to a decrease in investment income.

Income Tax Provision.

We recorded an income tax provision of $3.1 million in 2024, as compared to zero in 2023. This increase in our income tax provision was primarily attributable to a nonrecurring adjustment resulting from an ownership change as defined under Section 382 of the Internal Revenue Code.

Liquidity and capital resources

As of December 31, 2024, we had cash and cash equivalents of approximately $2.9 million and an accumulated deficit of approximately $292 million. For the year ended December 31, 2024, net cash used from operating activities was approximately $9.3 million. We have incurred recurring net losses from operations and negative cash flows from operating activities since inception. We issued a total of $1.5 million of related party notes payable in Q2 and Q3 2024 that will become due and payable on January 31, 2026.

These negative cash flows and additional costs associated with the Merger paid during the year ended December 31, 2023 have substantially depleted our cash. Following the Merger with Old Catheter, we further reduced staff and other costs while assuming the operating costs of Old Catheter. Since the first quarter of 2024, we've begun to rejuvenate our sales force and hired a Chief Commercial Officer. We will continue to monitor our operating costs and seek to reduce our current liabilities. Such actions may impair our ability to proceed with certain strategic activities.

We expect operating losses and negative cash flows to continue for the foreseeable future as we invest in our commercial capabilities. We expect that our operating expenses may increase significantly as we maintain and protect our intellectual property portfolio, hire additional personnel, expand our markets, implement new commercial and marketing strategies, and enhance our existing products. We believe that our current cash on hand of $787 thousand as of March 14, 2025 will not be sufficient to fund our current operations, including without limitation, to repay our outstanding short-term notes that will become due and payable on January 31, 2026. We expect the need to complete an additional financing sometime in the next three to six months. Because expected revenues are not adequate to fund our planned expenditures and anticipated operating costs and liabilities beyond such point, we are currently evaluating potential means of raising cash through future capital transactions and additional bridge loans. If we are unable to do so, we will be required to reduce our spending rate to align with expected revenue levels and cash reserves, although there can be no guarantee that we will be successful in doing so. Accordingly, we will likely be required to raise additional cash through debt or equity transactions and bridge loans to continue our operations and pay our debts as they come due, and if we are unable to do so, we will be required to suspend a portion or all of our operations and/or potentially seek relief from our creditors. We may not be able to secure financing in a timely manner or on favorable terms, if at all.

As a result of these factors, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern for a period of one year after the date the consolidated financial statements for the year ended December 31, 2024 are issued. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Cash flows for the years ended December 31, 2024 and 2023 (in thousands)

	For the Year Ended December 31,	
	2024	**2023**
Net cash provided by (used in):		
Operating activities	$ (9,271)	$ (20,619)
Investing activities	(67)	(61)
Financing activities	8,646	8,386
Net change in cash and cash equivalents	$ (692)	$ (12,294)

Net cash used in operating activities

During the year ended December 31, 2024, net cash used in operating activities of $9.3 million primarily consisted of a net loss of $16.6 million, partially offset by non-cash adjustments related to depreciation and amortization of $2.1 million, an increase in deferred income tax provision of $3.1 million, and change in fair value of royalties payable of $2.2 million.

During the year ended December 31, 2023, net cash used in operating activities of $20.6 million consisted of a net loss of $70.6 million, a change in fair value of royalties payable of $7.2 million, and a decrease in operating assets and liabilities of $7.1 million, partially offset by non-cash adjustments related to loss on impairment of goodwill of $60.9 million, stock-based compensation of $1.2 million, and depreciation and amortization of $2.1 million.

Net cash used in investing activities

During the year ended December 31, 2024, net cash used in investing activities of $67 thousand consisted of purchases of property and equipment.

During the year ended December 31, 2023, net cash used in investing activities of $61 thousand consisted of purchases of property and equipment of $76 thousand, offset by proceeds from cash acquired as part of the Merger of $15 thousand.

Net cash provided by financing activities

During the year ended December 31, 2024, net cash provided by financing activities of $8.6 million primarily consisted of net cash proceeds from the issuance of common stock and warrants of $7.3 million, the issuance of notes payable to related parties of $1.5 million, and the exercise of warrants of $1.2 million, partially offset by the payment of offering costs of $1.4 million.

During the year ended December 31, 2023, net cash provided by financing activities of $8.4 million primarily consisted of net cash proceeds from the private placement of securities of $8.0 million and proceeds from the exercise of warrants of $1.3 million, partially offset by the payment of offering costs of $0.6 million and payment of convertible promissory notes and accrued interest of $0.3 million.

Off-balance sheet arrangements

Subsequent to the Merger, we have not engaged in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, as a part of our ongoing business. Accordingly, we did not have any off-balance sheet arrangements during any of the periods presented.

The Company's Critical Accounting Estimates

The information set forth below relates to the Company's critical accounting policies and estimates. The discussion and analysis of our financial position and results of operations is based on our consolidated financial statements included elsewhere in this Annual Report, which have been prepared in accordance with U.S. GAAP. We believe certain of our accounting policies are critical to understanding our financial position and results of operations.

The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We regularly evaluate estimates and assumptions related to business combinations, including the determination of the purchase price and related allocations to the fair value of assets acquired and liabilities assumed, provisions for legal contingencies, income taxes, deferred income tax asset valuation allowances, valuation of warranties liabilities, royalties payable due to related parties, share based compensation, evaluation of impairment of long-lived assets and goodwill, valuation of long-lived assets and their associated estimated useful lives, and revenues. Our estimates are based on current facts, historical experience and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

We believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Accounting for long-lived assets - estimated useful lives

Intangible assets acquired from business combinations are initially measured at their estimated fair values and are then amortized on a straight-line basis over their estimated useful lives. Management evaluates whether events or circumstances have occurred that indicate the remaining useful life or carrying value of the amortizing intangible should be revised and adjusted, if necessary. Should the sum of the undiscounted expected future net cash flows be less than the carrying value, the Company would recognize an impairment loss at that date.

Accounting for impairment of long-lived assets

The Company periodically reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that such assets might be impaired and the carrying value of the long-lived assets may not be recoverable. If events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable and the expected undiscounted future cash flows attributable to the asset are less than the carrying amount of the asset, an impairment loss equal to the excess of the assets carrying value over its fair value is recorded in the Company’s consolidated statements of operations at that date.

Stock-based compensation

We calculate the cost of awards of equity instruments based on the grant date fair value of the option awards issued to employees, members of our board of directors and nonemployee consultants using the Black-Scholes option pricing valuation model ("Black-Scholes model"), which incorporates various assumptions including volatility, expected term and risk-free interest rate. The expected term of the options is the estimated period of time until exercise and was determined using the SEC's safe harbor rules, using an average of vesting and contractual terms, as we did not have sufficient historical experience of similar awards. Expected stock price volatility is based on historical volatilities of certain "guideline" companies, as the Company does not have sufficient historical stock price data. The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent term. The estimated fair value of stock-based compensation awards is amortized on a straight-line basis over the relevant vesting period, adjusted for actual forfeitures at the time they occur.

Royalties payable

We are obligated to pay royalties under various royalty agreements Old Cather had entered into. On January 9, 2023, prior to the consummation of the Merger, Old Catheter entered in an agreement with its convertible promissory noteholders, which substantially consisted of amounts due to David A. Jenkins, previously Old Catheter's Chairman of the Board of Directors prior to the Merger, and, currently, the Company's Executive Chairman of the Board of Directors and Chief Executive Officer, and certain of his affiliates, to forgive all accrued interest and future interest expense in exchange for a future royalty right. We will pay to the noteholders a total royalty equal to approximately 12% of net sales of LockeT, which commenced upon the first commercial sale in 2024, through December 31, 2035.

In addition, the Company finalized an Invention Assignment and Royalty Agreement (the "Royalty Agreement") that had previously been entered into by Old Catheter with the inventor of LockeT in exchange for the assignment and all rights to LockeT. Pursuant to the agreement, we will pay a 5% royalty on net sales up to $1 million in royalties. After $1 million has been paid, and if, and only if, a U.S. patent is granted by the United States Patent and Trademark Office, then we will continue to pay a royalty at a rate of 2% of LockeT net sales, until total cumulative royalties of $10 million have been paid. No royalty payments will be due under this Royalty Agreement after December 31, 2033.

During 2006 and 2007, Old Catheter entered into two investment grant agreements with a non-profit foundation for the purpose of funding the initial development of Old Catheter's AMIGO System. The agreement calls for the payment of sales-based royalties to the foundation, upon successful commercialization of the AMIGO System. We are not currently selling the AMIGO System.

New Accounting Pronouncements

See Note 2 in the consolidated financial statements included elsewhere in this Annual Report for a description of new accounting pronouncements, including the expected dates of adoption and estimated effects on our results of operations, financial position, and cash flows as applicable.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There were no such disagreements or events during the specified periods.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Executive Chairman of the Board and Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of December 31, 2024. Our objective in designing our disclosure controls and procedures is that they provide reasonable assurance of achieving their objectives of ensuring that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon this evaluation, due to the existence of the material weaknesses found in our internal controls over financial reporting described below, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2024, our disclosure controls and procedures were not effective at the reasonable assurance level. As disclosed in our Form 10-Qs for the quarters ended March 31, 2024, June 30, 2024 and September 30, 2024, for the reasons set forth therein, our Chief Executive Officer and then-Interim Chief Financial Officer concluded that, as of March 31, 2024, June 30, 2024, and September 30, 2024, our disclosure controls and procedures were not effective at the reasonable assurance level. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. In preparation of our financial statements for the period covered by this report, we identified material weaknesses in internal control over financial reporting related to our control environment that existed as of December 31, 2024, as described below. Specifically, we identified material weaknesses with respect to (1) the lack of segregation of duties, (2) the lack of designed and operating review controls with respect to oversight of the financial reporting process, and (3) review of work performed by service providers with regards to (i) management's provision of inputs for valuations to a third-party provider and (ii) the Section 382 calculation in the tax provision in that the Company's provision did not reference the correct dates when determining ownership changes resulting in material changes in the amount of expiring net operating losses available to be utilized. Notwithstanding the identified material weaknesses, management believes that the Financial Statements and related financial information included in this Annual Report fairly present, in all material respects, our balance sheets, statements of operations, shareholders' equity and cash flows as of and for the periods presented.

Remediation Plan

Management is in the process of developing a remediation plan. The material weaknesses will not be considered remediated until management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The Company will monitor the effectiveness of its remediation plans and will make changes management determines to be appropriate. Anticipated remediation measures include continuing assessment of the need to expand the Company's current accounting and financial reporting teams to include individuals with requisite experience to meet the requirements associated with the increasing operations of a publicly traded company, establishment of policies and procedures to ensure full review and sign offs with respect to the inputs sent to third-party service providers as well as the reports and documentation upon the completion of their work prior to any adjustments being made to the financial statements, and establishment of policies and procedures to review the inputs to fair value and tax provision calculations as well as the outputs impacting the balance at each reporting period. In January 2025, we hired a new Chief Financial Officer and are in the process of establishing additional controls intended to eliminate the disclosed material weaknesses.

Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2024, which were identified in connection with management's evaluation required by paragraph (d) of Rules 13a-15 and that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on the assessment, management has concluded that its internal control over financial reporting was not effective as of December 31, 2024 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP, due to the material weaknesses discussed above at "Evaluation of Disclosure Controls and Procedures." Our independent registered public accounting firm, WithumSmith+Brown, PC ("Withum"), is not required to and has not issued an attestation report as of December 31, 2024 because we are not an "accelerated filer" or a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

No director or officer (as defined in Rule 16a–1(f) under the Exchange Act) of the Company adopted or terminated (i) any contract, instruction or written plan for the purchase or sale of securities of the registrant intended to satisfy the affirmative defense conditions of Rule 10b5–1(c) under the Exchange Act; and/or (ii) any "non-Rule 10b5–1 trading arrangement" as defined in paragraph (c) of Item 408 of Regulation S-K, during the quarter ended December 31, 2024.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Composition of the Board

Our business and affairs are managed under the direction of our board of directors, or the Board, which currently consists of four members, three of whom are "independent" under NYSE American listing standards. Our bylaws provide that the number of directors will be fixed from time to time by resolution of the Board. All directors hold office until their successors have been elected and qualified or until their earlier death, resignation, disqualification or removal. We have divided the terms of office of the directors into three classes with staggered three year terms: Class I, whose term expires at the 2025 Annual Meeting of Stockholders; Class II, whose term expires at the 2026 Annual Meeting of Stockholders; and Class III, whose term expires at the 2027 Annual Meeting of Stockholders.

Information about the Board of Directors

The following table sets forth the names, ages as of March 12, 2025, and certain other information regarding each member of the Board. The following information has been furnished to us by the directors.

Name	Class	Age	Position	Director Since	Current Term Expires
David A. Jenkins	II	67	Executive Chairman of the Board of Directors and Chief Executive Officer	2023	2026
Martin Colombatto	I	66	Director	2017	2025
James Caruso	III	64	Director	2023	2027
Andrew Arno	III	64	Director	2024	2027

David A. Jenkins became Executive Chairman of the Board in January 2023. He became Interim Chief Executive Officer in April 2023 and was named Chief Executive Officer in January 2024. He has spent most of his career as an entrepreneur in the medical device industry, and has established numerous companies including Old Catheter, where he served as the CEO and as Chairman of Old Catheter's Board. He has been Chairman of the Board of Old Catheter since Catheter's inception in 2006 and has served as CEO of Old Catheter since December 2020. His prior experience includes having served as Chairman and CEO of Arrhythmia Research and overseeing the introduction to the market of Cardiolab, the first dual monitor, 32 channel electrophysiology recording system. This technology was later acquired by General Electric and continues to be sold into the market place today. Another of Mr. Jenkins' companies, EP MedSystems, Inc., was sold to St. Jude Medical, Inc., now part of Abbott, for approximately $93 million in 2008. Mr. Jenkins also founded and served as the CEO of Transneuronix, Inc., a maker of implantable stimulators for the treatment of weight loss, which was later sold to Medtronic for $267 million in 2005. Mr. Jenkins holds a degree in accounting from the University of Kansas, and a master's degree in business from the University of Texas, Austin. He began his career in public accounting with Coopers and Lybrand. We believe that Mr. Jenkins is qualified to serve as a director because of his extensive experience in the medical device industry.

Martin Colombatto has served as a director of the Company since January 2017. Mr. Colombatto has served as a Venture and Industry Partner of Seven Peaks Ventures LLP, a venture capital fund based in Bend, OR, since January 2016. From December 2013 to August 2014, Mr. Colombatto served as a director of PLX Technology, Inc., a technology company. Mr. Colombatto has also served as the Chief Executive Officer and President of Staccato Communications, Inc., an Ultra-Wideband semiconductor company, from January 2006 to March 2009 and as Executive Chairman of Staccato Communications, Inc., from January 2006 to September 2010. Prior to joining Staccato, Mr. Colombatto served as Vice President and General Manager of the Networking Business unit of Broadcom Corp., a broadband communication semiconductor company, from July 1996 to July 2002. Mr. Colombatto was also previously employed by LSI Logic, an application specific semiconductor company, from August 1987 to July 1996. Mr. Colombatto also previously held engineering positions at Reliance Electric, a production automation and control company, from August 1985 to June 1987 and Texas Instruments, an electronics company, from June 1982 to April 1985. Mr. Colombatto holds a Bachelor of Science degree in Electronic Engineering Technology from California State Polytechnic University, Pomona. We believe that Mr. Colombatto is qualified to serve as a member of our board of directors due to his extensive management experience and familiarity with our business and strategy.

James Caruso has held senior level financial positions in both public and private companies for more than 40 years, including serving as Chief Financial Officer at several publicly traded and privately held medical device companies. He has managed all financial aspects of businesses and is proficient in SEC reporting and compliance requirements. Mr. Caruso also has extensive operational experience and has led post-acquisition business integration activities on several occasions. Mr. Caruso served as Chief Financial Officer of Catheter Precision, the private company acquired by us in 2023, from 2010 through 2016. From 2016 to the present, Mr. Caruso was retired. Mr. Caruso also served as Chief Financial Officer of EP MedSystems, Inc. (NASDAQ:EPMD), a company focused on cardiac electrophysiology that was acquired by St Jude Medical in 2008; Hi-Tronics Designs, Inc., a privately held medical device design and manufacturing company that was acquired by Advanced Neuromodulation Systems, Inc. in 2001; and Micron Products, Inc., a publicly traded medical device manufacturing company that was acquired by Arrhythmia Research Technology in 1991. Mr. Caruso spent five years in the audit practice at Deloitte (formerly Deloitte & Touche). Mr. Caruso received his Bachelor of Science in Business Administration from Rutgers University and an MBA from Fordham University and is a Certified Public Accountant. We believe that Mr. Caruso is qualified to serve as a director because of his senior level financial experience with public and private companies.

Andrew Arno Mr. Arno has 30 years of experience handling a wide range of corporate and financial matters, including work as an investment banker and strategic advisor to emerging growth companies. Since October 2023, he has served as the Managing Member of Unterberg Legacy Capital, LLC. He was previously Vice Chairman of Special Equities Group, LLC, a privately held investment banking firm affiliated with Dawson James Securities Inc., and previously with Bradley Woods & Co. Ltd., and he held that role from June 2019 to March 2023. Prior to joining Special Equities Group, LLC, Mr. Arno served as Vice Chairman at Chardan Capital Markets, LLC, from July 2015 to June 2019. From June 2013 until July 2015, Mr. Arno served as Managing Director of Emerging Growth Equities, an investment bank, and Vice President of Sabr, Inc., a family investment group. He was previously President of LOMUSA Limited, an investment banking firm. From 2009 to 2012, Mr. Arno served as Vice Chairman and Chief Marketing Officer of Unterberg Capital, LLC, an investment advisory firm that he co-founded. He was also Vice Chairman and Head of Equity Capital Markets of Merriman Capital LLC, an investment banking firm, and served on the board of the parent company, Merriman Holdings, Inc. Mr. Arno currently serves on the boards of directors of Oncocyte Corporation, Smith Micro Software, Inc. and XXII Century Group, Inc., a tobacco products company, which are all public companies, and on the boards of Independa Inc., a software company, and Comhear Inc., an audio technology R&D company, both of which are private. Mr. Arno previously served as a director of Asterias Biotherapeutics, Inc. from August 2014 until it was acquired by Lineage Cell Therapeutics, Inc. ("Lineage") in March 2019. Mr. Arno received a BS degree from George Washington University. We believe Mr. Arno is qualified to serve on our Board of Directors because of his financial expertise and his experience as a director on other public company boards.

Executive Officers

David A Jenkins became Executive Chairman of the Board in January 2023. He became Interim Chief Executive Officer in April 2023 and was named Chief Executive Officer in January 2024. His biographical information is set forth above at "Information About the Board of Directors."

Philip Anderson, age 58, became Chief Financial Officer on January 6, 2025. Mr. Anderson was retired from November 2022 to December 2024. Previously, he served as the Chief Financial Officer of Heritage Distilling Corporation, an adult beverage distiller, from August 2021 to November 2022. From August 2020 to June 2021, he served as Chief Financial Officer of Crown Electrokinetics Corp., a pre-revenue technology/hardware company in the areas of smart windows, fiber optics and water quality solutions. He served as Chief Financial Officer of Kubient, Inc., a supplier of fraud detection and prevention solutions to the global digital advertising market, from June 2019 to January 2020. Prior to serving as a CFO Mr. Anderson was a hedge fund partner for 17 years focused on investing in small and microcap companies. He received a Bachelor of Arts in Business Management from Ithaca College and an MBA with concentration in Finance from Hofstra University.

Marie-Claude Jacques, age 40, became Chief Commercial Officer on May 1, 2024. From January 2023 to January 2024, she was the Director of Field Integration for Boston Scientific Corporation, a Fortune 500 manufacturer of medical devices used in rhythm management, endoscopy, neuromodulation, peripheral interventions and neurology/pelvic health. Ms. Jacques was employed with the AF Solutions Group of Boston Scientific's cardiology division. From February 2022 to December 2022, she was the Vice President of Sales, Access Solutions for that group. From August 2022 to December 2022, Ms. Jacques was Vice President of US sales for Baylis Medical Company Inc., a company that offers advanced transseptal access solutions as well as guidewires, sheaths and dilators used to support catheter-based left-heart procedures. From June 2014 to August 2022, Ms. Jacques was Director of US Sales for Baylis Medical Company Inc. Ms. Jacques has been a part of the medical device field for over 15 years. She began her career with Baylis Medical and was an integral part in growing and scaling the sales' US business. Mrs. Jacques led the company to double digit sales growth for consecutive years and participated in market development which led to the acquisition by Boston Scientific in 2022. She has a bachelor's degree in microbiology from Université Laval and a Master's degree in Business Administration from University of Warwick.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership and changes of ownership on Forms 3, 4 and 5 with the SEC. Such directors, executive officers and 10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of the copies of such forms, and written representations that we have received from certain reporting persons that they filed all required reports, we believe that all of our officers, directors and greater than 10% stockholders complied with all Section 16(a) filing requirements applicable to them with respect to transactions during 2024, other than one late Form 3 filed by Andrew Arno, who began serving as a director in July 2024.

Audit Committee

The members of our Audit Committee are Andrew Arno and James Caruso. Mr. Caruso serves as the chairperson of our Audit Committee. The Board has determined that each member of the Audit Committee is an independent director under the NYSE American listing rules, satisfies the additional independence criteria for audit committee members and satisfies the requirements for financial literacy under the NYSE American listing rules and Rule 10A-3 of the Exchange Act, as applicable. The Board has also determined that Mr. Caruso qualifies as an audit committee financial expert within the meaning of the applicable rules and regulations of the SEC and satisfies the financial sophistication requirements of the NYSE American listing rules.

Corporate Governance Principles and Code of Ethics and Conduct

The Board has adopted corporate governance principles. These principles address items such as the qualifications and responsibilities of our directors and director candidates and corporate governance policies and standards applicable to us in general. In addition, the Board has adopted a written code of ethics and conduct that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of our corporate governance principles and code of ethics and conduct are available on our website, *www.catheterprecision.com*, under the Investor tab under "Corporate Governance", then "Governance Documents." If the Board makes any substantive amendments to, or grants any waivers from, the code of ethics and conduct for any officer or director, it will disclose the nature of such amendment or waiver on the Company's website.

Insider Trading Policy

We have adopted an Insider Trading Policy and procedures governing the purchase, sale and/or other dispositions of our securities by directors, officers and employees that is reasonably designed to promote compliance with insider trading laws, rules and regulations, and the NYSE American listing standards applicable to us. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K for the year ended December 31, 2024. In addition, with regard to the Company's trading in its own securities, it is the Company's policy to comply with the federal securities laws and the applicable exchange listing requirements.

ITEM 11. EXECUTIVE COMPENSATION

Director Compensation

With respect to 2024, the compensation committee and the Board did not retain a compensation consultant in connection with determining compensation of non-employee directors. In January 2024, the compensation committee recommended, and the Board approved, 2024 compensation to all non-employee directors consisting of a cash retainer of $50,000 and an award of non-qualified stock options to purchase 2,500 shares of Company common stock to each non-employee director. Options were granted on January 8, 2024, have a purchase price of $4.00 per share, a 10-year term, and vest quarterly over three years. Then in January 2025, the compensation committee recommended, and the Board approved, that annual cash compensation be reduced from $50,000 to $30,000, effective July 1, 2024, with an adjustment made to the final payment to the non-employee directors for 2024. On January 28, 2025, the compensation committee recommended and granted, and the Board approved, an award of non-qualified stock options to purchase 100,000 shares of Company common stock to each non-employee director. Options were granted on January 29, 2025, have a purchase price of $0.42 per share, a 10-year term, and vested 33.33% on the grant date, with the remainder vesting 33.33% on the first anniversary of the grant date and 33.34% vesting on the second anniversary of the grant date. Retainer cash payments will be paid in cash on or about the last day of each fiscal quarter of the Company in arrears to each non-employee director.

We also reimburse our non-employee directors for reasonable, customary and documented travel expenses to attend meetings of our board of directors and committees of our board of directors.

Our non-employee directors remain eligible to receive equity awards and cash or other compensation outside of the compensation described above, as may be provided from time to time at the discretion of our Board of Directors.

2024 Director Compensation Table

The following table sets forth information regarding compensation earned or paid to our non-employee directors during the year ended December 31, 2024:

	Fees Earned or Paid in Cash ($)	Option Awards ($)(5)	Total ($)
Martin Colombatto (1)	40,000	9,538	49,538
James Caruso (2)	40,000	9,538	49,538
John P Francis (3)	12,500	9,538	22,038
Andrew Arno (4)	15,000	—	15,000

(1) Mr. Colombatto held vested options to purchase 631 shares of Company common stock and unvested options to purchase 1,876 shares of Company common stock as of December 31, 2024.
(2) Mr. Caruso held vested options to purchase 624 shares of Company common stock and unvested options to purchase 1,876 shares of Company common stock as of December 31, 2024.
(3) Mr. Francis served on the Board from January 2, 2024 to July 3, 2024.
(4) Mr. Arno joined the Board on July 3, 2024.
(5) See Note 15. Stock Based Compensation to our Consolidated Financial Statements included in this Annual Report for a discussion of the assumptions we made in the valuation of these option grants.

See *Executive Compensation* for information about the compensation of Mr. David Jenkins, a director who is also an executive officer.

Processes and Procedures for Executive Compensation

The Compensation Committee assists the Board in discharging the Board's responsibilities relating to oversight of the compensation of the chief executive officer and other executive officers, including reviewing and approving or making recommendations to the Board with respect to the compensation, plans, policies and programs for the chief executive officer and other executive officers and administering the equity compensation plans for executive officers and employees.

The Compensation Committee annually reviews the compensation, plans, policies and programs for the chief executive officer and other executive officers. In connection therewith, the Compensation Committee considers, among other things, each executive officer's performance in light of established individual and corporate goals and objectives and the recommendations of our chief executive officer. In particular, the Compensation Committee considers the recommendations of the chief executive officer when reviewing base salary and incentive performance compensation levels of the executive officers and when setting specific individual and corporate performance targets under the annual incentive bonus plan for the executive officers. While the chief executive officer provides input on his compensation, he does not participate in compensation committee or Board deliberations regarding his own compensation. The Compensation Committee may delegate its authority to a subcommittee, but it may not delegate any power or authority required by agreement, law, regulation or listing standard to be exercised by the Compensation Committee as a whole.

Named Executive Officers

The named executive officers for 2024 ("NEOs"), which consist of our principal executive officer, our former Interim Chief Financial Officer, and our Chief Commercial Officer, who were our only executive officers as of December 31, 2024, were as follows:

- David A. Jenkins, Executive Chairman and Chief Executive Officer;
- Margrit Thomassen, former Interim Chief Financial Officer and Secretary; and
- Marie-Claude Jacques, Chief Commercial Officer.

Mr. Jenkins was appointed Executive Chairman upon effectiveness of the Merger on January 9, 2023 and interim Chief Executive Officer beginning April 28, 2023, and Chief Executive Officer beginning January 2, 2024. Margrit Thomassen served as Interim Chief Financial Officer from January 1, 2024, through January 6, 2025. Marie-Claude Jacques was appointed as Chief Commercial Officer beginning May 1, 2024.

Summary Compensation Table

The following table provides information regarding the compensation of the NEOs for 2024 and 2023, as applicable:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
David A. Jenkins	2024	300,000						300,000
Executive Chairman and Chief Executive Officer	2023	300,000						300,000
Margrit Thomassen	2024	144,000	25,000		9,538			178,538
Former Interim Chief Financial Officer and Secretary								
Marie-Claude Jacques	2024	266,667			130,625			397,292
Chief Commercial Officer								

(1) See Note 15. Stock-Based Compensation to our Consolidated Financial Statements included in this Annual Report for a discussion of the assumptions we made in the valuation of these option grants.

Executive Employment Agreements and Arrangements

David A. Jenkins

In January 2023, we entered into an oral employment agreement with David A. Jenkins, Chairman of the Board. In accordance with the terms of Mr. Jenkins' employment agreement, he is entitled to annual compensation of $300,000.

Marie-Claude Jacques

In April 2024, we entered into an offer letter agreement with Marie-Claude Jacques, Chief Commercial Officer. In accordance with the terms of the offer letter, she is entitled to guaranteed annual salary compensation for the first two years of employment of $400,000. After two years her annual salary compensation is reduced to $240,000. She also received 25,000 non-plan stock options, at an exercise price of $5.321 per share, vesting annually over 5 years, exercisable over ten years per the terms of the offer letter.

Outstanding Equity Awards at 2024 Fiscal Year-End

As of December 31, 2024, NEOs held the following equity awards:

Name	Number of Securities Underlying Unexercised Options - Exercisable	Number of Securities Underlying Unexercised Options - Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date
David Jenkins	—	—	—	—	—
Margrit Thomassen	—	2,500	—	$4.00	1/8/2034
	1,676	—	—	$5.90	3/13/2031
Marie-Claude Jacques	—	25,000	—	$5.321	5/1/2034

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Non-Public Information

Option grants to employees, executive officers and non-employee directors are made by the Compensation Committee (the "Committee") under the 2023 Incentive Plan from time to time, as determined by the Committee. The Committee does take material non-public information into account when determining the timing and terms of stock awards, in that if the Company determines that it is in possession of material non-public information on an anticipated grant date, the Committee expects to defer the grant until a date on which the Company is not in possession of material non-public information. The Company does not time the release of material non-public information based on equity award grant dates or for the purpose of affecting the value of executive compensation. For all stock option awards, the exercise price is the closing price of our common stock on the NYSE American on the last trading day preceding the grant date.

The following table presents information regarding stock options issued to our NEOs in fiscal year 2024 during any period beginning four business days before the filing or furnishing of a periodic report or current report disclosing material non-public information and ending one business day after the filings or furnishing of such report with the SEC:

Name	Grant Date	Number of Securities Underlying the Award	Exercise Price of the Award ($/Sh)	Grant Date Fair Value of the Award	Percentage Change in the Closing Market Price of the Securities Underlying the Award Between the Trading Day Ending Immediately Prior to the Disclosure of Material Non-Public Information and the Trading Day Beginning Immediately Following the Disclosure of Material Non-Public Information
Margrit Thomassen	1/8/2024	2,500	$4.00	$9,538	0% (1)
Marie-Claude Jacques	5/1/2024	25,000	$5.321	$130,625	1.8%(2)

(1) Based on closing prices of the Company's common stock of $3.90 on January 11, 2024 and $3.90 on January 11, 2024.
(2) Based on closing prices of the Company's common stock of $5.50 on May 6, 2024 and $5.60 on May 7, 2024.

Perquisites, Health, Welfare and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees.

We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances**.** Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 17, 2025 by:

- each person, or group of affiliated persons, who we know to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage ownership information shown in the table is based on an aggregate of 9,268,632 shares of our common stock outstanding as of March 17, 2025.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to: (i) the exercise of stock options that are either immediately exercisable or exercisable on or before May 16,2025, which is 60 days after March 17, 2025 and (ii) outstanding warrants to purchase common stock held by that person that are either immediately exercisable or exercisable on or before May 16, 2025. These shares are deemed to be outstanding and beneficially owned by the person holding those options and warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise noted below, the address of each of the individuals and entities named in the table below is c/o Catheter Precision, Inc., 1670 Highway 160 West, Suite 205, Fort Mill, South Carolina 29708. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

	Number of Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned
5% Stockholders:		
Armistice Capital LLC (1)	932,079	9.99%
Jenkins Family Charitable Institute (2)	966,982	9.93%
Casey Jenkins (3)	972,565	9.99%
Directors and Named Executive Officers:		
David A. Jenkins (4)	194,182	2.07%
James J. Caruso (5)	34,548	*
Martin Colombatto (6)	34,417	*
Andrew Arno (7)	33,330	*
Margrit Thomassen (8)	12,176	*
Marie-Claude Jacques (9)	30,000	*
All directors and executive officers as a group (6 persons) (4)(5)(6)(7)(9)(10)	382,033	4.00%

(1) These securities are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund") and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. Certain information was obtained from a Schedule 13G/A filed by the shareholder on February 14, 2025. The precise number of shares beneficially owned by the shareholder depends upon the operation of certain beneficial ownership blockers contained in warrants held by the shareholder and the number of shares outstanding, and therefore may be greater or less than the number presented from time to time. The table does not include those warrants held by the shareholder that are not currently exercisable due to beneficial ownership blockers. The shareholder currently owns Prepaid Series H warrants to receive 657,000 shares of common stock, Prepaid Series I warrants to receive 1,500,000 shares of common stock, Series J warrants to purchase 1,500,000 shares of common stock and Series K warrants to purchase 8,065,962 shares of common stock. Address of stockholder is 510 Madison Avenue, 7th Floor, New York, NY 10022.

(2) Casey A. Jenkins, the daughter of Mr. Jenkins, is the trustee of Jenkins Family Charitable Institute. Includes 466,756 shares subject to currently exercisable Series I Warrants held by the Jenkins Family Charitable Institute. Does not include Series I and Series J Warrants held by the Jenkins Family Charitable Institute to purchase an aggregate of 583,244 shares of common stock and Series J Warrants held by Ms. Jenkins to purchase 150,000 shares of common stock which are not currently exercisable due to beneficial ownership blockers. Does not include 18.691 shares of Series X Preferred Stock held by the Jenkins Family Charitable Institute which are convertible into approximately 18,690 shares of common stock upon satisfaction of certain conditions that have not currently been met.

(3) Includes 466,756 shares subject to currently exercisable Series I Warrants held by the Jenkins Family Charitable Institute. Does not include Series I and Series J Warrants held by the Jenkins Family Charitable Institute to purchase an aggregate of 733,244 shares of common stock and 150,000 shares subject to Series J Warranted held by Ms. Jenkins which are currently not exercisable due to beneficial ownership blockers. Does not include 18.691 shares of Series X Preferred Stock held by the Jenkins Family Charitable Institute and 262.256 shares of Series X Preferred Stock held by Ms. Jenkins which are convertible into approximately 28,094 shares of common stock upon satisfaction of certain conditions that have not currently been met. Also does not include 5,583 shares held by Ms. Jenkins.

(4) Includes (i) 226 shares held by a charitable remainder unitrust of which Mr. Jenkins' wife is the trustee; and (ii) 70,970 shares held by a partnership of which Mr. Jenkins is the manager member of the managing partner. Excludes 23,532 shares held by certain adult immediate family members of Mr. Jenkins. Does not include 8,190.261 shares of Series X Preferred Stock held by Mr. Jenkins and his affiliates which are convertible into 819,026 shares of common stock but which are subject to certain beneficial ownership blockers and which may not be converted, at the earliest, until July 9, 2024. Also does not include 1,049.024 shares of Series X Preferred Stock held, in the aggregate, by certain adult immediate family members of Mr. Jenkins and which are convertible into 104,902 shares of common stock, but which are subject to certain beneficial ownership blockers and which may not be converted, at the earliest, until July 9, 2024. Also does not include exercisable options to purchase 24,581 shares of common stock and unvested options to purchase 42,000 shares of common stock held by Missiaen Huck, the non-executive chief operating officer of Catheter and Mr. Jenkins's adult daughter.

(5) Does not include 7.932 shares of Series X Preferred Stock held by Mr. Caruso which are convertible into 793 shares of common stock but which are subject to certain beneficial ownership blockers and which may not be converted, at the earliest, until July 9, 2024. Includes currently exercisable options to purchase 34,370 shares of common stock. Does not include unvested options to purchase 68,130 shares of common stock.

(6) Includes (i) 7 shares of common stock subject to options exercisable within 60 days of March 17, 2025, and (ii) exercisable options to purchase 34,370 shares of common stock. Does not include unvested options to purchase 68,130 shares of common stock.

(7) Includes exercisable options to purchase 33,330 shares of common stock. Does not include unvested options to purchase 66,670 shares of common stock.

(8) Includes (i) 1,676 shares of common stock underlying vested stock options held by Margrit Thomassen, the Company's Secretary; and (ii) exercisable options to purchase 10,500 shares of common stock. Does not include unvested options to purchase 42,000 shares of common stock.

(9) Includes exercisable options to purchase 30,000 shares of common stock. Does not include unvested options to purchase 213,750 shares of common stock.

(10) Includes exercisable options to purchase 55,556 shares of common stock held by Philip Anderson, the Company's Chief Financial Officer. Does not include unvested options to purchase 444,444 shares of common stock held by Mr. Anderson.

EQUITY COMPENSATION PLAN INFORMATION

Information as of December 31, 2024, regarding the Company's equity compensation plans is summarized in the following table:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Restricted Stock Units (a)	Weighted-Average Exercise Price of Outstanding Options (1) (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders (2)	53,507	$ 25.49	926,882
Equity compensation plans not approved by security holders (3)	42,097	$ 5.78	0
Total	95,604	$ 16.81	926,882

(1) The weighted average exercise price is based solely on outstanding options.

(2) Outstanding options were issued under the Company's 2018 Equity Incentive Plan (as amended, the "2018 Plan") and the Company's 2023 Equity Incentive Plan (the "2023 Plan"). The 2018 Plan was terminated in 2024 and no shares remain available for future issuance. The number of securities remaining available represents shares under the 2023 Plan, and excludes 1.5 million shares authorized by the Company's stockholders in January 2025, and 124,733 shares which become available on March 1, 2025, and additional shares which will become available in future quarters, pursuant to an adjustment feature under the 2023 Plan. Under the adjustment features, the number of shares available for issuance under the 2023 Plan increases on the first day of each fiscal quarter (each, an "Adjustment Date") by an amount equal to the lesser of: (i) 10% of the number equal to the number of shares of common stock outstanding on the applicable Adjustment Date less the number of shares of Common Stock outstanding at the beginning of the fiscal quarter immediately preceding the Adjustment Date, but if such number is a negative number, then the increase will be zero; or (ii) such lesser number of Shares as may be determined by the Board.

(3) Represents Old Catheter options assumed in connection with the January 9, 2023 acquisition of Old Catheter and non plan options issued to officers of the Company.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by the Item will be included in the 2025 Proxy Statement, and is incorporated herein by reference, or will be included in an amendment to this report if the 2025 Proxy Statement is not filed on or before April 30, 2025.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Our independent registered public accounting firm is Withum (auditor ID: 100) since June 21, 2023.

Fees Paid to the Independent Registered Public Accounting Firms

The following table represents aggregate fees for services provided to us in the fiscal year ended December 31, 2024 by Withum. It does not include fees billed to us for services rendered by our previous auditor, Haskell & White LLP, during 2024:

	2024 (Withum)	2023 (Withum)
Audit Fees (1)	$ 937,584	$ 660,872
Audit-Related Fees (2)	—	—
Tax Fees (3)	—	—
All Other Fees (4)	—	—
Total Fees	$ 937,584	$ 660,872

(1) "Audit Fees" consist of fees billed for professional services rendered during the respective fiscal year in connection with the audit of our annual financial statements, review of our quarterly financial statements, and services that are normally provided in connection with statutory and regulatory filings or engagements for those fiscal years. This includes consents and other services related to SEC matters and registration statements.

(2) "Audit-Related Fees" generally include fees incurred for assurance and related services that are reasonably related to the performance of the audit or review of the Company's financial statements but are not otherwise included as Audit Fees.

(3) "Tax Fees" consist of permissible tax compliance and tax advisory service fees. Withum did not bill us for any tax fees for the year ended December 31, 2024.

(4) "All Other Fees" consist of fees billed for services other than the services reported in Audit Fees, Audit-Related Fees, and Tax Fees.

Auditor Independence

During the year ended December 31, 2024, there were no other professional services provided by Withum that would have required our audit committee to consider their compatibility with maintaining Withum's independence.

Pre-Approval Policy

Our audit committee's policy is to pre-approve all audit and permissible non-audit services provided by the independent accountants and the related estimated fees. These services may include audit services, audit-related services, tax services and other services. Our audit committee generally pre-approves particular services or categories of services on a case-by-case basis. The independent registered public accounting firm and management are required to periodically report to our audit committee regarding the extent of services provided by the independent registered public accounting firm in accordance with these pre-approvals, and the fees for the services performed to date. All of Withum's services to the Company for fiscal year 2024 described above were pre-approved by our audit committee.

PART IV — FINANCIAL INFORMATION

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES.

(a) We have filed the following documents as part of this Annual Report:

1. *Financial Statements*.

	Page
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets	F-5
Consolidated Statements of Operations	F-6
Consolidated Statements of Stockholders' Equity	F-7
Consolidated Statements of Cash Flows	F-8
Notes to Consolidated Financial Statements	F-9

2. *Financial Statement Schedules*.

There are no financial statement schedules provided because the information called for is either not required or is shown either in the financial statements or the notes thereto.

3. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.2	Amended and Restated Agreement and Plan of Merger, dated January 9, 2023, by and among the Registrant, certain subsidiaries, and Catheter Precision, Inc.	8-K	001-38677	2.1	1/13/2023
3.1.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38677	3.1	10/1/2018
3.1.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant. (effective 11/16/20)	8-K	001-38677	3.1	11/17/2020
3.1.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant. (effective 09/30/22)	8-K	001-38677	3.1	9/20/2022
3.1.3.A	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (filed 7/11/2024, effective 7/15/2024)	8-K	001-38677	3.1	7/12/2024
3.1.3.B*	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (effective 1/13/2025)				
3.1.4	Certificate of Designation of Series X Convertible Preferred Stock.	8-K	001-38677	3.1	1/13/2023
3.1.5	Certificate of Designation of Series A Preferred Stock.	8-K	001-38677	3.2	1/13/2023
3.1.6	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (effective 08/17/23)	8-K	001-38677	3.1	8/4/2023
3.2.1	Amended and Restated Bylaws of the Registrant.	8-K	001-38677	3.2	10/1/2018
3.2.2	Amendment to Amended and Restated Bylaws of the Registrant.	8-K	001-38677	3.1	8/17/2022
4.1	RESERVED				
4.2*	Description of Capital Stock				
4.3	Form of warrant issued in May 2020.	8-K	001-38677	4.1	5/22/2020
4.4	Form of pre-funded warrant issued in May 2020.	8-K	001-38677	4.2	5/22/2020
4.5	Form of placement agent warrant issued in May 2020.	8-K	001-38677	4.3	5/22/2020
4.6	Form of warrant offered in July 2020.	S-1	333-239887	4.3	7/16/2020
4.7	Form of pre-funded warrant issued in July 2020.	S-1	333-239887	4.4	7/16/2020
4.8	Form of placement agent warrant offered in July 2020.	S-1	333-239887	4.5	7/16/2020
4.9	Form of placement agent warrant offered in October 2024	8-K	001-38677	4.2	11/5/2024
4.10	Form of Series B Warrant offered in February 2022.	S-1/A	333-262195	4.9	2/3/2022
4.11	Form of Series C Warrant issued in July 2022	8-K	001-38677	4.1	7/22/2022
4.12	Warrant Agency Agreement, dated February 8, 2022, by and between the Registrant and American Stock & Trust Company LLC.	8-K	001-38677	4.4	2/9/2022
4.12.1	Amendment No. 1, dated July 22, 2022, to February 8, 2022 Warrant Agency Agreement by and between the Company and American Stock Transfer & Trust Company, LLC.	10-Q	001-38677	4.7	8/15/2022
4.13	Form of Series E Warrant offered in January 2023.	8-K	001-38677	4.1	1/13/2023
4.14	Form of Series F Warrant issued in March 2023.	8-K	001-38677	4.2	1/13/2023

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
4.15	Form of Series G Warrant issued in March 2023.	8-K	001-38677	4.3	1/13/2023
4.15.1	Form of Series H Warrant offered in September 2024	8-K	001-38677	4.1	9/6/2024
4.15.2	Form of Series I Warrant offered in September 2024	8-K	001-38677	4.2	9/6/2024
4.15.3	Form of Series J Warrant offered in September 2024	8-K	001-38677	4.3	9/6/2024
4.15.4	Form of Series K Warrant offered in October 2024	8-K	001-38677	4.1	10/25/2024
4.16	Form of Pre-Funded Warrant offered in September 2024	8-K	001-38677	4.4	9/6/2024
4.17	Form of Underwriters' Warrant offered in September 2024	S-1	333-279930	4.17	6/26/2024
4.18	Form of Warrant Agency Agreement dated as of September 3, 2024 entered into by and between the Registrant and Equiniti Trust Company, LLC	8-K	001-38677	4.5	9/6/2024
10.1	[omitted.]				
10.2+	2018 Form of Indemnification Agreement between the Registrant and directors and executive officers.	S-1	333-226191	10.2	8/24/2018
10.3+	Ra Medical Systems, Inc. 2018 Stock Compensation Plan and Forms of Award Agreement thereunder.	S-1	333-226191	10.3	7/16/2018
10.4+	Ra Medical Systems, Inc. 2018 Equity Incentive Plan and Forms of Award Agreement thereunder, as amended.	8-K	001-38677	99.1	10/13/2020
10.5	[omitted.]				
10.6	[omitted.]				
10.7	[omitted.]				
10.8	[omitted]				
10.9	[omitted.]				
10.12	[omitted.]				
10.13	[omitted.]				
10.14	[omitted.]				
10.16	Corporate Integrity Agreement, between the Company and the Office of Inspector General of the Department of Health and Human Services, dated December 28, 2020.	10-K	001-38677	10.20	3/17/2021
10.16.1	Notice of Suspension of Corporate Integrity Agreement, dated January 11, 2023.	10-K	001-38677	10.16.1	3/28/2023
10.17	[omitted.]				
10.18	[omitted.]				
10.19	[omitted.]				
10.20	[omitted.]				
10.21	[omitted.]				
10.22	[omitted.]				
10.23	Warrant Inducement Offer Letter dated July 22, 2022.	8-K	001-38677	10.1	7/22/2022

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.25	Registration Rights Agreement, dated January 9, 2023.	8-K	001-38677	10.5	1/13/2023
10.27.1	Debt Settlement Agreement and Release including certain royalty rights with David A. Jenkins, dated January 9, 2023.	10-K	001-38677	10.27.1	3/28/2023
10.27.2	Debt Settlement Agreement and Release including certain royalty rights with Daniel C. Stanzione, Sr. Irrevocable Trust Dated December 31, 2007, dated January 9, 2023.	10-K	001-38677	10.27.2	3/28/2023
10.27.3	Debt Settlement Agreement and Release including certain royalty rights with Fatboy Capital, L.P., dated January 9, 2023.	10-K	001-38677	10.27.3	3/28/2023
10.28.1	LockeT Royalty Agreement with Auston Locke.	10-K	001-38677	10.28	3/28/2023
10.28.2	Assignment and Agreement from Auston Locke in relation to LockeT dated July 15, 2022	S-1	333-279930	10.28.2	6/4/2024
10.28.3	Assignment and Agreement from David A. Jenkins in relation to LockeT dated January 24, 2023	S-1	333-279930	10.28.3	6/4/2024
10.28.4	Invention Assignment and Royalty Agreement with Auston Locke in relation to LockeT dated May 28, 2024	8-K	001-38677	10.1	6/3/2024
10.30.1	Lease with respect to Fort Mill facility.	10-K	001-38677	10.30.1	3/28/2023
10.31	[omitted.]				
10.31.1	[omitted.]				
10.31.2+	2023 Equity Incentive Plan	DEF 14A	001-38677	Annex C	11/25/2024
10.31.3+	2023 Form of Nonstatutory Stock Option Agreement for Non-Employee Directors Under 2023 Equity Incentive Plan	10-K	001-38677	10.31.3	4/1/2024
10.31.4+	2023 Form of Nonstatutory Stock Option Agreement for Employees Under 2023 Equity Incentive Plan	10-K	001-38677	10.31.4	4/1/2024
10.31.5+	2023 form of Incentive Stock Option Agreement Under 2023 Equity Incentive Plan	10-K	001-38677	10.31.5	4/1/2024
10.31.6+	Notice of Stock Option Award granted March 13, 2021 to Margrit Thomassen under Old Catheter's 2009 Equity Incentive Plan	10-K	001-38677	10.31.6	4/1/2024
10.31.7+	Non-plan Stock Option Award granted May 1, 2024 to Marie-Claude Jacques	S-1	333-279930	10.31.7	6/4/2024
10.31.8*+	Non-plan Stock Option Award granted January 6, 2025 to Philip Anderson				
10.31.9*+	Offer Letter to Philip Anderson dated January 3, 2025				
10.31.10*+	Offer Letter to Marie-Claude Jacques dated April 24, 2024				
10.32	Software and Technology License Agreement dated May 1, 2016, with Peacs BV.	10-K	001-38677	10.32	3/28/2023
10.32.1	Settlement and Amendment Agreement dated May 24, 2021 with Peacs BV.	10-K	001-38677	10.32.1	3/28/2023

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.33	Warrant Inducement Letter Dated October 24, 2024	8-K	001-38677	10.1	10/25/2024
10.33.2	Waiver Agreement Dated October 29, 2024	8-K	001-38677	10.1	10/30/2024
10.33.3	[omitted.]				
10.33.4	[omitted.]				
10.33.5	Promissory Note dated May 30, 2024	8-K	001-38677	10.2	6/3/2024
10.33.6	Promissory Note dated June 25, 2024	8-K	001-38677	10.1	6/26/2024
10.33.7	Promissory Note dated July 1, 2024	8-K	001-38677	10.1	7/1/2024
10.33.8	Promissory Note dated July 18, 2024	8-K	001-38677	10.1	7/23/2024
10.33.9	Promissory Note dated July 25, 2024	8-K	001-38677	10.1	7/30/2024
10.34	Quality Agreement with Zien Medical Technologies, Inc. related to LockeT Manufacture, dated March 20, 2023	S-1	333-279930	10.34	6/4/2024
10.35	First Amendment to Promissory Note dated May 30, 2024	S-1	333-279930	10.33.5	8/27/2024
10.36	First Amendment to Promissory Notes dated June 25, 2024, July 1, 2024 and July 18, 2024	S-1	333-279930	10.33.6	8/27/2024
10.37	First Amendment to Promissory Note dated July 25, 2024	S-1	333-279930	10.33.7	8/27/2024
16.1	Letter re change in certifying accountant	8-K	001-38677	16.1	6/26/2023
19.1*	Insider Trading Policy dated March 21, 2025				
21.1	Subsidiaries of the Registrant				
23.1*	Consent of WithumSmith+Brown, PC, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (contained on signature page).				
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*^	Certifications of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*^	Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97.1	Policy Relating to the Recovery of Erroneously Awarded Compensation	10-K	001-38677	97	4/1/2024
101.INS*	Inline XBRL Instance Document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				

* Filed herewith.

^ The information in this exhibit is furnished and deemed not filed with the Securities and Exchange Commission for purposes of section 18 of the Exchange Act of 1934, as amended (Exchange Act), and is not to be incorporated by reference into any filing of Ra Medical Systems, Inc. under the Securities Act of 1933, as amended (Securities Act), or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

\+ Indicates a management contract or compensatory plan.

ITEM 16. FORM 10–K SUMMARY.

None.

SIGNATURES

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

CATHETER PRECISION, INC.

Date: March 28, 2025

By: /s/ David A. Jenkins
David A. Jenkins
Executive Chairman and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David A. Jenkins and Philip Anderson, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, to sign any and all amendments (including post-effective amendments) to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each of said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-facts and agents, or his substitute or substitutes, or any of them, shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ David A. Jenkins David A. Jenkins	Executive Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 28, 2025
/s/ Philip Anderson Philip Anderson	Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2025
/s/ James Caruso James Caruso	Director	March 28, 2025
/s/ Martin Colombatto Martin Colombatto	Director	March 28, 2025
/s/ Andrew Arno Andrew Arno	Director	March 28, 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Catheter Precision, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Catheter Precision, Inc., (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations and negative cash flows from operations and expects to continue to incur operating losses that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Fair Value of Royalties Payable

Description of the Matter

The Company had $9.2 million of royalties payable as of December 31, 2024, based on the fair value of the royalties payable related to the LockeT royalty agreements acquired in connection with the prior year merger. We identified the fair value of royalties payable as a critical audit matter. In determining the fair value, management must generate revenue projections through the expiration of the royalty agreements. They must also calculate a revenue-adjusted discount rate which is then applied to calculate the present value of the royalties payable. There is significant uncertainty associated with the projections due to limited sales history available as the related product only began sales in the current year. In addition, the calculation of the discount rate requires the involvement of management's valuation specialists.

How the Critical Matter was Addressed in the Audit

To determine the reasonableness of the fair value of the royalties payable, we:

- Assessed the reasonableness of the forecasts of future revenue by (i) comparing to historical revenue growth of the Company and (ii) assessing forecasts of future revenues against industry metrics and guideline companies.
- Utilized personnel with specialized knowledge and skill in valuation to assist in assessing the reasonableness of discount rates incorporated into the valuation models used by management.
- Recalculated the mathematical accuracy of the Company’s net present value calculation.
- Assessed the professional competence, experience, and objectivity of the Company’s external valuation specialist.

Assessment of ASC 360 Impairment Analysis

Description of the Matter

In accordance with ASC 360, *Impairment and Disposal of Long-Lived Assets* ("ASC 360"), the Company, at least annually or more frequently if certain events or changes in circumstances indicate the carrying value may not be recoverable, performs an impairment analysis. As a result of the sustained negative cash flows from operations and continued losses from operations, the Company assessed their intangible assets and long-lived assets for impairment.

To determine whether the carrying amount of the long-lived asset group is recoverable, the Company determined the estimated future cash flows of the group for a period consistent with that of the primary assets of the group. The sum of the undiscounted cash flows was then compared to the carrying amount of the long-lived assets as of December 31, 2024 to conclude whether the asset group carrying value is recoverable.

We identified the ASC 360 impairment analysis as a critical audit matter due to the estimation and subjectivity needed to identify impairment triggers and perform an impairment test. The inputs to the test are subjective as they are based on management's forecasts. Additionally, there is complexity that requires the Company to involve valuation specialists in performing the quantitative test.

How the Critical Matter was Addressed in the Audit

To determine the reasonableness of the conclusion the long-lived assets were not impaired we:

- Evaluated the reasonableness of management’s assumptions in the calculation of fair value of reporting unit, including the revenue growth rate in the projected future cash flows by comparing projections to historical results, actual results through year-end, relevant peer companies, and industry data.
- Utilized personnel with specialized knowledge and skill in valuation to assist in evaluating the appropriateness of the methodologies and valuation models utilized by management to determine the fair value of the reporting units.
- Assessed the professional competence, experience, and objectivity of the Company's external valuation specialist.

Accounting For Warrants Associated with September 2024 Public Offering

Description of the Matter

The Company issued warrants in connection with the September 2024 Public Offering. The accounting for the issuance of these warrants involves evaluation of complex accounting guidance to be performed by management as it relates to determining the accounting classification of the warrants.

This matter was identified as a critical audit matter due to the complexity in accounting for the warrants and the significant impact of these conclusions on the Company's consolidated financial statements.

How the Critical Matter was Addressed in the Audit

Our principal audit procedures performed to address this critical audit matter included the following:

- Reviewed the executed offering under the registration statement and associated agreements.
- Reviewed management’s technical accounting memo evaluating the terms and conditions of the executed agreements to determine the appropriate classification of the instruments.
- Utilized personnel with specialized knowledge and skills in technical accounting to assist in: (i) evaluating the terms of the offering documents in relation to the relevant accounting literature, and (ii) assessing the appropriateness of conclusions reached by the Company.

Accounting For Warrants and Modification of Warrants Associated with October 2024 Warrant Inducement

Description of the Matter

The Company modified the exercise price of existing warrants in connection with the October 2024 Warrant Inducement. In consideration for the exercise, warrant holders were issued new warrants. The accounting for the modification and issuance of these warrants involves complex and subjective judgment by management as it relates to determining the accounting classification of the warrants and determining the fair value of the warrants at issuance and modification dates.

This matter was identified as a critical audit matter due to the complexity in accounting for the warrants and the significant impact of these conclusions on the Company's consolidated financial statements.

How the Critical Matter was Addressed in the Audit

Our principal audit procedures performed to address this critical audit matter included the following:

- Reviewed the Warrant Inducement Offer to common stock purchase warrants.
- Reviewed management's technical accounting memo in conjunction with the terms and conditions of the executed warrant agreements to determine the appropriate classification of the instruments.
- Evaluated management's methodology and assumptions used in the valuation of the warrants.
- Utilized our internal valuation specialists to assess the reasonableness of the volatility inputs into the Company's Black-Scholes model.
- Assessed the professional competence, experience, and objectivity of the Company's external valuation specialist.
- Recalculated the mathematical accuracy of the Company's fair valuation of the warrants.

/s/ WithumSmith+Brown, PC

We have served as Catheter Precision, Inc.’s auditor since 2023.

East Brunswick, New Jersey

March 28, 2025

PCAOB ID Number 100

CATHETER PRECISION, INC.
Consolidated Balance Sheets
(in thousands, except par value data)

	December 31, 2024	December 31, 2023
ASSETS		
Current Assets		
Cash and cash equivalents	$ 2,873	$ 3,565
Accounts receivable, net	70	137
Inventories	33	44
Prepaid expenses and other current assets	316	415
Total current assets	3,292	4,161
Property and equipment, net	91	70
Operating lease right-of-use assets, net	105	179
Intangible assets, net	24,274	26,318
Other non-current assets	8	8
TOTAL ASSETS	$ 27,770	$ 30,736
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 230	$ 464
Accrued expenses	1,548	1,733
Notes payable	177	184
Current portion of royalties payable due to related parties	32	—
Current portion of operating lease liabilities	98	91
Total current liabilities	2,085	2,472
Royalties payable due to related parties	9,213	6,974
Deferred tax liability	3,141	—
Notes payable due to related parties	1,500	—
Interest payable due to related parties	61	—
Operating lease liabilities	13	97
Total liabilities	16,013	9,543
Commitments and contingencies (see Note 17)		
Stockholders' Equity		
Preferred Stock, $0.0001 par value, 10,000,000 shares authorized		
Series A Convertible Preferred Stock, $0.0001 par value, 7,203 shares designated; 0 and 4,578 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	—	—
Series X Convertible Preferred Stock, $0.0001 par value, 15,404 shares designated; 12,656 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.0001 par value, 30,000,000 shares authorized; 8,004,633 and 702,662 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	304,109	296,902
Accumulated deficit	(292,352)	(275,709)
Total stockholders' equity	11,757	21,193
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 27,770	$ 30,736

See accompanying notes to consolidated financial statements.

CATHETER PRECISION, INC.
Consolidated Statements of Operations
(in thousands, except per share data)

	Year Ended December 31,	
	2024	**2023**
Revenues	$ 420	$ 442
Cost of revenues	42	30
Gross profit	378	412
Operating expenses		
Loss on impairment of goodwill	—	60,934
Selling, general and administrative	11,349	17,122
Research and development	272	475
Total operating expenses	11,621	78,531
Operating loss	(11,243)	(78,119)
Other income (expense), net		
Interest income	81	347
Interest expense	(91)	—
Other expense, net	(10)	(8)
Change in fair value of royalties payable due to related parties	(2,239)	7,208
Total other income (expense), net	(2,259)	7,547
Loss from operations before income taxes	(13,502)	(70,572)
Income tax provision	3,141	—
Net loss	$ (16,643)	$ (70,572)
Deemed dividend on warrant inducement offer	(5,158)	(800)
Net loss attributable to common stockholders	$ (21,801)	$ (71,372)
Net loss per share attributable to common stockholders, basic and diluted	$ (6.68)	$ (129.88)
Weighted-average common shares used in computing net loss per share, basic and diluted	3,263,586	549,507

See accompanying notes to consolidated financial statements.

CATHETER PRECISION, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Series A Convertible Preferred Stock		Series X Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2022	—	$ —	—	$ —	**216,127**	$ —	$ **214,397**	$ **(205,137)**	$ **9,260**
Common stock issued upon exercise of options	—	—	—	—	40,233	—	238	—	238
Restricted stock awards cancelled or vested	—	—	—	—	(42)	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	1,217	—	1,217
Issuance of Series X Convertible Preferred Stock in merger	—	—	14,650	—	—	—	72,544	—	72,544
Conversion of Series X Convertible Preferred Stock	—	—	(1,994)	—	199,359	—	—	—	—
Issuance of Series A Convertible Preferred Stock in connection with private placement, net	7,203	—	—	—	49,791	—	7,360	—	7,360
Warrants exercised (see Note 13)	—	—	—	—	33,161	—	1,145	—	1,145
Conversion of Series A Convertible Preferred Stock	(2,625)	—	—	—	164,033	—	1	—	1
Net loss	—	—	—	—	—	—	—	(70,572)	(70,572)
Balance at December 31, 2023	4,578	$ —	12,656	$ —	702,662	$ —	$ 296,902	$ (275,709)	$ 21,193
Stock-based compensation	—	—	—	—	—	—	54	—	54
Issuance of common stock upon exercise of Pre-Funded Warrants (see Note 13)	—	—	—	—	2,773,000	—	—	—	—
Issuance of common stock and other equity-classified contracts from September 2024 Public Offering, net of issuance costs	—	—	—	—	805,900	—	2,612	—	2,612
Issuance of common stock through October 2024 Warrant Inducement Offer, net of issuance costs	—	—	—	—	2,251,981	—	3,356	—	3,356
Issuance of common stock upon exercise of Series Warrants (see Note 13)	—	—	—	—	1,185,000	—	1,185	—	1,185
Conversion of Series A Convertible Preferred Stock	(4,578)	—	—	—	286,090	—	—	—	—
Net loss	—	—	—	—	—	—	—	(16,643)	(16,643)
Balance at December 31, 2024	—	$ —	**12,656**	$ —	**8,004,633**	$ —	$ **304,109**	$ **(292,352)**	$ **11,757**

See accompanying notes to consolidated financial statements.

CATHETER PRECISION, INC.
Consolidated Statements of Cash Flows
(in thousands)

	For the Years Ended December 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (16,643)	$ (70,572)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on impairment of goodwill	—	60,934
Depreciation and amortization	2,109	2,075
Stock-based compensation	54	1,217
Change in fair value of royalties payable due to related parties	2,239	(7,208)
Deferred income tax provision	3,141	—
Changes in operating assets and liabilities:		
Accounts receivable	67	(66)
Inventories	(8)	8
Prepaid expenses and other current assets	99	876
Operating lease right-of-use assets and lease liabilities	(3)	4
Current portion of royalties payable due to related parties	32	—
Accounts payable	(234)	(550)
Accrued expenses	(185)	(7,139)
Interest payable due to related parties	61	(198)
Net cash used in operating activities	(9,271)	(20,619)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(67)	(76)
Cash acquired as part of business combination	—	15
Net cash used in investing activities	(67)	(61)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants	—	238
Proceeds from issuance of common stock and other equity-classified contracts from the September 2024 Public Offering, net of issuance costs	2,612	—
Proceeds from issuance of common stock from the October 2024 Warrant Inducement Offer, net of issuance costs	3,356	—
Proceeds from notes payable due to related parties	1,500	—
Payment on notes payable	(256)	(107)
Proceeds from notes payable	249	—
Proceeds from exercise of warrants	1,185	1,326
Payment of costs related to the warrant repricing	—	(181)
Payment of convertible promissory notes and accrued interest	—	(250)
Proceeds from the private placement of securities	—	8,000
Payments of offering costs related to the private placement of securities	—	(640)
Net cash provided by financing activities	8,646	8,386
NET CHANGE IN CASH AND CASH EQUIVALENTS	(692)	(12,294)
CASH AND CASH EQUIVALENTS, beginning of year	3,565	15,859
CASH AND CASH EQUIVALENTS, end of year	$ 2,873	$ 3,565
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	$ 31	$ 204
SUPPLEMENTAL SCHEDULE OF NONCASH FINANCING AND INVESTING ACTIVITIES		
Property and equipment reclassified from inventories	$ 19	$ —
Conversion of Series A Convertible Preferred Stock for common stock	$ —	$ 1
Non-cash consideration for Catheter acquisition	$ —	$ 72,544
Deemed dividend on warrant inducement offer	$ (5,158)	$ (800)

See accompanying notes to consolidated financial statements.

Note 1. Organization and Nature of Operations

The Company

Catheter Precision, Inc. ("Catheter" or the "Company") was incorporated in California on September 4, 2002, and reincorporated in Delaware in July 2018. Catheter was initially formed to develop, commercialize and market its advanced excimer laser-based platform for use in the treatment of vascular and dermatological immune-mediated inflammatory diseases.

On January 9, 2023, Catheter entered into the Amended and Restated Agreement and Plan of Merger (the "Merger Agreement") with Catheter Precision, Inc. ("Old Catheter"), a privately held Delaware corporation. Under the terms of the Merger Agreement, Old Catheter became a wholly owned subsidiary of Catheter, together referred to as the Company, in a stock-for-stock merger transaction (the "Merger").

Prior to the Merger, Catheter developed the advanced excimer laser-based platform, which was developed as a tool in the treatment of Peripheral Artery Disease, which commonly occurs in the legs. After the Merger, and looking forward, this legacy Destruction of Arteriosclerotic Blockages by laser Radiation Ablation, laser and single-use catheter (together referred to as "DABRA") and related assets were no longer used. The Company ceased operations and marketing with respect to DABRA, and Catheter's legacy lines of business were discontinued. The Company shifted the focus of its operations to Old Catheter's product lines. Accordingly, the Company's current activities primarily relate to Old Catheter's historical business, which comprises the design, manufacture and sale of new and innovative medical technologies in the field of cardiac electrophysiology ("EP").

One of the Company's two primary products is the VIVO System, which is an acronym for View into Ventricular Onset ("VIVO" or "VIVO System"). VIVO is a non-invasive imaging system that offers 3D cardiac mapping to help with localizing the sites of origin of idiopathic ventricular arrhythmias in patients with structurally normal hearts prior to EP procedures. The VIVO System is commercially available in the European Union and has been placed at several hospitals in Europe. United States Food and Drug Administration ("FDA") 510(k) clearance was received, and the Company began a limited commercial release of VIVO in 2021 in the United States.

The Company's newest product, LockeT® ("LockeT"), is a suture retention device indicated for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure and is intended to temporarily secure sutures and aid clinicians in locating and removing sutures efficiently. In addition, LockeT is a sterile, Class I product that was registered with the FDA in February 2023, at which time initial shipments began to distributors. Clinical studies for LockeT began during the year ended December 31, 2023. These studies are planned to show the product's effectiveness and benefits, including faster wound closure and earlier ambulation, potentially leading to early hospital discharge and cost benefits. This information is intended to provide crucial data for marketing. The Company recorded its first commercial sale of LockeT to distributors in May 2024.

The Company's product portfolio also includes the Amigo® Remote Catheter System (the "AMIGO" or "AMIGO System"), a robotic arm that serves as a catheter control device. Prior to 2018, Old Catheter marketed AMIGO. The Company owns the intellectual property related to AMIGO, and this product is under consideration for future research and development of a generation 2 product.

Reverse stock split

On July 3, 2024, at the annual meeting of stockholders of the Company, the stockholders approved an amendment to the Amended and Restated Certificate of Incorporation of the Company (the "Amendment"), which included a decrease in the authorized common stock and authorization for the Board, in its discretion, to effect a reverse stock split within specified parameters. The Amendment was effective July 15, 2024, reducing the authorized common stock to 30 million shares and effecting a reverse stock split in which each ten (10) shares of the Company's common stock, par value $0.0001 per share, issued and outstanding immediately prior to the effective time, automatically combined into one (1) validly issued, fully paid and non-assessable share of the Company's common stock, par value $0.0001 per share.

No fractional shares were issued as a result of the reverse stock split. Stockholders who would otherwise have been entitled to receive a fractional share were entitled to receive their pro rata portion of the net proceeds obtained from the aggregation and sale by the exchange agent of the fractional shares resulting from the reverse stock split (reduced by any customary brokerage fees, commissions and other expenses). All references to share and per share amounts for all periods presented in the consolidated financial statements have been retrospectively restated to reflect this reverse stock split. All rights to receive shares of common stock under outstanding securities, including but not limited to, warrants and options, were adjusted to give effect to the reverse stock split. Furthermore, proportionate adjustments were made to the per share exercise price and the number of shares of Common Stock that may be purchased upon exercise of outstanding warrants and stock options granted by the Company, and the number of shares of Common Stock reserved for future issuance under the Company's Equity Incentive Plan.

Going concern

The consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

The Company has incurred recurring net losses from operations and negative cash flows from operating activities since inception. As of December 31, 2024, the Company had cash and cash equivalents of approximately $2.9 million. For the year ended December 31, 2024, the Company used $9.3 million in cash for operating activities. As of December 31, 2024, the Company had an accumulated deficit of approximately $292.4 million.

Management expects operating losses and negative cash flows to continue for the foreseeable future as the Company invests in its commercial capabilities. These negative cash flows have substantially depleted the Company's cash. Following the Merger with Old Catheter, Management further reduced costs while assuming the operating costs of Old Catheter. Management will continue to monitor its operating costs and seek to reduce its current liabilities. Such actions may impair its ability to proceed with certain strategic activities.

Between May 30, 2024 and July 25, 2024, the Company issued five short-term promissory notes with related parties totaling $1.5 million with an 8% interest rate and a maturity date of August 30, 2024 (the "Related Party Notes"). On August 23, 2024, the Company amended the Related Party Notes to extend the maturity date to January 31, 2026. As part of the amendment, all interest accrued as of the amendment date was repaid to the noteholders and the contractual interest rate increased to 12% per annum as of the amendment date. See Note 9, Notes Payable for additional information.

On August 30, 2024, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Ladenburg Thalmann & Co. Inc. as representative (the "Representative") of the underwriters named in the Underwriting Agreement (the "Underwriters"). Pursuant to the Underwriting Agreement, the Company completed a public offering of its securities on September 3, 2024 (the "September 2024 Public Offering") and sold an aggregate of (i) 805,900 Common Stock Units and (ii) 2,773,000 Pre-Funded Units. The Company collected gross proceeds of approximately $3.6 million before deducting underwriting discounts, commissions, and offering expenses payable by the Company of $1.0 million. See Note 13, Equity Offerings for additional information.

On October 25, 2024, the Company executed the Warrant Inducement Offer Letters (the "2024 Warrant Inducement Offer") with certain holders of the Company's existing warrants. Following the close of the 2024 Warrant Inducement Offer, such warrant holders immediately exercised an aggregate of (i) 33,160.8 Series E Warrants, (ii) 499,909.34 Series F Warrants, (iii) 499,909.34 Series G Warrants, (iv) 1,990,000 Series H Warrants, and (v) 2,325,000 Series I Warrants (collectively the "2024 Existing Warrants") to purchase 5,347,981 shares of the Company's common stock at a reduced exercise price of $0.70 per share of common stock. In consideration for the immediate exercise of the 2024 Existing Warrants for cash, the Company agreed to issue unregistered new Series K Common Stock Purchase Warrants ("Series K Warrants") to purchase up to 10,695,962 shares of common stock. The Company received aggregate gross proceeds of $3.7 million in cash, prior to deducting placement agent fees and offering expense of $0.4 million. See Note 13, Equity Offerings for additional information.

Based on the Company's liquidity resources, there is substantial doubt about the Company's ability to continue as a going concern within 12 months from the date of issuance of the consolidated financial statements. The accompanying consolidated financial statements have been prepared on the basis of the Company continuing to operate in the normal course of business and do not reflect any adjustments to the assets and liabilities related to the substantial doubt of its ability to continue as a going concern.

Management's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management plans to raise additional capital through public or private equity or debt financings to fulfill its operating and capital requirements for at least 12 months from the date of the issuance of the consolidated financial statements. However, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders.

Note 2. Summary of Significant Accounting Policies

Principles of consolidation

The consolidated financial statements of the Company include the accounts of the Company and Old Catheter. All intercompany transactions have been eliminated in consolidation.

Basis of presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The Financial Accounting Standards Board ("FASB") establishes these principles to ensure financial condition, results of operations, and cash flows are consistently reported. Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative nongovernmental GAAP as found in the FASB Accounting Standards Codification ("ASC").

Use of estimates

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses

during the reporting periods. Actual results could differ from those estimates. The Company's consolidated financial statements are based upon a number of estimates including, but not limited to, the accounting for the Old Catheter business combination (see Note 3, Business Combination), allowance for credit losses, evaluation of impairment of long-lived assets and goodwill, valuation of long-lived assets and their associated estimated useful lives, reserves for warranty costs, fair value of royalties payable due to related parties, evaluation of probable loss contingencies, fair value of preferred stock and warrants issued, including valuation of the deemed dividend, and fair value of equity awards granted.

Concentrations of credit risk

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company generally maintains cash and cash equivalent balances in various operating accounts at financial institutions with high quality credit in amounts in excess of federally insured limits of $250,000. As of December 31, 2024, the Company had deposits in financial institutions in excess of federally insured limits of $2.6 million. The Company has not experienced any losses related to its cash and cash equivalents and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company has no significant off-balance sheet risk, such as foreign exchange contracts, option contracts, or other hedging arrangements.

The Company extends credit to customers in the normal course of business. Concentrations of credit risk with respect to accounts receivable exist to the full extent of amounts presented in the consolidated balance sheets. The Company does not require collateral from its customers to secure accounts receivable.

The Company had 3 customers that represented 62% and 67% of the Company's consolidated revenues for the years ended December 31, 2024 and 2023, respectively.

Reclassifications

Certain prior year financial statement amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on our previously reported results of operations or accumulated deficit. In the current year, the Company separately discloses interest income and interest expense in the consolidated statement of operations. For comparative purposes, amounts in the prior years have been reclassified to conform to current year presentations.

Segment reporting

The Company operates in one reportable segment, which includes all activities related to the marketing, sales, and development of medical technologies in the cardiac electrophysiology field. While the commercial efforts that coordinate the marketing, sales, and distribution of these products are organized by geographic region and product, all of these activities are supported by a single corporate team and distribution channels. The determination of a single reportable segment is consistent with the consolidated financial information available and regularly reviewed by the Company's chief operating decision maker ("CODM").

The CODM is the Company's chief executive officer, who reviews and evaluates consolidated net loss reported on the consolidated statements of operations for purposes of assessing performance, making operating decisions, allocating resources and planning and forecasting for future periods. As the Company's operations are managed at the consolidated level, there are no differences between the measurement of the reportable segments' profit or losses and the Company's consolidated statements of operations. Segment asset measures are not used as a basis for the CODM to evaluate the performance of or to allocate resources to the segment.

The following table summarizes segment revenues and significant segment expenses included in the measure of segment profit or loss (consolidated net loss) reviewed by the CODM:

	For the Year Ended December 31,	
	2024	**2023**
Revenues	$ 420	$ 442
Less:		
Cost of revenues	42	30
Loss on impairment of goodwill	—	60,934
Depreciation and amortization expense	2,109	2,075
Stock-based compensation expense	54	1,217
Salaries and benefits expense	4,192	4,661
Professional fees	2,034	5,622
Research and development expenses	272	475
Interest income	(81)	(347)
Interest expense	91	—
Change in fair value of royalties payable due to related parties	2,239	(7,208)
Income tax expense	3,141	—
Other segment items (1)	2,970	3,555
Segment net loss	(16,643)	(70,572)
Reconciliation of net loss		
Adjustments and reconciling items	—	—
Consolidated net loss	(16,643)	(70,572)

(1) Other segment items include other expenses, net of $10 thousand, consulting fees of $505 thousand, investor relations and SEC fees of $459 thousand, insurance fees of $533 thousand, and other selling, general, and administrative expenses of $1,462 thousand for the year ended December 31, 2024. Other segment items include other expenses, net of $8 thousand, consulting fees of $730 thousand, investor relations and SEC fees of $691 thousand, insurance fees of $704 thousand, and other selling, general, and administrative expenses of $1,422 thousand for the year ended December 31, 2023. Other selling, general, and administrative expenses primarily consist of travel expenses, computer and information technology expenses, and rent expenses.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with an original maturity date of ninety days or less at the date of purchase to be cash equivalents. Cash and cash equivalents primarily represent funds invested in readily available checking and money market accounts.

Fair value measurements

Fair value represents the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants and is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier fair value hierarchy is used to identify inputs used in measuring fair value as follows:

Level 1 - Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets;

Level 2 - Inputs other than the quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and

Level 3 - Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

Cash equivalents, prepaid expenses, accounts receivable, accounts payable, and accrued expenses are reported on the consolidated balance sheets at carrying value which approximates fair value due to the short-term maturities of these instruments. The carrying value of our notes payable and notes payable due to related parties approximates the instruments' fair value due to the short-term maturities of these debt instruments.

The following table details the fair value measurements within the fair value hierarchy of the Company's financial instruments:

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash Equivalents				
Mutual fund	$ 2,803	$ 2,803	$ —	$ —
Money market fund	12	12	—	—
Total assets	$ 2,815	$ 2,815	$ —	$ —
Liabilities				
Royalties payable due to related parties	$ 9,213	$ —	$ —	$ 9,213
Total liabilities	$ 9,213	$ —	$ —	$ 9,213

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash Equivalents				
Mutual fund	$ 3,397	$ 3,397	$ —	$ —
Money market fund	10	10	—	—
Total assets	$ 3,407	$ 3,407	$ —	$ —
Liabilities				
Royalties payable due to related parties	$ 6,974	$ —	$ —	$ 6,974
Total liabilities	$ 6,974	$ —	$ —	$ 6,974

The fair value measurement of royalties payable due to related parties includes unobservable inputs that are not supported by any market data. Royalties payable due to related parties equals the present value of estimated future royalty payments, wherein the Company applies an internally developed, revenue adjusted discount rate ("RADR") to discount back the forecasted royalty payments. The RADR is based on the Company's weighted average cost of capital ("WACC") adjusted for the product revenue's risk profile. The risk-free rate used to determine the cost of equity for the RADR is adjusted to be commensurate with the term of the royalty agreements. Furthermore, the Beta and Risk Premium used to determine the cost of equity are also adjusted to reflect the product revenue's volatility. All other inputs for the RADR and the Company's WACC are the same.

The following tables summarize the significant unobservable inputs used in the fair value measurement of Level 3 instruments:

		December 31, 2024	
Instrument	Valuation Technique	Unobservable Input	Input Range
Royalties payable due to related parties	Discounted future cash flows	Revenue adjusted discount rate	22.5%

		December 31, 2023	
Instrument	Valuation Technique	Unobservable Input	Input Range
Royalties payable due to related parties	Discounted future cash flows	Revenue adjusted discount rate	28.0%

Increases or decreases in the fair value of royalties payable due to related parties can result from updates to assumptions, such as changes in discount rates, projected cash flows, among other assumptions. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Changes or updates to assumptions could have a material impact on the reported fair value, the change in fair value, and the results of operations in any given period.

The table below summarizes the change in fair value of royalties payable to related parties for the years ended December 31, 2024 and 2023 (in thousands):

	2024	2023
Beginning Balance at January 1,	$ 6,974	$ —
AMIGO royalty payable recognized in connection with the Merger	—	160
LockeT royalty payable recognized in connection with the Merger	—	14,022
Change in fair value of royalties payable due to related parties	2,239	(7,208)
Ending Balance at December 31,	$ 9,213	$ 6,974

Accounts receivable and allowances for credit losses

Accounts receivable consists of trade receivables recorded at invoiced amounts. Accounts receivable is presented net of any discounts and allowance for credit losses, is unsecured and does not bear interest. Accounts receivable are evaluated for collectability based on historical credit loss experience, adjusted for asset-specific risk characteristics, current economic conditions, and reasonable forecasts, including the probability of future collection and estimated loss rates based on aging schedules. Accounts receivable are assessed for collectability based on three portfolio segments: Hospitals - United States, Hospitals - Europe, and Distributors. The determination of portfolio segments is based on the customers' industry and geographical location.

Changes in the estimated collectability of accounts receivable are recorded in the results of operations in the period in which the estimate is revised. Accounts receivable are written off as uncollectible after all means of collection are exhausted. Any subsequent recoveries are credited to the allowance for credit losses. As of December 31, 2024 and 2023, the allowance for credit losses related to accounts receivable was immaterial.

Inventories

Inventories are stated at the lower of cost (determined by the first-in, first-out method) or net realizable value. Cost includes materials, labor, and manufacturing overhead related to the purchase and production of inventories. The Company reduces the carrying value of inventories for those items that are potentially in excess, obsolete or slow-moving based on changes in customer demand, technological developments or other economic factors.

Property and equipment

Property and equipment are recorded at cost, less accumulated depreciation. Property and equipment are depreciated on a straight-line basis over their estimated useful lives as follows:

Machinery and equipment	2 - 5 years
Computer hardware and software	1 - 5 years
LockeT animation video	3 years
VIVO DEMO/Clinical Systems	1-5 years

The Company periodically reviews the residual values and estimated useful lives of each class of its property and equipment for ongoing reasonableness, considering the long-term views of their intended use and the level of planned improvements to maintain and enhance those assets. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from their respective account balances and any resulting gain or loss is recognized in the Company's consolidated statements of operations. The cost of repairs and maintenance are expensed as incurred, whereas significant renewals and betterments are capitalized.

Impairment of long-lived assets

In accordance with ASC 360, *Impairment and Disposals of Long-lived Assets*, the Company periodically reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that such assets might be impaired and the carrying value of the long-lived assets may not be recoverable. If events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable and the expected undiscounted future cash flows attributable to the asset are less than the carrying amount of the asset, an impairment loss equal to the excess of the assets carrying value over its fair value is recorded in the Company's consolidated statements of operations at that date.

As a result of the sustained decline of the Company's stock, the Company assessed its long-lived assets for impairment. To evaluate whether the carrying amount of the long-lived asset group is recoverable, the Company determined the estimated future cash flows of the group for a period consistent with that of the primary assets of the group. The sum of the undiscounted cash flows was then compared to the carrying amount of the long-lived assets as of December 31, 2024. The Company concluded there was no impairment as of December 31, 2024.

Goodwill

In accordance with ASC 350, *Intangibles – Goodwill and Other*, goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair value of net assets acquired. Goodwill, which represents the excess of purchase price of Old Catheter over the fair value of net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value-based test. The Company reviews goodwill for possible impairment annually during the fourth quarter, or whenever events or circumstances indicate that the carrying amount may not be recoverable.

To determine whether goodwill is impaired, annually or more frequently if needed, the Company performs a multi-step impairment test. The Company first has the option to assess qualitative factors to determine if it is more likely than not that the carrying value of a reporting unit exceeds its estimated fair value. The Company may also elect to skip the qualitative testing and proceed directly to the quantitative testing. When performing quantitative testing, the Company first estimates the fair values of its reporting units using a combination of an income and market-based approach. To determine fair values, the Company is required to make assumptions about a wide variety of internal and external factors. Significant assumptions used in the impairment analysis include financial projections of free cash flow (including significant assumptions about operations, including the rate of future revenue growth, capital requirements, and income taxes), long-term growth rates for determining terminal value and discount rates. Comparative market multiples are used to corroborate the results of the discounted cash flow test. These assumptions require significant judgment. Pursuant to ASU 2017-04, *Simplifying the Test for Goodwill Impairment*, the single step is to determine the estimated fair value of the reporting unit and compare it to the carrying value of the reporting unit, including goodwill. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. The majority of the inputs used in the discounted cash flow model are unobservable and thus are considered to be Level 3 inputs. The inputs for the market capitalization calculation are considered Level 1 inputs.

There were impairment charges of $60.9 million recognized during the year ended December 31, 2023 (see Note 3, Business Combination and Note 7, Goodwill for additional details). As of December 31, 2023, goodwill was fully impaired.

Royalties payable due to related parties

The Company is obligated to pay royalties related to sales of LockeT and AMIGO System under various royalty agreements executed by Old Catheter. The Company recognizes a liability for royalty fees incurred and payable based on actual sales of products under current portion of royalties payable due to related parties in the consolidated balance sheets. The Company recognizes a liability for future, estimated royalty payments at fair value under the royalties payable due to related parties in the consolidated balance sheets. The royalties payable due to related parties is remeasured at each reporting period. Changes in fair value of royalties payable due to related parties are recorded on the consolidated statements of operations in the period in which they occur. See Note 10, Royalties Payable for additional information.

Product warranty

The Company offers product warranties against defects in material and workmanship when the products are used for their intended purpose and properly maintained.

Warranty expenses are included in cost of revenues in the accompanying consolidated statements of operations. Changes in estimates to previously established warranty accruals result from current period updates to assumptions regarding repair and product recall costs and are included in current period warranty expense. As of December 31, 2024 and December 31, 2023, there was no accrued product warranty balance.

Distinguishing liabilities from equity

The Company evaluates equity or liability classification for freestanding financial instruments, including convertible preferred stock, warrants, and options, pursuant to the guidance under ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480"). The Company classifies as liabilities all freestanding financial instruments that are (i) mandatorily redeemable, (ii) represent an obligation to repurchase the Company's equity shares by transferring assets, or (iii) represent an unconditional obligation (or conditional obligation if the financial instrument is not an outstanding share) to issue a variable number of shares predominantly based on a fixed monetary amount, variations in something other than the fair value of the Company's equity shares, or variations inversely related to changes in fair value of the Company's equity shares.

If a freestanding financial instrument does not represent an outstanding equity share and does not meet liability classification under ASC 480, the Company then assesses whether the freestanding financial instrument is indexed to its own stock and meets equity classification pursuant to ASC 815-40, *Derivatives and Hedging* ("ASC 815"). The Company further assesses whether the freestanding financial instruments should be classified as temporary equity. Freestanding financial instruments that are redeemable for cash or other assets at a fixed or determinable date, at the option of the holder, or upon the occurrence of an event are classified in temporary equity in accordance with ASC 480. Otherwise, the freestanding financial instruments are classified in permanent equity.

Revenue recognition

In accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company accounts for contracts with customers when there is a legally enforceable contract, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. Revenue is measured as the amount of consideration expected to be received in exchange for transferring promised goods or services. The amount of consideration to be received and revenue recognized may vary due to discounts. A performance obligation is a promise in a contract to transfer a distinct good or service. If there are multiple performance obligations in the customer contract, the Company allocates the transaction price in the contract to each performance obligation based on the relative standalone selling price. The Company does not adjust revenue for the effects of a significant financing component for contracts if the period between the transfer of control and corresponding payment is expected to be one year or less. Revenue is recognized when performance obligations in the customer contract are satisfied. This generally occurs when the customer obtains control of a promised good at a point in time or when a customer receives a promised service over time.

Pursuant to ASC 606, the Company applies the following five steps to each customer contract:

Step 1: Identify the contract with the customer

Step 2: Identify the performance obligations in the contract

Step 3: Determine the transaction price

Step 4: Allocate the transaction price to the performance obligations in the contract

Step 5: Recognize revenue when the Company satisfies a performance obligation

VIVO System

The VIVO System offers 3D cardiac mapping to help localize the sites of origin of idiopathic ventricular arrhythmias in patients with structurally normal hearts prior to electrophysiology studies. Customers are provided with VIVO Positioning Patch Sets, which are custom patches, that are used in conjunction with the VIVO System. The VIVO Positioning Patch Sets are integral to the functionality of the VIVO System. The VIVO System, including the VIVO Positioning Patch Sets, represents the Company's primary performance obligation. The Company recognizes revenue when physical possession and control of the VIVO System is transferred to the customer upon delivery. The Company also offers customers software upgrades for the VIVO System, which may be purchased and paid in advance at contract inception. Software upgrades represent stand-ready services, whereby the Company promises to provide software upgrades to the customer when and as upgrades are available. Software upgrade services may be offered for initial contract terms of one to multiple years. Customers have the option to renew software upgrades services at the end of each term. The software upgrade services represent the Company's second performance obligation, which is recognized evenly over time over the contract term. There were no software upgrade services revenues during the years ended December 31, 2024 and 2023.

The Company invoices the customer for the VIVO System and related software upgrades after physical possession and control of the VIVO System has been transferred to the customer. Subsequent renewals for software upgrades are invoiced at inception of the renewed term. The timing of payment for the corresponding invoices depends on the credit terms identified in each customer contract.

LockeT

LockeT was launched by the Company in February 2023 and is a suture retention device indicated for wound healing by distributing suture tension over a larger area in the patient in conjunction with a figure of eight suture closure. LockeT is intended to temporarily secure sutures and aid clinicians in locating and removing sutures efficiently. The LockeT device represents a performance obligation in the customer contract. The Company recognizes revenue when it transfers control of the LockeT device to the customer, which happens when the Company delivers the product to the customer.

The Company has elected as a practical expedient to expense as incurred any costs incurred to obtain a contract as the related amortization period would be one year or less.

Disaggregation of revenue

The following table summarizes disaggregated product sales by geographic area (in thousands):

	Year Ended December 31,	
	2024	**2023**
Product Sales		
US	$ 278	$ 331
Europe	142	111
	$ 420	$ 442

Shipping and handling costs

Shipping and handling costs charged to customers are included in net product sales, while all other shipping and handling costs are included in selling, general and administrative expenses in the accompanying consolidated statements of operations.

Advertising and marketing

Advertising costs are expensed as incurred and included in selling, general and administrative expenses. Advertising costs were $170 thousand and $95 thousand during the years ended December 31, 2024 and 2023, respectively.

Patents

The Company expenses patent costs, including related legal costs, as incurred and records such costs as selling, general and administrative expenses in the accompanying consolidated statements of operations.

Research and development

Major components of research and development costs include consulting, research grants, supplies and clinical trial expenses. Research and development expenses are charged to operations in the period incurred.

Stock-based compensation

The Company recognizes stock-based compensation expense associated with stock options, restricted stock awards ("RSAs") and restricted stock units ("RSUs") issued to employees, members of the Company's board of directors and consultants in accordance with ASC Topic 718, *Compensation – Stock Compensation* ("ASC 718"). The Company evaluates whether stock-based awards should be classified and accounted for as liability or equity awards on the date of grant. Furthermore, the Company measures all stock-based awards granted based on the fair value of the award on the date of grant. Stock options are measured at fair value using the Black-Scholes option pricing valuation model (the "Black-Scholes model"), which incorporates various assumptions, including expected term, volatility and risk-free interest rate. Stock-based compensation expense for all stock-based awards is recognized over the requisite service period, which is generally the vesting period of the respective stock award. Stock-based compensation expense for stock-based awards with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not probable or is not met, no stock-based compensation expense is recognized, and any previously recognized compensation expense is reversed. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur.

As a result of the Merger, all unvested Old Catheter stock options were subject to accelerated vesting and became fully vested as of the closing date of the business combination. The Company recognized the fair value of the replacement options as included in consideration transferred to the extent they do not exceed the fair value of the equivalent Old Catheter options. Any incremental fair value was recognized in stock-based compensation expense in the post-combination period, with this recognized as a Day 1 expense due to the Old Catheter options becoming fully vested concurrent with the closing of the business combination.

Income taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences reverse. Any resulting net deferred tax assets are evaluated for recoverability and, accordingly, a valuation allowance is provided when it is more likely than not that all or some portion of the deferred tax asset will not be realized.

The Company accounts for uncertainty in income taxes using a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining whether it is more likely than not that the position will be sustained on an audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. An uncertain tax position is considered effectively settled on completion of an examination by a taxing authority if certain other conditions are satisfied. Should the Company incur interest and penalties relating to tax uncertainties, such amounts would be classified as a component of interest expense and other expense, respectively.

Basic and diluted net loss per share of common stock

Earnings per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines earnings per share for the holders of the Company's common shares and participating securities. The Company's Series A Convertible Preferred Stock, Series X Convertible Preferred Stock, and outstanding warrants are participating securities as they contain participating rights in distributions made to common stockholders. Since the participating securities do not include a contractual obligation to share in the losses of the Company, they are not included in the calculation of net loss per share in the periods that have a net loss. In addition, common stock equivalent shares (whether or not participating) are excluded from the computation of diluted earnings per share in periods in which they have an anti-dilutive effect on net loss per common share.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method and treasury stock method, as applicable. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. Diluted net loss per share is equivalent to basic net loss per share for the periods presented herein because common stock equivalent shares from warrants, stock options, non-vested restricted stock awards, restricted stock units, Series A Convertible Preferred Stock, and Series X Convertible Preferred Stock were anti-dilutive (see Note 12, Net Loss per Share).

Net loss attributable to common stockholders consists of net income or loss, as adjusted for actual and deemed dividends declared. The Company recorded a deemed dividend for the modification of existing warrants and issuance of new warrants of $5.2 million and $0.8 million for the years ended December 31, 2024 and 2023, respectively. The deemed dividend is added to net loss in determining the net loss available to common stockholders for the years ended December 31, 2024 and 2023.

Recently adopted accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). The amendments in ASU 2023-07 require disclosure of significant segment expenses that are regularly provided to the chief operating decision maker ("CODM") and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items to reconcile to segment profit or loss, and the title and position of the entity's CODM. The amendments in this update also expand the interim segment disclosure requirements. These amendments do not change how a public entity identifies its operating segments, aggregates those operating segments, or applies the quantitative thresholds to determine its reportable segments. The company adopted the amended guidance for the fiscal year-ended December 31, 2024. The adoption of ASU 2023-07 expanded certain disclosures but did not have a material impact on our consolidated financial statements. Refer to Note 2, Summary of Significant Accounting Policies, for more information about our segment reporting.

Recently issued accounting pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires public entities to disclose consistent categories and greater disaggregation of information in the rate reconciliation and for income taxes paid. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The guidance is effective for financial statements issued for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is required to adopt this standard prospectively in fiscal year 2025 for the annual reporting period ending December 31, 2025. The Company does not believe the impact of the new guidance and related codification improvements will have a material impact to its financial position, results of operations and cash flows.

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). ASU 2024-03 requires the disaggregation of certain costs and expenses in the notes to the financial statements to provide enhanced transparency into the expense captions presented on the face of the income statement. ASU 2024-03 is effective for the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2027 and for interim periods beginning in 2028. The guidance may be applied on a prospective or retrospective basis and early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2024-03 on its consolidated financial statements.

Note 3. Business Combination

On January 9, 2023, the Company completed the acquisition of Old Catheter for the purpose of acquiring Old Catheter's existing and developing product lines based on unique electrophysiology technology.

Pursuant to the Merger Agreement, all Old Catheter common stock shares issued and outstanding and convertible promissory notes, representing an aggregate principal of $25.2 million, were converted into a right to receive 14,649.592 shares of a new class of the Company's preferred stock, designated Series X Convertible Preferred Stock. Additionally, all outstanding stock options to purchase Old Catheter common stock were assumed and converted into options to purchase approximately 75,367 shares of the Company's common stock.

The total purchase consideration for the Merger was $72.5 million which represents the sum of the (i) estimated fair value of the 14,649.592 Series X Convertible Preferred Stock issued and (ii) the portion of the estimated fair value of $3.4 million representing the Company stock options issued in replacement of Old Catheter share-based payment awards as required under FASB Topic 805, *Business Combinations* ("Topic 805").

The fair value of the Series X Convertible Preferred Stock includes certain discounts applied to the closing stock price of the Company, on January 9, 2023, of $60.90 per share.

The following table summarizes the fair value of the consideration associated with the Merger (in thousands):

Description	Fair Value as of January 9, 2023
Fair value of 14,649.592 Series X convertible preferred stock issued	$ 69,140
Fair value of Old Catheter's fully vested stock options	3,404
Total Purchase Price	$ 72,544

The Merger was accounted for as a business combination in accordance with Topic 805, and the Company has been determined to be the accounting acquirer. The Company allocated the purchase price to the assets acquired and liabilities assumed at fair value. The purchase price allocation reflects various fair value estimates and analyses, including certain tangible assets acquired and liabilities assumed, the valuation of intangible assets acquired, liabilities assumed, and goodwill, which were subject to change within the measurement period as valuations were being finalized (generally one year from the acquisition date). Measurement period adjustments were recorded in the reporting period in which the estimates are finalized, and adjustment amounts were determined. During the three months ended June 30, 2023, the Company recorded measurement period adjustments based on changes to certain estimates and assumptions and their related impact to the purchase price allocation. Developed technology was revised from $35.1 million to $27.0 million; trademarks were revised from $1.7 million to $1.3 million; customer relationships were revised from $220 thousand to $62 thousand; goodwill was revised from $56.0 million to $60.9 million; and royalties payable due to related parties were revised from $7.6 million to $14.2 million.

The following table summarizes the final purchase price allocations relating to the Merger (in thousands):

Description	Fair Value
Assets acquired:	
Cash and cash equivalents	$ 15
Accounts receivable	71
Inventories	52
Prepaid expenses and other current assets	23
Property and equipment, net	26
Lease right-of-use assets	119
Other assets	8
Developed technology	27,014
Customer relationships	62
Trademarks	1,285
Goodwill	60,934
Total assets acquired	$ 89,609
Liabilities assumed:	
Accounts payable	$ 922
Accrued expenses	1,389
Lease liability	124
Interest payable	198
Convertible promissory notes	250
Royalties payable due to related parties	14,182
Total liabilities assumed	17,065
Total purchase price	$ 72,544

All intangible assets acquired are subject to amortization and their associated estimated acquisition date fair values and estimated useful lives are as follows:

Intangible Assets	Estimated Fair Value	Estimated Useful Life
Developed technology- VIVO	$ 8,244	15
Developed technology- LockeT	18,770	14
Customer relationships	62	6
Trademark- VIVO	876	9
Trademark- LockeT	409	9
	$ 28,361	

Notwithstanding the above, as described in Note 7, management determined that there were indicators of asset impairment during the year ended December 31, 2023, and assessed the carrying values of the Company's intangible assets and goodwill. As a result, the Company recorded an impairment charge relating to goodwill of $60.9 million during the year ended December 31, 2023. This amount represented the purchase price amount ascribed to goodwill.

Transaction costs incurred in connection with this business combination amounted to approximately $1.7 million during the year ended December 31, 2023.

Pro forma financial information

The following table represents the revenue, net loss and net loss per share effect of the acquired company, as reported on a pro forma basis as if the acquisition occurred on January 1, 2023. These pro forma results are not necessarily indicative of the results that would have occurred if the acquisition had occurred on the first day of the period presented, nor does the pro forma financial information purport to represent the results of operations for future periods. The following information for the year ended December 31, 2023 and is presented in thousands except for the per share data (in thousands, except per share data):

	For the Year Ended December 31, 2023
Revenues	$ 445
Net loss	$ (70,742)
Net loss attributable to common stockholders	$ (71,542)
Basic and diluted net loss per share – on a pro forma basis	$ (118.30)

Note 4. Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2024	2023
Raw materials	$ 18	$ 27
Finished goods	15	17
Inventories	$ 33	$ 44

There were no charges for inventory obsolescence or allowance recorded for the years ended December 31, 2024 and 2023.

Note 5. Property and Equipment

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2024	2023
Machinery and equipment	$ 29	$ 16
Computer hardware and software	29	17
LockeT animation video	29	—
VIVO DEMO/Clinical Systems	101	69
Property and equipment, gross	188	102
Accumulated depreciation	(97)	(32)
Property and equipment, net	$ 91	$ 70

Depreciation expense was $65 thousand and $32 thousand for the years ended December 31, 2024 and 2023, respectively.

Note 6. Intangible Assets

The following table summarizes the Company's intangible assets as of December 31, 2024 (in thousands):

	Estimated Useful Life Years	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Developed technology - VIVO	15	$ 8,244	$ (1,099)	$ 7,145
Developed technology - LockeT	14	18,770	(2,681)	16,089
Customer relationships	6	62	(21)	41
Trademarks/trade names - VIVO	9	876	(195)	681
Trademarks/trade names - LockeT	9	409	(91)	318
		$ 28,361	$ (4,087)	$ 24,274

The following table summarizes the Company's intangible assets as of December 31, 2023 (in thousands):

	Estimated Useful Life Years	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Developed technology - VIVO	15	$ 8,244	$ (550)	$ 7,694
Developed technology - LockeT	14	18,770	(1,341)	17,429
Customer relationships	6	62	(10)	52
Trademarks/trade names - VIVO	9	876	(97)	779
Trademarks/trade names - LockeT	9	409	(45)	364
		$ 28,361	$ (2,043)	$ 26,318

The estimated future amortization expense for the next five years and thereafter is as follows (in thousands):

Years ending December 31,	Future Amortization Expense
2025	$ 2,043
2026	2,043
2027	2,043
2028	2,043
2029	2,033
Thereafter	14,069
Total	$ 24,274

The Company uses the straight-line method to determine amortization expense for its definite lived intangible assets. Amortization expense, included within selling, general and administrative expenses, related to the Company's intangible assets was $2.0 million and $2.0 million for the years ended December 31, 2024 and 2023, respectively.

Note 7. Goodwill

In connection with the Merger, the excess of the purchase price over the estimated fair value of the net assets assumed of $60.9 million was recognized as goodwill. The Merger was accounted for as a business combination in accordance with Topic 805, and the Company has been determined to be the accounting acquirer. The Company allocated the purchase price to the assets acquired and liabilities assumed at fair value. During the three months ended June 30, 2023, the Company recorded measurement period adjustments based on changes to certain estimates and assumptions and their related impact to the purchase price allocation. As a result, goodwill was revised from $56.0 million to $60.9 million.

The Company tests Goodwill for impairment at the reporting unit level annually in the fourth quarter or more frequently if a change in circumstances or the occurrence of events indicates that potential impairment exists. Due to a sustained decrease in the Company's share price during the quarter ended March 31, 2023, the Company concluded that, in accordance with ASC 350, a triggering event occurred indicating that potential impairment exists and required the Company to assess if impairment exists as of March 31, 2023. In accordance with ASC 350, the Company performed a quantitative goodwill impairment test, which resulted in the carrying amount of the reporting unit exceeding the estimated fair value of the reporting unit, indicating that the goodwill of the reporting unit was impaired. The Company utilized a combination of an income and market-based approach to assess the fair value of the reporting unit. The income approach considered the discounted cash flow model, considering projected future cash flows (including timing and profitability), discount rate reflecting the risk inherent in future cash flows, perpetual growth rate, and projected future economic and market conditions. The guideline public company market approach considered marketplace earnings multiples from within a peer public company group. As of December 31, 2023, cumulative goodwill impairment charges of $60.9 million were incurred related to the Company's single reporting unit and no goodwill remains as of this date.

Note 8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2024	**2023**
Legal expenses	$ 81	$ 102
Offering costs	1,356	1,356
Compensation and related benefits	35	43
Other accrued expenses	76	232
Accrued expenses	$ 1,548	$ 1,733

The product warranty accrual related to the voluntary recall of DABRA catheters was initiated in September 2019. The recall was closed by the FDA in July 2023 and no claims have been submitted in approximately 2 years. As such, the Company derecognized the warranty liability of $192 thousand as of December 31, 2023. The accrued warranty balance was $0 as of December 31, 2024 and 2023.

Note 9. Notes Payable

Note Payable - Director & Officer Liability Insurance

The Company purchased director and officer liability insurance coverage on October 16, 2023 for $447 thousand. A down payment of $157 thousand was made and the remaining balance of $290 thousand was financed over 8 months through a short-term financing arrangement with its insurance carrier. The interest rate on the loan was 8.99%. Interest expense on this loan was $4 thousand and $6 thousand for the years ended December 31, 2024 and 2023, respectively. The loan balance was $184 thousand as of December 31, 2023. The loan balance was paid off in May 2024, such that there is no remaining balance as of December 31, 2024.

The Company purchased director and officer liability insurance coverage on September 26, 2024 for $293 thousand. A down payment of $44 thousand was made and the remaining balance of $249 thousand was financed over 10 months through a short-term financing arrangement with its insurance carrier. The interest rate on the loan is 9.99%. Interest expense on this loan was $6 thousand for the year ended December 31, 2024. The loan balance was $177 thousand as of December 31, 2024.

Promissory Notes (collectively, the "Related Party Notes")

On May 30, 2024, David A. Jenkins loaned $500,000 to the Company in exchange for a short-term promissory note.

On June 25, 2024, an entity controlled by Mr. Jenkins loaned $150,000 to the Company in exchange for a short-term promissory note.

On July 1, 2024 and July 18, 2024, the Company entered into two short-term promissory notes with an affiliate of Mr. Jenkins, wherein the affiliate loaned $250,000 and $100,000, respectively, to the Company in exchange for the short-term promissory notes.

On July 25, 2024, the Company entered into a short-term promissory note with a Trust, of which Mr. Jenkins' adult daughter is the trustee, wherein the Trust loaned $500,000 to the Company in exchange for the short-term promissory note.

All of these short-term promissory notes (the "Related Party Notes") had a maturity date of August 30, 2024 and interest at 8% per annum.

On August 23, 2024, the Company entered in the first amendment of the Related Party Notes, which extended the maturity date to January 31, 2026 and increased the interest rate to 12% per annum after August 31, 2024. All other terms and conditions remained substantially unchanged. As part of the amendment, the Company paid down all accrued interest to date of $21 thousand. The amendment was accounted for as a debt modification in accordance with ASC 470-50, *Debt Modifications and Extinguishment* ("ASC 470-50"). Since the modified terms and conditions were not substantially different from the prior terms and conditions, the Company accounted for the debt modification as a continuation of the original debt instrument. The Company further concluded that the debt modification did not result in any adjustments to the carrying value of the Related Party Notes.

The Related Party Notes, including all principal and interest, accelerate and become immediately due and payable upon the occurrence of certain customary events of default, including failure to pay amounts owed when due, material breach of the Company's representations or warranties (unless waived by the holders of the Related Party Notes or cured within 10 days following notice), certain events involving the discontinuation of the Company's business and/or certain types of proceedings involving insolvency, bankruptcy, receivership and the like.

Interest expense on the Related Party Notes was $81 thousand for the year ended December 31, 2024. The Related Party Notes and related accrued interest totaled $1.6 million as of December 31, 2024, $61 thousand of which related to accrued interest and was recorded under interest payable due to related parties on the consolidated balance sheets. The principal balance of $1.5 million of the Related Party Notes is recorded under notes payable due to related parties on the consolidated balance sheets.

See Note 19, Related Parties for additional details.

Note 10. Royalties Payable

LockeT Royalty

On January 9, 2023, Old Catheter entered into an agreement with the Noteholders to forgive all accrued interest and future interest expense in exchange for a future royalty right. Under these agreements, the Company is obligated to pay the Noteholders a total royalty equal to 11.82% of net sales of its LockeT device on a quarterly basis, commencing upon the first commercial sale, which occurred in April 2024, through December 31, 2035. As of December 31, 2024, the fair value of the royalty payable related to the agreement with the Noteholders was $9.2 million. The Company recorded a loss on the change in the fair value of $2.2 million for the year ended December 31, 2024.

An additional royalty will be paid to the inventor of the LockeT device as detailed in the Royalty Agreement. In exchange for the assignment and all rights to LockeT, the Company will pay a 5% royalty on net sales up to $1.0 million in royalties, payable annually in arrears, starting with the year ending December 31, 2022. After $1.0 million has been paid, and if, and only if, a US patent is granted by the United States Patent and Trademark Office, the Company will continue to pay a royalty at a rate of 2% of net sales, until total cumulative royalties of $10.0 million have been paid. The royalty payments will apply to revenues through December 31, 2033, then will terminate regardless of whether the full $10.0 million has been paid.

The Company recorded its first sales of LockeT devices during the year ended December 31, 2024, such that the Company owes $32 thousand in connection with the royalty agreements as of December 31, 2024. The Company did not owe any royalty payments as of December 31, 2023.

AMIGO System Royalty

During 2006 and 2007, Old Catheter entered into two investment grant agreements with a non-profit foundation for the purpose of funding the initial development of Old Catheter's AMIGO System, receiving a total of $1.6 million from the foundation. The agreement calls for the payment of the following sales-based royalties by Old Catheter to the foundation upon successful commercialization of the AMIGO System (in thousands, except for percentages):

Royalty Percentage		Until Royalty Payment Reaches a Total of	
4	%	$	1,589
2	%	$	3,179
1%			In perpetuity

The Company is not actively marketing and selling the AMIGO System, such that there was no royalty expense recorded for the years ended December 31, 2024 and 2023 in relation to the AMIGO System. The AMIGO System royalty has been earned and payment has been deferred to a future date. The AMIGO System royalty payable is recorded under royalties payable due to related parties in the consolidated balance sheets.

Note 11. Leases

The Company determines if an arrangement contains a lease at contract inception based on its ability to control a physically distinct asset in exchange for consideration. If the arrangement contains a lease, the Company then determines the classification of the lease as either operating or finance. For the years ended December 31, 2024 and 2023, the Company only had operating leases.

For operating leases, right-of-use ("ROU") assets and lease liabilities are initially recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. The present values of future lease payments are discounted using the interest rate implicit in the lease if it is readily determinable. As most leases do not provide an implicit rate, the Company applies an incremental borrowing rate based on the information available at commencement date to determine the present value of future lease payments over the lease term. The Company benchmarked itself against other companies with similar credit ratings and of comparable quality to derive an incremental borrowing rate. Lease expense is recognized on a straight-line basis over the lease term in the consolidated statements of operations.

The Company elected to utilize the short-term lease exemption to exclude recognition of ROU assets and lease liabilities from the balance sheet for leases with an initial term of 12 months or less, with payments instead being expensed on a straight-line basis over the lease term. If a lease includes options to extend the lease term, the Company does not assume the option will be exercised in its initial lease term assessment unless there is reasonable certainty that the Company will renew based on an assessment of economic factors present as of the lease commencement date. The Company monitors its plans to renew its material lease each reporting period.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components include costs that do not provide a right-to-use a leased asset but instead provide a service such as maintenance costs. The Company has elected to account for the lease and non-lease components together as a single component for all classes of underlying assets. Variable costs associated with the lease, such as maintenance and utilities, are not included in the measurement of ROU assets and liabilities. Variable costs are expensed when the events determining the amount of variable consideration to be paid have occurred.

South Carolina Office Lease Agreement

On September 27, 2022, Old Catheter entered into a lease agreement for office space located in Fort Mill, South Carolina. The space is used for office and general use. The lease term began on October 1, 2022, is 38 months, and includes two months of free rent from the commencement date of the lease. The lease contains two distinct 36-month renewal periods, which require 180 days' notice of the Company's intention to exercise. As of December 31, 2024, the Company does not intend to exercise either of the two extension options. Total rent is $3,435 per month for the first ten months following the two months of free rent, with annual increases on the anniversary of the effective date.

New Jersey Office Lease Agreement

On December 7, 2022, Old Catheter entered into a lease agreement for office space located in Augusta, New Jersey. The space is used for office and general use. The lease term began on January 1, 2023 and is 24 months. The lease contains one 24-month renewal period, which requires 9 months' notice of the Company's intent to exercise. In March 2024, the Company notified the landlord of its intent to extend the lease for a 12-month period. In April 2024, a lease extension agreement was entered into extending the lease through December 31, 2025. Total rent is $1,207 per month through December 31, 2024, and $1,267 for the remaining term of the extended lease.

Park City Office Lease Agreement

On March 19, 2023, the Company entered into a lease agreement for office space located in Park City, Utah. The space is used for office and general use. The lease term began on May 1, 2023 and is 36 months. The lease contains one 36-month renewal period, which requires 180 days' notice of the Company's intention to exercise. As of December 31, 2024, the Company does not intend to exercise the extension option. Total rent is $3,200 per month for the first year with an annual increase of three percent per year on the anniversary of the effective date.

The following tables present supplemental balance sheet information related to operating leases for the years ended December 31, 2024 and 2023:

	For the Year Ended December 31,	
	2024	2023
Operating lease expense	$ 108	$ 94
Cash paid for leases	$ 104	$ 95

	For the Year Ended December 31,	
	2024	2023
Weighted average remaining lease term (in years) - operating leases	1.12	2.05
Weighted average discount rate - operating leases	8.58%	8.56%

Future minimum lease payments for all lease obligations for the following five fiscal years and thereafter are as follows (in thousands):

Years ending December 31:	Operating Leases
2025	$ 98
2026	14
Total minimum lease payments	112
Less effects of discounting	(1)
Present value of future minimum lease payments	$ 111

Operating lease right-of-use assets and lease liabilities were recorded in the consolidated balance sheets as follows:

	December 31,	
	2024	2023
Assets		
Operating lease right-of-use assets, net	$ 105	$ 179
Current portion of operating lease liabilities	$ 98	$ 91
Operating lease liabilities	13	97
Total lease liabilities	$ 111	$ 188

Note 12. Net Loss per Share

The Company's Series A Convertible Preferred Stock, of which no shares were outstanding as of December 31, 2024, and outstanding warrants to purchase common stock have participation rights to any dividends that may be declared in the future, such that they are participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to the participating securities since the holders have no contractual obligation to share in the losses of the Company.

Anti-dilutive common share equivalents excluded from the computation of diluted net loss per share at December 31, 2024, consisted of 1,265,601 shares of common stock issuable upon conversion of Series X Convertible Preferred Stock, 16,539,513 shares of common stock issuable upon exercise of outstanding warrants, and 95,605 shares of common stock issuable upon exercise of vested stock options. The weighted-average number of common shares outstanding as of December 31, 2024 includes the shares held in abeyance upon the exercise of certain existing warrants (see Note 13, Equity Offerings). In connection with the 2024 Warrant Inducement Offer, the Company agreed to issue the number of shares of common stock that would not cause a holder to exceed their beneficial ownership limitation and to hold the remaining balance of shares of common stock in abeyance. Accordingly, the Company held 3,096,00 shares of common stock in abeyance as of December 31, 2024 (the "Abeyance Shares"). The Abeyance Shares are evidenced through the holders' existing warrants, which are now deemed to be fully prepaid. Since the Abeyance Shares are issuable for no consideration and do not contain any other conditions that must be satisfied by the holder to ultimately receive such shares of common stock, the Abeyance Shares were included in the weighted-average number of common shares and excluded from the anti-dilutive number of warrants included above as of December 31, 2024.

Anti-dilutive common share equivalents excluded from the computation of diluted net loss per share at December 31, 2023, consisted of 286,125 shares of Series A Convertible Preferred Stock, 1,265,601 shares of Series X Convertible Preferred Stock, 1,104,214 warrants, and 21,465 stock options.

Net loss attributable to common stockholders consists of net loss adjusted for deemed dividends. The Company recorded a deemed dividend for the modification of existing warrants and issuance of new warrants (see Note 13, Equity Offerings) of $5.2 million and $0.8 million for the years ended December 31, 2024 and 2023, respectively.

Note 13. Equity Offerings

2023 Warrant Inducement Offer

On January 9, 2023, the Company reduced the exercise price of certain existing warrants (the "2023 Existing Warrants) held by an investor (the "Investor") with exercise prices ranging from $140.00 to $5,265 per share of common stock to $40.00 per share of common stock (the "2023 Warrant Repricing"). The 2023 Existing Warrants were exercisable for 33,161 shares of the Company's common stock. In connection with the 2023 Warrant Repricing, the Company entered into a Warrant Inducement Offer Letter with the Investor pursuant to which the Investor agreed to exercise the 2023 Existing Warrants at the reduced exercise price of $40.00 per share of common stock (the "2023 Warrant Inducement Offer"). The Company received approximately $1.3 million in gross proceeds. The Company paid placement agent aggregate cash fees plus other offering costs of approximately $0.2 million, resulting in net proceeds of $1.1 million. In consideration for exercising the 2023 Existing Warrants, the Company issued the Investor a new Series E common stock purchase warrant (the "Series E Warrant") to purchase 33,161 shares of common stock at an exercise price of $40.00 per share. The Series E Warrant is exercisable for five years from the date of stockholder approval. Exercise of the Series E Warrant in full was subject to approval of the Company's stockholders other than the Investor, which was obtained at a special meeting of the Company's stockholders held on March 21, 2023 (the "Stockholders' Meeting"). The incremental fair value of the repriced warrants amounted to $0.3 million and the fair value of Series E Warrants totaled $1.9 million. The relative fair value of such amounts was recorded to additional paid-in capital concurrent with the exercise of the 2023 Existing Warrants.

As a result of the 2023 Warrant Inducement Offer, the Company presents a deemed dividend for the modification of the 2023 Existing Warrants and issuance of the Series E Warrants of $0.8 million for the year ended December 31, 2023. The deemed dividend was included in net loss attributable to common stockholders in the calculation of net loss per share in the consolidated statements of operations.

The 2023 Existing Warrants were valued on the date of the 2023 Warrant Repricing using the Black-Scholes model based on the following assumptions:

	5/22/2020 Raise	8/3/2020 Raise	Series B	Series C
Risk-free interest rate	4.06%	4.06%	3.60%	3.66%
Volatility	135.35%	132.55%	115.42%	127.65%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Expected life (in years)	2.4	2.6	6.5	4.5

The Series E Warrants were also valued on the date of the 2023 Warrant Repricing at approximately $1.9 million using the Black-Scholes model based on the following assumptions:

Risk-free interest rate	3.66%
Volatility	124.07%
Expected dividend yield	0.00%
Expected life (in years)	5.0

Private Placement

On January 9, 2023, the Company entered into a Securities Purchase Agreement ("Securities Purchase Agreement") for a private placement ("Private Placement") with the Investor. Pursuant to the Securities Purchase Agreement, the Investor agreed to purchase, for an aggregate purchase price of approximately $8.0 million, (a) Class A Units at a price that was the lower of $3.00 per unit and 90% of the 5 day volume weighted average price of the Company's common stock immediately prior to obtainment of the approval of the Company's stockholders to convert the PIPE Preferred Stock and PIPE Warrants (as each are defined below), without adjusting such price for the reverse stock split, each consisting of one tenth of one share of common stock, one tenth of one Series F common stock purchase warrant ("Series F Warrant") and one tenth of one Series G common stock purchase warrant ("Series G Warrant", and together with the Series F Warrants, the "PIPE Warrants") and (b) Class B Units at a price of $1,000 per unit, each consisting of one share of a new series of the Company's preferred stock, designated as Series A Convertible Preferred Stock (the "PIPE Preferred Stock"), par value $0.0001, and one tenth of one Series F Warrant and one tenth of one Series G Warrant for each one-tenth of one share of the Company's common stock underlying the PIPE Preferred Stock (each share of which is convertible into a number of shares of the Company's common stock equal to $1,000 divided by the lower of $30.00 and 90% of the 5 day volume weighted average closing price, multiplied by ten in order to reflect the impact of the reverse stock split of the Company's common stock immediately prior to the obtainment of the approval of the Company's stockholders of the conversion of the PIPE Preferred Stock and PIPE Warrants, or the Preferred Conversion Rate). The closing under the Securities Purchase Agreement and the sale and issuance of the Class A Units and Class B Units (and the issuance of any underlying common stock) were approved at the Stockholders' Meeting. At the closing of the Private Placement, the Company issued 497,908 Class A Units for proceeds of approximately $0.9 million and 7,203 Class B Units for proceeds of approximately $7.1 million, which contained preferred shares that were convertible into up to 450,123 shares of common stock, as well as the issuance of warrants described below.

The PIPE Warrants, including Series F Warrants and Series G Warrants, were exercisable at an exercise price of $30.00 per share, subject to adjustments as provided under the terms of the PIPE Warrants. The PIPE Warrants were exercisable at any time on or after the closing date of the Private Placement until the expiration thereof, except that the PIPE Warrants could not be exercised if, after giving effect thereto, the purchaser would beneficially own more than 4.99%, or the Maximum Percentage, of the outstanding shares of common stock of the Company, which Maximum Percentage could be increased or decreased by the purchaser with written notice to the Company to any other percentage specified not in excess of 9.99%. The Series F Warrants had a term of two years from the date of stockholder approval, and the Series G Warrants had a term of six years from the date of stockholder approval. The Series F Warrants and Series G Warrants were approved at the Stockholders' Meeting.

The Series F Warrants and Series G Warrants were valued, in aggregate, at approximately $5.5 million using the Black-Scholes model based on the following assumptions:

	Series F	Series G
Risk-free interest rate	3.8%	3.4%
Volatility	80.0%	74.0%
Expected dividend yield	0.0%	0.0%
Expected life (in years)	2.0	6.0

The proceeds from the Securities Purchase Agreement were allocated to the equity instruments issued based on their relative fair values and recorded in additional paid-in capital.

Shares of PIPE Preferred Stock, the conversion of which was approved at the Stockholders' Meeting, were convertible into common stock at the option of the holder at the Preferred Conversion Rate, subject to certain ownership limitations as described below. The conversion price was subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

Subject to limited exceptions, holders of shares of PIPE Preferred Stock did not have the right to convert any portion of their Preferred Stock if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or up to 9.99% at the election of the holder) of the number of shares of the Company's common stock outstanding immediately after giving effect to its conversion.

Holders of PIPE Preferred Stock were entitled to receive dividends on shares of PIPE Preferred Stock equal, on an as-if-converted-to-common stock basis, and in the same form as dividends actually paid on shares of the common stock. Except as otherwise required by law, the PIPE Preferred Stock did not have voting rights.

The Company also entered into a registration rights agreement with the purchasers requiring the Company to register the resale of the shares of common stock, the shares issuable upon exercise of the Warrants and the shares issuable upon the conversion of the PIPE Preferred Stock.

Placement fees

In connection with offerings completed by the Company in 2022, (the "2022 Offerings"), the Company entered into an agreement with a placement agent that, subject to satisfaction of the requirements contained therein, called for a placement fee payable based on capital raised from certain investors for a definitive time following the expiration of the agreement. The accrued placement fee of approximately $1.4 million related to the 2022 Offerings is included in accrued expenses in the consolidated balance sheets as of December 31, 2024 and 2023. Additionally, the agreement called for the issuance of warrants with the following terms:

Number of shares	Exercise Price	Expiration
3,300	$ 312.50	5 years
3,100	$ 175.00	5 years

The warrants were valued on the date of the 2022 Offerings using the Black-Scholes model based on the following assumptions:

Value ($ in millions)	Expected Volatility	Risk-Free Interest Rate	Expected Dividend Yield	Expected Term (years)
$ 0.4	93.25%	1.81%	0%	5.0
$ 0.2	96.70%	2.87%	0%	5.0

September 2024 Public Offering

On September 3, 2024, in connection with the September Public Offering (see Note 1), the Company sold an aggregate of 805,900 Common Stock Units and 2,773,000 Pre-Funded Warrant Units at a public offering price of $1.00 per Common Stock Unit and $0.9999 per Pre-Funded Warrant Unit. The Company received gross proceeds of approximately $3.6 million less underwriting discounts and commissions of $1.0 million, resulting in net proceeds of $2.6 million.

Each Common Stock Unit consists of: (i) one share of the Company's Common Stock, (ii) a Series H Warrant to purchase one share of Common Stock at an exercise price of $1.00 per share that expires six months from the date of issuance, (iii) a Series I Warrant to purchase one share of Common Stock at an exercise price of $1.00 per share that expires eighteen months from the date of issuance, and (iv) a Series J Warrant to purchase one share of Common Stock at an exercise price of $1.00 per share that expires five years from the date of issuance.

Each Pre-Funded Warrant Unit consists of: (i) one Pre-Funded Warrant to purchase one share of Common Stock at an exercise price of $0.0001 per share with no expiration date, (ii) one Series H Warrant, (iii) one Series I Warrant (iv) and one Series J Warrant.

Pursuant to the Underwriting Agreement, the Company granted the Representative a 45-day Overallotment Option to purchase up to (i) 468,041 additional shares of Common Stock, (ii) 468,041 additional Series H Warrants, (iii) 468,041 additional Series I Warrants, and/or (iv) 468,041 additional Series J Warrants, solely to cover over-allotments. On August 30, 2024, the Underwriters partially exercised the Overallotment Option to purchase an additional 458,623 shares of Common Stock, 458,623 Series H Warrants, 458,623 Series I Warrants, and 458,623 Series J Warrants, or 458,623 Common Stock Units. The Common Stock Units issued through the exercise of the Overallotment Option are included in the 805,900 Common Stock Units noted above. The Overallotment Option expired on October 14, 2024.

Furthermore, at the closing date, the Company agreed to deliver to the Representative warrants to purchase an aggregate number of shares of Common Stock equal to 6% of the shares of Common Stock (i) issued in connection with the September 2024 Public Offering and (ii) issuable upon the exercise of the Pre-Funded Warrants. Therefore, the Company issued 214,734 warrants to the Representative and its designees (the “Representative Warrants”). The Representative Warrants are part of the underwriter costs and commissions incurred in connection with the September 2024 Public Offering. The Representative Warrants may be exercised to purchase one share of Common Stock at an exercise price of $1.55 per share and expire five years from the date of issuance.

Each Series H Warrant, Series I Warrant, Series J Warrant (collectively, the “Series Warrants”), and Pre-Funded Warrant is immediately exercisable. The exercise price of the Series Warrants and Pre-Funded Warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Company’s Common Stock. Subject to limited exceptions, a holder of the Series Warrants will not have the right to exercise any portion of its Series Warrants if the holder (together with such holder’s affiliates) would beneficially own a number of shares of common stock in excess of 4.99%, or in the case of certain holders 9.99%, of the shares of Common Stock then outstanding (the “Beneficial Ownership Limitation”). Similarly, a holder of the Pre-Funded Warrants has a Beneficial Ownership Limitation of 9.99%. At the holder’s option, the holder of the Series Warrants may increase the beneficial ownership limitation to 19.99% of the shares of Common Stock then outstanding, with any such increase becoming effective upon 61 days’ prior notice to the Company.

The Representative Warrants are exercisable six months after the effective date of the Registration Statement filed by the Company on August 29, 2024. The Representative Warrants further have a Beneficial Ownership Limitation of 4.99%, which may be increased to 9.99% of the shares of Common Stock then outstanding at the option of the Representative. Any increase in the Beneficial Ownership Limitation will become effective upon 61 days’ prior notice to the Company.

The Company assessed the Series Warrants, Pre-Funded Warrants, and Representative Warrants issued in connection with the September 2024 Public Offering (collectively, the “September 2024 Warrants”) and determined that they do not require liability classification pursuant to ASC 480. Furthermore, the September 2024 Warrants do not have any net cash settlement provisions that would preclude equity classification under ASC 815-40. Accordingly, the September 2024 Warrants were recorded to additional paid-in capital in the consolidated balance sheets.

2024 Warrant Inducement Offer

On October 25, 2024, the Company executed the 2024 Warrant Inducement Offer (see Note 1) with certain holders of the Company's existing warrants (Series E, Series F, Series G, Series H and Series I Warrants, collectively the "2024 Existing Warrants"). Pursuant to the terms of the 2024 Warrant Inducement Offer, the Company agreed to lower the exercise price per share of common stock for all holders of the 2024 Existing Warrants, including those that did not participate in the 2024 Warrant Inducement Offer. The 2024 Existing Warrants had exercise prices ranging from $1.00 to $40.00 per share of Common Stock. Following the closing of the 2024 Warrant Inducement Offer, the Holders immediately exercised an aggregate of (i) 33,160.8 Series E Warrants, (ii) 499,909.34 Series F Warrants, (iii) 499,909.34 Series G Warrants, (iv) 1,990,000 Series H Warrants, and (v) 2,325,000 Series I Warrants to purchase 5,347,981 shares of common stock at a reduced exercise price of $0.70 per share. The Company received aggregate gross proceeds of $3.7 million in cash, prior to deducting placement agent fees and offering expense of $0.4 million.

In consideration for the immediate exercise of the 2024 Existing Warrants for cash, the Company issued unregistered new Series K common stock purchase warrants ("Series K Warrants") to purchase up to 10,695,962 shares of common stock. The Series K Warrants have an exercise price of $0.70 per share of common stock, were not exercisable until stockholders approval was obtained ("Stockholder Approval"), and have a term of 5.5 years following Stockholder Approval. Stockholder Approval was obtained on January 13, 2025.

In connection with the closing, the Company issued Placement Agent Warrants to the Placement Agent to purchase up to 320,879 shares of common stock on the same terms as the Series K Warrants, except that the exercise price is $1.085 per share and the warrants are exercisable six months after the date of issuance.

As a result of the 2024 Warrant Inducement Offer, the Company recorded a deemed dividend for the modification of the 2024 Existing Warrants and issuance of the Series K Warrants of $5.2 million for the year ended December 31, 2024. The deemed dividend was included in net loss attributable to common stockholders in the calculation of net loss per share in the consolidated statements of operations.

Pursuant to the terms of the 2024 Warrant Inducement Offer, in the event that the exercise of the 2024 Existing Warrants would cause a holder to exceed the beneficial ownership limitations included therein, the Company would issue the number of shares of common stock that would not cause a holder to exceed such beneficial ownership limitations and hold the remaining balance of shares of common stock in abeyance. Accordingly, as of December 31, 2024, the Company held an aggregate of 3,096,000 shares of common stock in abeyance (the "Abeyance Shares"). The Abeyance Shares are evidenced through the holder's existing warrants, which are deemed to be prepaid. The Abeyance Shares will be held by the Company until the holder sends notice that the remaining balance of shares of common stock may be issued without surpassing the beneficial ownership limitations. Until such time, the Abeyance Shares are evidenced through the holder's existing warrants (September 2024 Prepaid Series H Warrants and September 2024 Prepaid Series I Warrants) and are included in the Company's table of outstanding warrants below.

Warrants

The following table presents the number of common stock warrants outstanding:

Warrants outstanding, December 31, 2023	1,104,217
Issued	24,741,275
Exercised	(6,209,979)
Expired	—
Warrants outstanding, December 31, 2024	19,635,513

As of December 31, 2024 and December 31, 2023, all warrants outstanding are recorded in additional paid-in capital in the consolidated balance sheets. The following table presents the number and type of common stock purchase warrants outstanding, their exercise price, and expiration dates as of December 31, 2024:

Warrant Type	Warrants Outstanding		Exercise Price	Expiration Date
May 2020 Warrants	1,275	$	5,625.00	5/20/2025
May 2020 Placement Agent Warrants	124	$	7,031.25	5/20/2025
August 2020 Warrants	1,943	$	4,375.00	8/3/2025
August 2020 Placement Agent Warrants	192	$	5,468.75	7/30/2025
August 2021 Pharos Banker Warrants	148	$	1,495.00	8/16/2026
February 2022 Series B Warrants	39,153	$	140.00	2/4/2029
July 2022 Series C Warrants	28,402	$	140.00	7/22/2027
September 2024 Series H Warrants	578,900	$	0.70	3/3/2025
September 2024 Prepaid Series H Warrants (1)	1,366,000	$	—	None
September 2024 Series I Warrants	1,078,900	$	0.70	3/3/2026
September 2024 Prepaid Series I Warrants (1)	1,730,000	$	—	None
September 2024 Series J Warrants	3,578,901	$	1.00	9/3/2029
September 2024 Representative Warrants	214,734	$	1.55	8/29/2029
October 2024 Series K Warrants	10,695,962	$	0.70	7/13/2030
October 2024 Placement Agent Warrants	320,879	$	1.09	4/25/2030
	19,635,513			

As of December 31, 2024, the warrants issued by the Company had a weighted average exercise price of $2.05.

(1) In calculating net loss per share, the Abeyance Shares were included in the weighted-average number of common shares and excluded from the anti-dilutive number of warrants excluded from the net loss per share calculation (see Note 12, Net Loss Per Share).

Note 14. Preferred Stock

Series X Convertible Preferred Stock

As described in Note 3, above, pursuant to the Merger Agreement, all Old Catheter common stock shares issued and outstanding and convertible promissory notes, representing an aggregate principal balance of $25.2 million, were converted into a right to receive 14,649.592 shares of a new class of the Company's preferred stock, designated Series X Convertible Preferred Stock.

Series X Convertible Preferred Stock has no voting rights prior to the conversion into common stock. While there are generally no voting rights of the Series X Convertible Preferred Stock, there are protective rights regarding the sales of the company, change of control, etc. Series X Preferred Stock may convert into common stock only if the Company's common stock has been delisted from the NYSE American or has been approved for initial listing on the NYSE American or another stock exchange, at a rate of 100 shares of common stock for each share of Series X Convertible Preferred Stock.

Other than dividends payable in shares of Common Stock, Holders of Series X Convertible Preferred Stock will be entitled to receive dividends on shares of Series X Convertible Preferred Stock equal, on an as-if-converted-to-common stock basis, and in the same form as dividends actually paid on shares of Common Stock.

Upon consummation of the Merger, each holder of Old Catheter convertible promissory notes received, in exchange for discharge of the principal of their Notes, a number of shares of the Company's Series X Convertible Preferred Stock representing a potential right to convert into the Company's common stock in an amount equal to one common share for each $32.00 of principal amount.

On March 21, 2023, the Company held the Stockholders' Meeting, at which the stockholders approved, among other things, the issuance of 199,359 shares of common stock upon the conversion of 1,993.581 of Series X Convertible Preferred Stock which were issued upon the closing of the Merger (see Note 3, Business Combination). On March 23, 2023, the Company issued 197,491 shares of common stock upon the conversion of 1,974.905 of Series X Convertible Preferred Stock. On October 24, 2023, the remaining 1,868 shares of common stock were issued upon the conversion of 18.676 shares of Series X Convertible Preferred Stock. The remaining 12,656 shares of Series X Convertible Preferred Stock are expected to remain outstanding until the Company meets the initial listing standards of the NYSE American or another national securities exchange or is delisted from the NYSE American, at which time they will convert into common stock.

Series A Convertible Preferred Stock

As described in Note 13, on January 9, 2023, the Company entered into a Securities Purchase Agreement for a Private Placement with the Investor. Pursuant to the Securities Purchase Agreement, shares of Series A Convertible Preferred Stock were issued, the conversion of which was approved at the Stockholders' Meeting. After the final conversion on July 23, 2024, the Company had no shares of Series A Convertible Preferred Stock outstanding.

The Series A Convertible Preferred Stock converted into common stock at the option of the holder at the Preferred Conversion Rate, subject to certain ownership limitations as described below. The conversion price was subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

Subject to limited exceptions, holders of shares of Series A Convertible Preferred Stock did not have the right to convert any portion of their Series A Convertible Preferred Stock if the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to its conversion.

Holders of Series A Convertible Preferred Stock were entitled to receive dividends on shares of Series A Convertible Preferred Stock equal, on an as-if-converted-to-common stock basis, and in the same form as dividends actually paid on shares of the common stock. Except as otherwise required by law, the Series A Convertible Preferred Stock did not have voting rights.

The Company also entered into a registration rights agreement with the purchasers requiring the Company to register for resale the shares of common stock issuable upon the conversion of the Series A Convertible Preferred Stock. Those shares of common stock were registered for resale on an effective registration statement on Form S-1.

The following conversions of Series A Convertible Preferred Stock occurred subsequent to the issuance and prior to December 31, 2024:

Date of Conversion	Series A Shares Converted	Common Shares Issued
July 5, 2023	1,750	109,355
July 24, 2023	875	54,678
January 24, 2024	875	54,678
July 1, 2024	1,303	81,423
July 11, 2024	1,000	62,489
July 22, 2024	1,000	62,500
July 23, 2024	400	25,000

Each share of Series A Convertible Preferred Stock was convertible into approximately 62.5 shares of common stock. The common stock was issued pursuant to the exemption contained in Section 3(a)(9) of the Securities Act of 1933, as amended (the "Act"), which applies to transactions in which a security is exchanged by an issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. The shares issued have been registered for resale on an effective registration statement on Form S-1.

As of December 31, 2024, the Company had no shares of Series A Convertible Preferred Stock outstanding.

Note 15. Stock-Based Compensation

2018 Equity Incentive Plan

In September 2018, the Company's board of directors adopted, and the Company's stockholders approved, the 2018 Equity Incentive Plan (the "2018 Plan"), which provided for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, performance-based stock awards and other forms of equity compensation to the Company's employees, directors and consultants. In July 2023, the 2018 Plan was replaced by the 2023 Equity Incentive Plan (the "2023 Plan"), as described below. As of July 2023, no additional awards could be made under the 2018 Plan and no shares of common stock were reserved for future issuance. As of December 31, 2024, there are 7 non-statutory stock options outstanding under the 2018 Plan. Three expire in June 2028 and four expire in January 2030.

2018 Employee Stock Purchase Plan

In September 2018, the Company's board of directors adopted the 2018 Employee Stock Purchase Plan (the "ESPP"), which permitted eligible employees to purchase the Company's common stock at a discount through payroll deductions during defined offering periods. Eligible employees could elect to withhold up to 15% of their base earnings to purchase shares of the Company's common stock at a price equal to 85% of the fair market value on the first day of the offering period or the purchase date, whichever was lower. The number of shares of common stock reserved for issuance under the ESPP automatically increased on January 1 of each fiscal year by the lesser of (1) 23 shares, (2) 1.25% of the total number of shares outstanding on December 31 of the preceding fiscal year, or (3) such other amount as the Company's board of directors may determine.

In April 2024, the Company formally terminated the ESPP. For the years ended December 31, 2024 and December 31, 2023, no cash was received from the exercise of purchase rights under the ESPP in each respective period.

As of December 31, 2024, the Company had issued 95 shares of common stock since inception of the ESPP, and no shares were reserved for future issuance.

As of December 31, 2023, the Company had issued 95 shares of common stock since inception of the ESPP, and 2 shares were reserved for future issuance.

Upon termination of the ESPP in April 2024, the reserved shares were released back to the authorized pool.

2020 Inducement Equity Incentive Plan

In March 2020, the Company adopted the 2020 Inducement Equity Incentive Plan (the "2020 Plan") for the purpose of attracting, retaining and incentivizing employees in furtherance of the Company's success. The 2020 Plan was adopted without stockholder approval pursuant to Rule 303A.08 of the New York Stock Exchange. The 2020 Plan is used to offer equity awards as material inducements for new employees to join the Company. Upon adoption of the 2020 Plan, 64 shares of common stock were reserved for the granting of inducement stock options, restricted stock awards, restricted stock units and other forms of equity awards. As of December 31, 2024 and December 31, 2023, 0 and 54 shares of common stock were reserved for future issuance under the 2020 Plan. In April 2024, the Company terminated the 2020 Plan at which time the reserved shares were released back to the authorized pool.

Stock options assumed in Merger (See Note 3, Business Combination)

At the closing of the Merger, each outstanding option to purchase Old Catheter common stock that had not previously been exercised prior to the closing of the Merger was assumed and converted into options to purchase 75,367 shares of the Company's common stock ("Replacement Options"). Additionally, no Old Catheter options were amended in connection with the Merger. All the Replacement Options vested in accordance with the original terms of the grants in place at the time of the Merger. As a result, $3.4 million of the purchase price consideration, which represented the estimated fair value of Old Catheter's assumed stock options, and $1.1 million of stock-based compensation expense, which represents the excess of the estimated fair value of the Replacement Options over the assumed Old Catheter stock options, were recognized upon the closing of the Merger.

2023 Equity Incentive Plan

In July 2023, the Company's stockholders approved the 2023 Plan as defined above, which provided for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, performance-based stock awards and other forms of equity compensation to the Company's employees, directors and consultants. Stock options granted under the 2023 Plan to employees and consultants generally will vest annually over a five-year period or as determined by the Board's Compensation Committee, while grants to non-employee directors generally vest quarterly over a three-year period. As of December 31, 2024 and December 31, 2023, 926,882 and 50,186 shares of common stock were reserved for issuance pursuant to future awards under the 2023 Plan. The number of shares available for issuance under the 2023 Plan also includes a quarterly increase commencing on September 1, 2023 by an amount equal to the lesser of (i) 10% of the number equal to the number of shares of common stock outstanding on the applicable adjustment date less the number of shares of common stock outstanding at the beginning of the fiscal quarter immediately preceding the adjustment date, but if such number is a negative number, then the increase will be zero; or (ii) such lesser number of shares as may be determined by the Board.

On January 8, 2024, the Compensation Committee (the "Committee") of the Board approved the issuance of a total of 28,500 non-qualified stock options under the 2023 Plan. During 2024, 7,500 of these non-qualified options were issued to non-employee directors that vest at 8 1/3% per quarter for 3 years with an exercise price of $4.00 and expiration date of January 8, 2034. The remaining 21,000 non-qualified options were issued to employees and consultants and vest at 20% per year for 5 years with an exercise price of $4.00 and expiration date of January 8, 2034.

On February 26, 2024, the Committee approved the issuance of a total of 15,000 incentive stock options under the 2023 Plan. All options were issued to employees and vest at 20% per year for 5 years with an exercise price of $4.20 and expiration date of February 26, 2034.

On April 24, 2024, the Committee approved the issuance of a total of 12,500 incentive stock options under the 2023 Plan. All options were issued to employees and vest at 20% per year for 5 years with an exercise price of $4.60 and expiration date of April 24, 2034.

On July 9, 2024, the Committee approved the issuance of a total of 10,000 incentive stock options under the 2023 Plan. All options were issued to employees and vest at 20% per year for 5 years with an exercise price of $3.50 and expiration date of July 9, 2034.

The options issued for the 2023 Plan for the year ended December 31, 2024 were valued at approximately $262 thousand using the Black-Scholes model based on the following assumptions on the date of issue:

	Non-Employee Director Options Issued January 8, 2024	Employee Options Issued January 8, 2024	Employee Options Issued February 26, 2024	Employee Options Issued April 24, 2024	Employee Options Issued July 9, 2024
Risk-free interest rate	4.01%	4.01%	4.28%	4.65%	4.30%
Volatility	175.36%	175.36%	178.14%	211.61%	214.61%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%
Expected life (in years)	6.5	6.5	6.5	6.5	6.5

The following is a summary of stock option activity for the options for the year ended December 31, 2024 (in thousands, except for weighted average price and remaining life):

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life	Aggregate Intrinsic Value
Outstanding at December 31, 2023	21,465	$ 64.71	6.38	$ —
Options exercised	—	—	—	—
Options granted	66,000	4.08	—	—
Cancelled/forfeited	(16,860)	4.49	—	—
Outstanding at December 31, 2024	70,605	$ 20.88	8.38	$ —
Vested and expected to vest at December 31, 2024	70,605	$ 20.88	8.38	$ —
Exercisable at December 31, 2024	18,352	$ 68.64	5.96	$ —

Non-Plan Options Issued

On April 24, 2024, the Board approved the issuance of a total of 25,000 Non-Plan Options as an employment incentive for the position of Chief Commercial Officer. The options were issued on May 1, 2024, the first day of employment and vest at 20% per year for 5 years with an exercise price of $5.321 and an expiration date of May 1, 2034.

The Non-Plan Options issued were valued at approximately $131 thousand using the Black-Scholes model based on the following assumptions on the date of issue:

	Non-Plan Options Issued May 1, 2024
Risk-free interest rate	4.63%
Volatility	211.61%
Expected dividend yield	0.00%
Expected life (in years)	6.5

The following is a summary of stock option activity for the Non-Plan options for the year ended December 31, 2024 (in thousands, except for weighted average price and remaining life):

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life	Aggregate Intrinsic Value
Outstanding at December 31, 2023	—	$ —	—	$ —
Options exercised	—	—	—	—
Options granted	25,000	5.32	—	—
Cancelled/forfeited	—	—	—	—
Outstanding at December 31, 2024	25,000	$ 5.32	9.33	$ —
Vested and expected to vest at December 31, 2024	25,000	$ 5.32	9.33	$ —
Exercisable at December 31, 2024	—	$ —	—	$ —

Restricted Stock Units

All restricted stock units have been forfeited or vested as of December 31, 2023.

Restricted Stock Awards

All restricted stock awards have been forfeited or vested as of December 31, 2023.

Stock-based compensation expense for the years ended December 31, 2024 and 2023 was $54 thousand and $1.2 million, respectively, in selling, general and administrative expenses in the consolidated statements of operations.

Total unrecognized estimated stock-based compensation expense by award type and the remaining weighted average recognition period over which such expense is expected to be recognized at December 31, 2024 was as follows:

	Unrecognized Expense (in thousands)	Remaining Weighted Average Recognition Period (in years)
Stock options (Non-Plan Options)	$ 113	4.3
Stock options (2023 Plan Options)	$ 178	
Restricted stock awards	$ —	—
Restricted stock units	$ —	—

Note 16. Income Taxes

A reconciliation of the differences between the U.S. statutory federal income tax rate and the effective tax rate as provided in the consolidated statements of operations is as follows:

	For the Year Ended December 31,	
	2024	2023
U.S. federal statutory rate	(21.0)%	(21.0)%
Section 382 NOL limitation	75.7%	—
Nondeductible expenses	0.1%	0.2%
State income taxes, net of federal benefits	33.8%	2.2%
Stock-based compensation	0.3%	6.4%
Royalty mark to market	3.5%	(2.1)%
Change in valuation allowance	(70.7)%	16.7%
Purchase accounting	—	(20.5)%
Goodwill impairment	—	18.1%
Other	1.6%	—
Effective tax rate	23.3%	0.0%

The federal and state income tax provision is summarized as follows (in thousands):

	For the Year Ended December 31,	
	2024	2023
Current		
Federal	$ —	$ —
State	—	—
	—	—
Deferred		
Federal	3,049	—
State	91	—
	3,141	—
Income tax expense	$ 3,141	$ —

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for tax purposes, and (b) operating losses and tax credit carryforwards.

The tax effects of significant components of the Company's deferred tax assets (liabilities) are as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 12,358	$ 24,829
Stock-based compensation	15	49
Capitalized research and development	896	1,201
Intangible assets	41	53
Operating lease liabilities	25	44
Accrued compensation	5	2
Other accruals	3	—
Fixed asset basis	3	—
R&D credits	—	589
Total gross deferred tax assets	13,346	26,767
Deferred tax liabilities:		
Fixed asset basis	—	(1)
Operating lease right-of-use assets	(24)	(42)
Intangible assets	(5,506)	(6,216)
Total gross deferred tax liabilities	(5,530)	(6,259)
Valuation allowance	(10,957)	(20,508)
Net deferred tax liabilities	$ (3,141)	$ —

At December 31, 2024, and December 31, 2023 the Company had available Federal Net Operating Loss (NOL) carryforwards of $104.3 million. For State purposes, such NOL carryforwards were $63.8 million. The net operating losses begin expiring in 2027. Use of these NOL carryforwards may be significantly limited under the tax rules regarding the use of losses following an ownership change under Internal Revenue Code ("IRC") Section 382. The Company experienced a change in control during 2023 and 2024. Accordingly, utilization of its respective consolidated and/or separately computed NOL's is subject to an annual limitation for federal tax purposes under IRC Section 382. Due to this change in control, the Company estimates that $46.2 million of $104.3 million federal NOL carryforward is effectively eliminated under IRC Section 382. Moreover, $61.2 million of its $63.8 million state NOL carry forward is also eliminated. As a result of these eliminations, the Company's federal and state NOLs were reduced to approximately $58.2 million and $2.6 million, respectively, before valuation allowance.

The valuation allowance relates to deferred tax assets for certain items that will be deductible for income tax purposes under very limited circumstances and for which the Company believes it is not more likely than not that it will realize the associated tax benefit. However, in the event that the Company determines that it would be able to realize more or less than the recorded amount of net deferred tax assets, an adjustment to the deferred tax asset valuation allowance would be recorded in the period such a determination is made. In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some portion of all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods), projected future taxable income, and tax planning strategies in making this assessment. Based upon the levels of historical taxable income, projections of future taxable income and the reversal of deferred tax liabilities over the periods in which the deferred tax assets are deductible, management believes it is more-likely-than-not that the Company will not realize the benefits of these deductible differences, net of the existing valuation allowance. The amount of deferred tax asset considered realizable, however, could change in the near term if estimates which require significant judgment of future taxable income during the carryforward period are increased or decreased. The valuation allowance decreased by $9.5 million from $20.5 million as of December 31, 2023 to $11.0 million as of December 31, 2024.

The Company recognizes interest and penalties relating to uncertain tax positions in income tax expense. No amounts were recorded in 2024 and 2023.

Effective January 1, 2023, repurchases of Company stock are subject to a nondeductible excise tax under the Inflation Reduction Act of 2022 equal to 1.0% of the fair market value of the shares repurchased, subject to certain limitations. There was no impact to the Company's financial condition or results of operations in 2023 and 2024 as a result of the excise tax.

The Company files income tax returns as prescribed by tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal, state and local jurisdictions where applicable based on the statute of limitations that apply in each jurisdiction. The Company has no open income tax audits with any taxing authority as of December 31, 2024. The Company is still subject to income tax examinations by U.S. federal and state tax authorities for the years 2021 through 2023. However, to the extent allowed by law, the tax authorities may have the right to examine prior periods where net operating losses were generated and carried forward, and make adjustments up to the amount of the net operating loss carryforward amount.

Note 17. Commitments and Contingencies

In the normal course of business, the Company is at times subject to pending and threatened legal actions. In management's opinion, any potential loss resulting from the resolution of these matters will not have a material effect on the results of operations, financial position or cash flows of the Company.

As of December 31, 2024, the Company had no outstanding litigation.

Note 18. Employee Benefit Plan

In January 2019, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code ("401(k) Plan"). Under the terms of the 401(k) Plan, all full-time employees were eligible to make voluntary contributions as a percentage or defined amount of compensation. The Company made matching contributions based on 100% of each employee's contribution up to 3% and 50% of contributions between 3% and 5%, with the match-eligible contribution limited to 4% of the employee's eligible compensation. The Company cancelled the 401(k) Plan effective March 10, 2023 and distributed all assets held by the 401(k) Plan to the participants. The Company had no expenses related to the matching contributions for the years ended December 31, 2024 and 2023.

Note 19. Related Parties

Prior to the Merger, David A. Jenkins, the Company's current Executive Chairman of the Board and Chief Executive Officer, and Old Catheter's Chairman of the Board of Directors, and his affiliates held approximately $25.1 million of Old Catheter's Convertible Promissory Notes, or the Notes, that were converted into 7,856.251 shares of Series X Convertible Preferred Stock in connection with the Merger (see Note 3, Business Combination, and Note 14, Preferred Stock). In consideration for forgiving the interest accrued but remaining unpaid under the Notes in an aggregate amount of approximately $13.9 million, Mr. Jenkins and his affiliates also received royalty rights equal to approximately 12% of the net sales, if any, of LockeT, commencing upon the first commercial sale and through December 31, 2035. The Company entered into an additional royalty agreement for the LockeT device with Auston Locke, who is the son of Robert Locke, VP of Product Development. Under this agreement, the Company will pay a 5% royalty rate on net sales up to $1 million in cumulative royalties. If a patent is obtained, the royalty rate will be 2% of net sales until the Company has paid a total of $10 million in cumulative royalties. Refer to Note 2, Summary of Significant Accounting Policies and Note 10, Royalties Payable for additional information over the royalties payable due to these related parties.

In addition to the shares described above that were issued in connection with the Notes, Mr. Jenkins and his affiliates received 1,325.838 shares of Series X Convertible Preferred Stock in the Merger, and Mr. Jenkins' adult children received 1,284.344 shares of Series X Convertible Preferred Stock in the Merger, all in exchange for their equity interests in Old Catheter in accordance with the Merger exchange ratio.

In connection with the Merger (see Note 3, Business Combination), the Company assumed $1.4 million of accrued expenses and advances, of which $1.1 million was due to Mr. Jenkins and was paid on January 10, 2023.

Mr. Jenkins' daughter, the Company's non-executive Chief Operating Officer, received options to purchase 14,416 shares of the Company's common stock upon the closing of the Merger in exchange for her options to purchase shares of Old Catheter common stock, converted based on the exchange ratio in the Merger. Of the total options to purchase 14,416 shares of the Company's common stock, 14,081 options have an exercise price of $5.90 per share, and the remaining 335 options have an exercise price of $20.20 per share.

Following stockholder approval on March 21, 2023, the Company issued 99,182 shares of common stock to Mr. Jenkins and affiliates upon conversion of 991.828 shares of Series X Convertible Preferred Stock, and 23,532 shares of common stock to his adult children upon conversion of 235.320 shares of Series X Convertible Preferred Stock.

On May 1, 2024, Marie-Claude Jacques, the Company's Chief Commercial Officer, received a non-plan option to purchase 25,000 shares of the Company's common stock. The options have an exercise price of $5.321 per share, vest at 20% per year for 5 years and expire in May 2034.

During the year ended December 31, 2024, the Company entered into various short-term promissory notes with various related parties (the "Related Party Notes"). These Related Party Notes had a maturity date of August 30, 2024 and interest rates of 8% per annum. On August 23, 2024, the Notes were amended to extend the maturity date to January 31, 2026 and increase the interest rate to 12% per annum effective August 31, 2024. See Note 9, Notes Payable for further information.

The related parties and the amounts owed to each related party are summarized in the following table (in thousands):

Related Party	Issuance Date	Principal Amount	Interest Paid	Interest Accrued
David Jenkins	5/30/2024	$ 500	$ 10	$ 20
FatBoy Capital	6/25/2024	$ 150	$ 2	$ 6
FatBoy Capital	7/1/2024	$ 250	$ 4	$ 10
FatBoy Capital	7/18/2024	$ 100	$ 1	$ 4
Jenkins Family Charitable Institute	7/25/2024	$ 500	$ 4	$ 21

On September 3, 2024, the Jenkins Family Charitable Institute also invested approximately $500,000 in the Company's public offering and received 265,000 shares of common stock; 235,000 pre funded warrants with an exercise price of $0.0001 and no expiration date; 500,000 Series H Warrants with an exercise price of $1.00 per share that expire on March 3, 2025; 500,000 Series I Warrants with an exercise price of $1.00 per share that expire on March 3, 2026; and 500,000 Series J Warrants with an exercise price of $1.00 per share that expire on September 3, 2029.

On October 28, 2024, the Jenkins Family Charitable Institute exercised all 235,000 pre funded warrants and received 235,000 shares of common stock of the Company. On December 31, 2024, the Jenkins Family Charitable Institute distributed 450,000 Series J warrants to its trustee and two advisors, who are daughters of Mr. Jenkins.

Note 20. Subsequent Events

Issuance of Common Stock

In connection with the October 2024 Warrant Inducement Offer, shares were held in abeyance in the event that the exercise of the 2024 Existing Warrants would have otherwise caused a holder to exceed the beneficial ownership limitations set forth in the 2024 Existing Warrant. These Abeyance Shares are held as Pre-Funded Warrants until notice is received from the holder that the balance, or portion thereof, may be issued in compliance with the beneficial ownership limitations. On January 3, 2025, the Company released and issued 939,000 Abeyance Shares.

Amendment to the Amended and Restated Certificate of Incorporation

On January 13, 2025, at the Special Meeting of Stockholders of the Company, the stockholders approved an amendment to the Amended and Restated Certificate of Incorporation of the Company (the "Amendment") which included an increase in the authorized capital stock to 70 million shares, consisting of 60 million shares of common stock and 10 million shares of preferred stock.

Series K Warrants

On January 13, 2025, at the Special Meeting of Stockholders of the Company, the stockholders approved the issuance of up to 10,695,962 shares of the Company's common outstanding stock, upon the exercise of the Series K Warrants. See Note 13, Equity Offerings for additional information over the Series K Warrants issued in connection with the October 2024 Warrant Inducement Offer.

2023 Equity Incentive Plan

On January 13, 2025, at the Special Meeting of Stockholders of the Company, the stockholders of the Company approved an additional 1.5 million shares of common stock for issuance pursuant to the Company's 2023 Equity Incentive Plan.

On January 29, 2025, the Board approved the issuance of options to purchase a total of 1,627,500 shares of common stock to employees, consultants and non-employee directors with various vesting provisions, an exercise price of $0.42 per share and expiration date of January 29, 2035. Included in the option issuance was a grant of 450,000 shares to Mr. Jenkins, the Company's Executive Chairman and Chief Executive Officer, a grant of 50,000 shares to Mr. Jenkins' daughter, the Company's non-executive Chief Operating Officer, and a grant of 250,000 options to Marie-Claude Jacques, Chief Commercial Officer.

On January 31, 2025, the Board approved a restricted stock grant to a consultant of the Company pursuant to the Company's 2023 Equity Incentive Plan. The grant calls for the issuance of 100,000 shares of common stock of the Company through June 16, 2025.

Non-Plan Options

On January 3, 2025, the Board approved, as an inducement grant, the issuance of 500,000 non-plan options to the Chief Financial Officer of the Company to vest monthly over 3 years with an exercise price of $0.53 per share and expiration date of January 6, 2035.

PeriKard Acquisition

On January 14, 2025, the Company entered into a Membership Interest Purchase Agreement ("the Agreement") with Cardiofront, LLC ("Seller") to purchase the issued and outstanding membership interests of PeriKard, LLC, a wholly-owned subsidiary of Seller. The primary purpose was to purchase patented technology for commercialization within the broader cardiac treatment/electrophysiology industry. Pursuant to the Agreement, the Company issued 275,000 shares of its common stock to the Seller in exchange for 100% of the membership interests of PeriKard, LLC ("Acquisition"). Additional future royalty cash payments may be due to the Seller equal

to 10% of aggregate future net sales activity of PeriKard's pericardial access kits, to the extent the product is successfully commercialized, for five years from the acquisition's closing date. This transaction closed on January 24, 2025.

The accounting for the Acquisition is incomplete due to the proximity of the closing date of the Acquisition to the date of this filing. As a result, the Company is unable to disclose certain information including the major classes of assets acquired and liabilities assumed, nor provisional fair value estimates of the identifiable net assets acquired. Due to its insignificant size relative to the Company, the Company does not expect to provide supplemental pro forma financial information of the combined entity for the current and prior reporting periods. The Company will recognize and provide additional disclosures regarding the Acquisition within its first quarter 2025 Quarterly Report on Form 10-Q.

Formation of New Subsidiary

On February 17, 2025, the Company incorporated Cardionomix, Inc. in Nevada. Cardionomix, Inc. currently holds no assets and is inactive.

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

FORM 10-K/A
(Amendment No. 1)

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

For the Fiscal Year Ended December 31, 2024

OR

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

For the Transition Period From to
Commission file number: 001-38677

Catheter Precision, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**38-3661826**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1670 Highway 160 West, Suite 205 Fort Mill, South Carolina	**29708**
(Address of principal executive offices)	**(Zip Code)**

(973) 691-2000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of the exchange on which registered**
Common Stock, $0.0001 par value	**VTAK**	**NYSE American**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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.

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 Exchange Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of common stock on June 30, 2024 as reported by the NYSE American on such date was approximately $3.9 million. Shares of the registrant's common stock held by each executive officer, director and other persons who may be deemed an affiliate of the registrant have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 17, 2025, the registrant had 9,268,632 shares of common stock, par value $0.0001, outstanding.

Documents Incorporated by Reference

None.

EXPLANATORY NOTE

This Amendment No. 1 (this "Amendment") amends the Annual Report on Form 10-K for the year ended December 31, 2024 of Catheter Precision, Inc. (the "Company"), filed with the Securities and Exchange Commission (the "SEC") on March 31, 2025 (the "Original Form 10-K"). The purpose of this Amendment is to amend Part III, Item 13 of the Original Form 10-K to include information previously omitted from the Original Form 10-K in reliance on General Instruction G(3) to Form 10-K. Accordingly, Part III, Item 13 of the Original Form 10-K is hereby amended and restated as set forth below. The information included in the Form 10-K as required by Part III of Form 10-K is more limited than what is required to be included in the definitive proxy statement to be filed in connection with our annual meeting of stockholders. Accordingly, the definitive proxy statement to be filed at a later date will include additional information not required by Part III of Form 10-K.

The reference on the cover page of the Original Form 10-K to the incorporation by reference of our definitive proxy statement into Part III of the Original Form 10-K is hereby deleted.

In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), new certifications by our principal executive officer and principal financial officer are filed as exhibits to this Amendment under Item 15 of Part IV hereof. Because no financial statements have been included in this Amendment and this Amendment does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 3,4 and 5 of the certifications have been omitted.

Except as stated herein, the Amendment does not reflect events occurring after the filing of the Original Form 10-K with the SEC on March 31, 2025 and no attempt has been made in this Amendment to modify or update other disclosures as presented in the Original Form 10-K.

PART III

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Person Transactions

Pursuant to SEC rules, a "transaction" with a related party includes any transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which the Company was or is a participant and the related person had or will have a direct or indirect material interest where the amount involved exceeds the lesser of $120,000 or one percent of the average of the Company's total assets at year-end for the last two completed fiscal years. Accordingly, the applicable threshold for us is $120,000.

Since January 1, 2023, we have engaged in the following transactions in which our executive officers, directors, promoters or beneficial owners of more than 5% of our common stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under "*Executive Compensation*." We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Employment and Related Agreements

We currently do not have written employment agreements with our executive officers.

In January 2023, we entered into an oral employment agreement with Missiaen Huck, Mr. David Jenkins' adult daughter. Mr. Jenkins is our Chief Executive Officer and Chairman of the Board. Ms. Huck serves as the non-executive chief operating officer of Catheter and receives annual compensation of $165,000. In January 2024, Ms. Huck received a grant of options to purchase 2,500 shares of Company common stock which have an exercise price of $4.00 per share, vest ratably over five years and have a term of 10 years. In January 2025, Ms. Huck received a grant of options to purchase 50,000 shares of Company common stock which have an exercise price of $0.42 per share, vest ratably over 4 years, with the first tranche vesting on the issue date and have a term of 10 years. As noted below, Ms. Huck also holds options to purchase an additional 14,081 shares of Company common stock which were originally issued by the private company Catheter Precision, Inc. that we acquired in January 2023 ("Old Catheter") and assumed in the merger (the "Merger") in which we acquired Old Catheter.

Merger-Related Transactions

Mr. Jenkins and his affiliates held approximately $25.1 million of Old Catheter's Convertible Promissory Notes, or the Notes, that were converted in the Merger into 7,856.251 shares of Series X Preferred Stock. Upon consummation of the Merger, each such Noteholder received, in exchange for discharge of the principal of his or its Notes, a number of shares of our Series X Preferred Stock representing a potential right to convert into our common stock in an amount equal to one common share for each $32.00 of principal amount. In consideration for forgiving the interest accrued but remaining unpaid under the Notes in an aggregate amount of approximately $13.9 million, Mr. Jenkins and his affiliates also received royalties equal to 11.77% of the net sales, if any, of the LockeT device, commencing upon the first commercial sale and through December 31, 2035.

In addition to the shares described above that were issued in connection with the Notes, Mr. Jenkins and his affiliates received 1,325.838 shares of Series X Preferred Stock in the Merger, and Mr. Jenkins' adult children received 1,284.344 shares of Series X Preferred Stock in the merger, all in exchange for their equity interests in Old Catheter in accordance with the merger exchange ratio. Additional, noninterest-bearing demand loans totaling $1,075,000 from David Jenkins to Old Catheter were repaid by the Company at or shortly after the closing of the merger.

Mr. Jenkins' daughter, Missiaen Huck, received options to purchase 14,416 shares of the Company's common stock upon the closing of the Merger in exchange for her options to purchase shares of Catheter common stock, converted based on the exchange ratio in the merger. Of the total options to purchase 14,416 shares of the Company's common stock, 14,081 options have an exercise price of $5.90 per share, and the remaining 335 options expired in March 2025.

Ms. Margrit Thomassen, our Secretary and previous Interim Chief Financial Officer, received options to purchase 1,676 shares of the Company's common stock upon the closing of the Merger in exchange for her options to purchase shares of Catheter common stock, converted based on the exchange ratio in the Merger. The options have an exercise price of $5.90 per share.

Following stockholder approval on March 21, 2023, we issued 99,182 shares of common stock to Mr. Jenkins and affiliates upon conversion of 991.828 shares of Series X Preferred Stock, and 23,532 shares of common stock to his adult children upon conversion of 235.320 shares of Series X Preferred Stock.

Warrant Inducement Offer

On January 9, 2023, the Company reduced the exercise price of certain existing warrants (the "Existing Warrants"), exercisable for 33,160 shares of the Company's common stock held by Armistice Capital Master Fund Ltd. ("Armistice"), the beneficial owner of in excess of 5% of our common stock, with exercise prices ranging from $140.00 to $5,265.00 per share to $40.00 per share (the "2023 Warrant Repricing"). In connection with the 2023 Warrant Repricing, the Company entered into a warrant inducement offer letter (the "2023 Inducement Letter") with Armistice pursuant to which it would exercise up to all of the 33,160 Existing Warrants (the "Inducement Offer"). In consideration for exercising the Existing Warrants pursuant to the terms of the 2023 Inducement Letter, the Company received approximately $1.3 million in gross proceeds. The Company paid the placement agent aggregate cash fees of approximately $0.2 million related to the Inducement Offer which represented 8.0% of the gross proceeds received from the Inducement Offer plus other offering costs resulting in net proceeds to the Company of $1.1 million. In consideration for exercising the Existing Warrants pursuant to the terms of the 2023 Inducement Letter, the Company issued Armistice a new Series E common stock purchase warrant, or Series E Warrant (the "Series E Warrant"), to purchase 33,160 shares of common stock at an exercise price of $40.00 per share. The Series E Warrant was exercisable for five years from the date of stockholder approval. Exercise of the Series E Warrant in full was subject to approval of the Company's stockholders other than Armistice which was obtained at the stockholders' meeting held on March 21, 2023 (the "Stockholders' Meeting"). The Series E Warrant was exercised in October 2024 as part of the October 2024 Warrant Inducement Offer described below. No Series E Warrants remain outstanding.

Private Placement

On January 9, 2023, the Company entered into a Securities Purchase Agreement ("Securities Purchase Agreement") for a private placement ("Private Placement") with Armistice. Pursuant to the Securities Purchase Agreement, Armistice agreed to purchase, for an aggregate purchase price of approximately $8.0 million, (a) Class A units at a price that was the lower of $3.00 per unit and 90% of the 5 day volume weighted average price of the Company's common stock immediately prior to obtainment of the approval of the Company's stockholders of conversion of the PIPE Preferred Stock and PIPE Warrants (as each are defined below), each consisting of one share of common stock, one Series F common stock purchase warrant, or Series F Warrant, and one Series G common stock purchase warrant, or Series G Warrant, and together with the Series F Warrants (the "PIPE Warrants") and (b) Class B units at a price of $1,000 per unit, each consisting of one share of a new series of the Company's preferred stock, designated as Series A Convertible Preferred Stock (the "PIPE Preferred Stock"), par value $0.0001, and one Series F Warrant and one Series G Warrant for each share of the Company's common stock underlying the PIPE Preferred Stock (each share of which is convertible into a number of shares of the Company's common stock equal to $1,000 divided by the lower of $30.00 and 90% of the 5 day volume weighted average closing price of the Company's common stock immediately prior to the obtainment of the approval of the Company's stockholders of conversion of the PIPE Preferred Stock and PIPE Warrants, or the Preferred Conversion Rate). The closing under the Securities Purchase Agreement and the sale and issuance of the Class A units and Class B units (and the issuance of any underlying common stock) were approved at the Stockholders' Meeting. At the closing of the Private Placement, the Company issued 49,790 Class A units for proceeds of approximately $0.9 million and 7,203 Class B units for proceeds of approximately $7.1 million, the preferred stock underlying which is convertible into up to 450,106 shares of common stock, as well as the issuance of warrants described below.

The PIPE Warrants, including Series F warrants and Series G warrants, were exercisable at an exercise price of $30.00 per share, subject to adjustments as provided under the terms of the PIPE Warrants. The PIPE Warrants were exercisable at any time on or after the closing date of the Private Placement until the expiration thereof, except that the PIPE Warrants could not be exercised if, after giving effect thereto, the purchaser would beneficially own more than 4.99%, or the Maximum Percentage, of the outstanding shares of common stock of the Company, which Maximum Percentage could be increased or decreased by the purchaser with written notice to the Company to any other percentage specified not in excess of 9.99%. The Series F Warrants had a term of two years from the date of stockholder approval, and the Series G Warrants had a term of six years from the date of stockholder approval. The Series F Warrants and Series G Warrants were approved at the Stockholders' Meeting. The Series F Warrants and Series G Warrants were exercised in October 2024 as part of the October 2024 Warrant Inducement Offer. No Series F Warrants or Series G Warrants remain outstanding.

September 2024 Public Offering

On September 3, 2024 the Company completed a public offering of its securities and sold an aggregate of (i) 805,900 Common Stock Units and (ii) 2,773,000 Pre-funded Units at a public offering price of $1.00 per Common Stock Unit and $0.9999 per Pre-Funded Warrant Unit. The Company collected gross proceeds of approximately $3.6 million. Each Common Stock Unit consists of (i) one share of the Company's Common Stock, (ii) a Series H Warrant to purchase one share of Common Stock at an exercise price of $1.00 per share that expires six months from the date of issuance, (iii) a Series I Warrant to purchase one share of Common Stock at an exercise price of $1.00 per share that expires eighteen months from the date of issuance, and (iv) a Series J Warrant to purchase one share of Common Stock at an exercise price of $1.00 per share that expires five years from the date of issuance. Each Pre-Funded Warrant Unit consists of (i) one Pre-Funded Warrant to purchase one share of Common Stock at an exercise price of $0.0001 per share with no expiration date, (ii) one Series H Warrant, (iii) one Series I Warrant and (iv) one Series J Warrant.

The Company issued 214,734 warrants to the Underwriter and its designees as part of the underwriter costs and commissions in connection with the September 2024 Public Offering. The warrants may be exercised to purchase one share of Common Stock at an exercise price of $1.55 per share and expire five years from the date of issuance. Armistice purchased (i) 132,000 Common Stock Units and (ii) 1,368,000 Pre-funded Units in the public offering for an aggregate purchase price of $1.5 million.

2024 Warrant Inducement Offer

On October 25, 2024, The Company executed the 2024 Warrant Inducement Offer with certain holders of the Company's existing Series E, Series F, Series G, Series H and Series I Warrants, collectively, the "2024 Existing Warrants". The 2024 Existing Warrants had exercise prices ranging from $1.00 to $40.00 per share of Common Stock. Following the closing of the 2024 Warrant Inducement Offer, the Holders immediately exercised an aggregate of (i) 33,160.8 Series E Warrants, (ii) 499,909.34 Series F Warrants, (iii) 499,909.34 Series G Warrants, (iv) 1,990,000 Series H Warrants, and (v) 2,325,000 Series I Warrants to purchase 5,347,981 shares of common stock at a reduced price of $0.70 per share. The Company received aggregate gross proceeds of $3.7 million in cash.

In consideration of the immediate exercise of the 2024 Existing Warrants for cash, the Company issued unregistered new Series K common stock purchase warrants ("Series K Warrants") to purchase up to 10,695,962 shares of common stock. The Series K Warrants have an exercise price of $0.70 per share of common stock, became exercisable on January 13, 2025, when stockholder approval was received at the special meeting of stockholders, and have a term of 5.5 years following stockholder approval.

Pursuant to the 2024 Warrant Inducement Offer, Armistice exercised 33,161 Series E Warrants, 499,910 Series F Warrants, 499,910 Series G Warrants, 1,500,000 Series H Warrants, and 1,500,000 Series I Warrants for an aggregate exercise price of $2.8 million, and it received 8,065,962 Series K Warrants. Of the 4,032,981 Warrants exercised by Armistice 500,000 shares of common stock were issued and 3,532,981 shares remained subject to prefunded Warrants due to the application of beneficial ownership blockers.

Although it did not participate in the 2024 Warrant Inducement Offer, 500,000 Series H Warrants and 500,0000 Series I Warrants with exercise prices of $1.00 per share owned by the Jenkins Family Charitable Institute, which is the beneficial owner of in excess of 5% of our outstanding common stock and whose trustee is the adult daughter of our CEO David Jenkins, were repriced in the 2024 Warrant Inducement Offer to an exercise price of $0.70 per share.

Issuance of Securities upon Conversion of Series A Preferred

The following conversions of Series A Convertible Preferred Stock by Armistice occurred through December 31, 2024. Each share of Series A Convertible Preferred Stock was convertible into approximately 62.5 shares of common stock. As of December 31, 2024 there were no shares of Series A Convertible Preferred Stock outstanding.

Date of Conversion	Series A Shares Converted	Common Shares Issued
July 5, 2023	1,750	109,355
July 24, 2023	875	54,678
January 24, 2024	875	54,678
July 1, 2024	1,303	81,423
July 11, 2024	1,000	62,489
July 22, 2024	1,000	62,500
July 23, 2024	400	25,000

Issuance of Securities upon Exercise of Prefunded Warrants

The following exercises of Prefunded Warrants by Armistice occurred through April 11, 2025:

Date of Exercise	Prefunded Warrants Exercised	Common Shares Issued
October 25, 2024	666,981	666,981
January 3, 2025	709,000	709,000

The Prefunded Warrants have an exercise price of $0 per share. As of April, 11, 2025, Armistice owns 2,157,000 outstanding Prefunded Warrants.

Waiver of Beneficial Ownership Blocker and Exercise of Prefunded Warrants

In October 2025, the Audit Committee of the Board of Directors authorized the Company to waive the 9.99% beneficial blocker that prohibited the Jenkins Family Charitable Institute from exercising 235,0000 Prefunded Warrants that it had purchased in the Company's September 2025 public offering. The Company granted this waiver, and the Jenkins Family Charitable Institute exercised these Prefunded Warrants in October 2025. The exercise price of the Prefunded Warrants was $0.001 per share.

Related Party Loans

On May 30, 2024, David A. Jenkins, Executive Chair and Chief Executive Officer, loaned $500,000 to the Company in exchange for a promissory note. The note had a maturity date of August 30, 2024, and bore interest at the rate of 8% per annum.

On June 25, 2024, FatBoy Capital, L.P. ("FatBoy"), an entity controlled by David A. Jenkins, loaned $150,000 to the Company in exchange for a promissory note. The note had a maturity date of August 30, 2024, and bore interest at the rate of 8% per annum.

On July 1, 2024, FatBoy loaned an additional $250,000 to the Company in exchange for a promissory note. The note had a maturity date of August 30, 2024, and bore interest at the rate of 8% per annum.

On July 18, 2024, FatBoy loaned an additional $100,000 to the Company in exchange for a promissory note. The note had a maturity date of August 30, 2024, and bore interest at the rate of 8% per annum.

On July 25, 2024, the Jenkins Family Charitable Institute loaned $500,000 to the Company in exchange for a promissory note. The note had a maturity date of August 30, 2024, and bore interest at the rate of 8% per annum.

On August 23, 2024, the Company amended each of its currently outstanding 8% Short Term Promissory Notes described above to:

- extend the Maturity Date to January 31, 2026,
- increase the Interest Rate to 12% from and after August 31, 2024; and
- provide that interest accrued through August 30, 2024, was due and payable as of such date.

The amendments were each memorialized by a First Amendment to 8% Short Term Promissory Note(s) entered into between the Company and the Holder of the relevant note.

No principal payments have been made on any of the above-referenced notes, and their principal balances remain unchanged since the dates of issuance. Accrued interest of $10,222 to Mr. Jenkins, $6,511 to FatBoy and $4,111 to the Jenkins Family Charitable Institute was paid on August 30, 2024. All accrued interest subsequent to that date will be due on January 31, 2026. No interest is paid on unpaid accrued interest. Mr. Jenkins is the sole manager of the managing member of FatBoy. Mr. Jenkins and members of his immediate family have a 100% economic interest in FatBoy.

Proposed Acquisition of Certain Assets of Cardionomic, Inc.

In February 2025, we formed our subsidiary Cardionomix, Inc., a Nevada Corporation ("Cardionomix"), in order to pursue the possible acquisition of certain assets of Cardionomic, Inc., a Delaware corporation, which has ceased operations. We issued 82% of the common stock of Cardionomix to us, 5% to David Jenkins, 7% to FatBoy and 6% to certain business associates of Mr. Jenkins. These minority interests were issued to compensate these persons for bringing this business opportunity to the Company.

On April 22, 2025, we and Cardionomix entered into an asset purchase agreement with Cardionomic (assignment for the benefit of creditors), LLC, a California limited liability company (the "Seller"), in its sole and limited capacity as assignee for the benefit of creditors of Cardionomic, Inc., a Delaware corporation (the "Assignor"), pursuant to which Cardionomix agreed to purchase the Assignor's assets related to its late-stage treatment in development for acute decompensated heart failure (the "Purchased Assets"). At the closing of the transaction, the Purchased Assets will be acquired on an "AS IS" and "WHERE IS" basis, with limited representations from the Seller, in exchange for the issuance by us of 1,000,000 shares of restricted common stock and the issuance by Cardionomix of a promissory note in the amount of $1.5 million, with simple interest accruing at 4% per annum and no interest or principal payable until the due date, which will be three years from the date of issuance of the note.

Following the closing of the proposed acquisition, Cardionomix will have no significant assets other than the Purchased Assets. Accordingly, it will need to raise funds in order to develop the Purchased Assets. We have begun discussions with potential investors, but there can be no guarantee that we will be able to raise sufficient funds for this purpose on a timely basis or at all. Any such financing is likely to entail the issuance of additional securities by Cardionomix to such investors, which securities are also likely to provide certain corporate governance rights. Such an issuance is expected to reduce the Company's ownership interest in Cardionomix, although it is expected to remain a majority owned consolidated entity. The information set forth in this Annual Report on Form 10-K is not an offer to sell or exchange, or solicitation of an offer to buy, any securities.

Indemnification of Officers and Directors

We have historically entered into indemnification agreements with directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws, and we may also do so in the future. The indemnification agreements and our amended and restated certificate of incorporation and amended and restated bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Director Independence

Our common stock is listed on the NYSE American. Under the rules of the NYSE American, independent directors must comprise a majority of a listed company's board of directors within a specified period of the completion of such company's initial public offering. In addition, the rules of the NYSE American require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees be independent. Under the rules of the NYSE American, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered independent for purposes of Rule 10A-3 under the Securities Exchange Act of 1934, as amended, and under the rules of NYSE American, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries or controlling persons.

In 2024, our board of directors undertook a review of the independence of our directors and considered whether any director had a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Specifically, our board of directors considered whether Mr. John Francis's association with Catalysis Partners, one of our stockholders, and previously a stockholder of Old Catheter, the predecessor to our subsidiary, Catheter Precision, LLC, created a conflict of interest based on Catalysis Partners' ownership of shares in the Company or Old Catheter, and determined that no actual conflict existed and that our board of directors would take appropriate measures if an actual conflict does arise in the future. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, which included that Mr. Francis' spouse was a director of the Company until December 28, 2023, and Mr. Caruso's prior service as Chief Financial Officer and consultant to Old Catheter, our board of directors determined that each of Martin Colombatto, John P. Francis, James Caruso, and Andrew Arno was "independent" as that term is defined under the rules of the NYSE American. Mr. Francis left the Board in July 2024.

Our board of directors also determined that James Caruso (Chairperson) and Andrew Arno, who currently comprise our audit committee, Martin Colombatto (Chairperson) and James Caruso, who currently comprise our compensation committee, and Andrew Arno (Chairperson) and Martin Colombatto, who currently comprise our nominating and corporate governance committee, satisfy the independence standards for those committees established by applicable Securities and Exchange Commission, or SEC, rules and the listing standards of the NYSE American.

In making these determinations, our board of directors considered the relationships that each non-employee director with us, including those described above, and all other facts and circumstances our board of directors deemed relevant in determining their independence, including business relationships, family relationships and the beneficial ownership of our capital stock by each non-employee director.

Caution Regarding Forward Looking Statements

This Form 10-K/A contains forward-looking statements. Forward-looking statements can be identified by words such as "believe," "anticipate," "may," "might," "can," "could," "continue," "depends," "expect," "expand," "forecast," "intend," "predict," "plan," "rely," "should," "will," "may," "seek," "promising," "potential," or the negative of these terms and other similar expressions, although not all forward-looking statements contain these words. These forward-looking statements are subject to the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements contained in this press release include, but are not limited to, express and implied statements regarding the following: our expectation to acquire assets of Cardionomic, Inc.; our expectations regarding those assets; our expectation to conclude financing for the new subsidiary and that the proceeds of such financing will fund development of the acquired assets independent of VTAK's balance sheet. The Company's expectations and beliefs regarding these matters may not materialize. Actual outcomes and results may differ materially from those contemplated by these forward-looking statements as a result of uncertainties, risks and changes in circumstances, including but not limited to risks and uncertainties included under the caption "Risk Factors" in the Company's 2024 Form 10-K filed with the SEC and available at www.sec.gov. These risks and uncertainties include, but aren't limited to: that the closing of the asset acquisition described above remains subject to important closing conditions that may not be met; that our ability to develop and commercialize the assets could be adversely impacted if we are unable to maintain protection of the patents and trade names related thereto, which we are acquiring on an as is basis without recourse; that we may not be able to obtain the financing for Cardionomix that we anticipate and/or such financing even if obtained may not be adequate for the development of the assets; and that we may not adequately address the lessons learned from the pilot studies related to the assets, which included fatigue to nerves if stimulation is delivered for too long; high amplitude stimulation can lead to unstable hemodynamics, rhythm disturbances, and patient sensation; optimal stimulation response is dependent on more than just contractility; stimulation beyond 48 hours did not show additional benefit; stimulator modifications required to reduce procedure time, complexity, and improve user experience; and minor catheter modifications needed to accommodate larger anatomy in heart failure patients. FDA review of the assets is likely to be costly and lengthy, and there is no guarantee that clearance and approval will ever occur or occur on a timetable that is beneficial to the Company. Additionally, Cardionomix has other, minority investors aside from the Company, and future financings are expected to involve the issuance of securities by Cardionomix, which will reduce the Company's share in the profits, if any, from the Purchased Assets and Cardionomix, and is likely to involve the grant of special corporate governance rights to other subsidiary investors so that the Company will not have unfettered control of Cardionomix. There is no guarantee that the success of the pilot studies will be repeated in future trials or ultimately lead to a successful commercialization of the Purchased Assets. The medical device industry in general is highly competitive, and some of our competitors have longer, more established operating histories, with significantly greater financial, technical, marketing, sales, distribution, and other resources. The Purchased Assets are not the only device-based neuromodulation therapy currently in development for the treatment of heart failure and further must also compete against potential new drug therapies. In general, results of anticipated trials may not turn out as we currently expect, and future trials may not occur on the time tables we expect or may be more costly than anticipated. In addition, our forward looking statements are subject to the following additional uncertainties and risks: we do not have sufficient liquidity to fund our business unless we are able to obtain additional financing or enter into a strategic transaction that would provide additional liquidity during the next three to six months, we will not be able to reach profitability unless we are able to achieve our product expansion and growth goals, our research and development and commercialization efforts may depend on entering into agreements with corporate collaborators, we have in the past entered into joint marketing agreements with respect to our products, and may again enter into additional joint marketing agreements in the future that could reduce our revenues from product sales, if we experience significant disruptions in our information technology systems, our business may be adversely affected, litigation and other legal proceedings may adversely affect our business, if we make acquisitions or divestitures, we could encounter difficulties that harm our business, failure to attract and retain sufficient qualified personnel could also impede our growth, failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock, we have determined that our internal controls and disclosure controls were not effective as of March 31, 2024, June 30, 2024, September 30, 2024, and December 31, 2024, and as a result, without effective remediation of the material weaknesses that we have identified, we may not be able to accurately report our financial results or prevent fraud, our revenues may depend on our customers' receipt of adequate reimbursement from private insurers and government sponsored healthcare programs, we may be unable to compete successfully with companies in our highly competitive industry, many of whom have substantially greater resources than we do, our future operating results depend upon our ability to obtain components in sufficient quantities on commercially reasonable terms or according to schedules, prices, quality and volumes that are acceptable to us, and suppliers may fail to deliver components, or we may be unable to manage these components effectively or obtain these components on such terms, if hospitals, physicians and patients do not accept our current and future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any, our medical device operations are subject to pervasive and continuing FDA regulatory requirements, our products may be subject to additional recalls, revocations or suspensions after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business, changes in trade policies among the U.S. and other countries, in particular the imposition of new or higher tariffs by the U.S. and/or its trading partners could increase our expenses, require us to increase prices, potentially lowering demand for our products, and/or reduce our revenues and operating

results, and such increase , or the imposition of other barriers to international trade, could have a material adverse effect on our revenues and operating results. The risks and uncertainties described above may be amplified by the COVID-19 pandemic, which has caused significant economic uncertainty, or other pandemics, supply chain disruptions from the Ukraine war or Israeli-Hamas conflict and otherwise, and ongoing volatility in the stock markets and the U.S. economy in general.

The forward-looking statements included in this Form 10-K/A are made only as of the date hereof. The Company assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

PART IV — FINANCIAL INFORMATION

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES.

(a)(1) The Company's consolidated financial statements and report of WithumSmith+Brown, PC, Independent Registered Public Accounting Firm, are included in Section IV of the Original Form 10-K beginning on page F-1.

(a)(2) Schedules have been omitted because they are not applicable or are not required or the information required to be set forth therein is included in the consolidated financial statement or related notes thereto.

(a)(3) Exhibits

The following Exhibits are filed as part of, or incorporated by reference into this report:

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.2	Amended and Restated Agreement and Plan of Merger, dated January 9, 2023, by and among the Registrant, certain subsidiaries, and Catheter Precision, Inc.	8-K	001-38677	2.1	1/13/2023
3.1.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38677	3.1	10/1/2018
3.1.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant. (effective 11/16/20)	8-K	001-38677	3.1	11/17/2020
3.1.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant. (effective 09/30/22)	8-K	001-38677	3.1	9/20/2022
3.1.3.A	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (filed 7/11/2024, effective 7/15/2024)	8-K	001-38677	3.1	7/12/2024
3.1.3.B	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (effective 1/13/2025)	10-K	001-38677	3.1	3/31/2025
3.1.4	Certificate of Designation of Series X Convertible Preferred Stock.	8-K	001-38677	3.1	1/13/2023
3.1.5	Certificate of Designation of Series A Preferred Stock.	8-K	001-38677	3.2	1/13/2023
3.1.6	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (effective 08/17/23)	8-K	001-38677	3.1	8/4/2023
3.2.1	Amended and Restated Bylaws of the Registrant.	8-K	001-38677	3.2	10/1/2018
3.2.2	Amendment to Amended and Restated Bylaws of the Registrant.	8-K	001-38677	3.1	8/17/2022
4.1	RESERVED				
4.2	Description of Capital Stock	10-K	001-38677	4.2	3/31/2025
4.3	Form of warrant issued in May 2020.	8-K	001-38677	4.1	5/22/2020
4.4	Form of pre-funded warrant issued in May 2020.	8-K	001-38677	4.2	5/22/2020
4.5	Form of placement agent warrant issued in May 2020.	8-K	001-38677	4.3	5/22/2020
4.6	Form of warrant offered in July 2020.	S-1	333-239887	4.3	7/16/2020
4.7	Form of pre-funded warrant issued in July 2020.	S-1	333-239887	4.4	7/16/2020
4.8	Form of placement agent warrant offered in July 2020.	S-1	333-239887	4.5	7/16/2020
4.9	Form of placement agent warrant offered in October 2024	8-K	001-38677	4.2	11/5/2024
4.10	Form of Series B Warrant offered in February 2022.	S-1/A	333-262195	4.9	2/3/2022
4.11	Form of Series C Warrant issued in July 2022	8-K	001-38677	4.1	7/22/2022
4.12	Warrant Agency Agreement, dated February 8, 2022, by and between the Registrant and American Stock & Trust Company LLC.	8-K	001-38677	4.4	2/9/2022
4.12.1	Amendment No. 1, dated July 22, 2022, to February 8, 2022 Warrant Agency Agreement by and between the Company and American Stock Transfer & Trust Company, LLC.	10-Q	001-38677	4.7	8/15/2022
4.13	Form of Series E Warrant offered in January 2023.	8-K	001-38677	4.1	1/13/2023
4.14	Form of Series F Warrant issued in March 2023.	8-K	001-38677	4.2	1/13/2023

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
4.15	Form of Series G Warrant issued in March 2023.	8-K	001-38677	4.3	1/13/2023
4.15.1	Form of Series H Warrant offered in September 2024	8-K	001-38677	4.1	9/6/2024
4.15.2	Form of Series I Warrant offered in September 2024	8-K	001-38677	4.2	9/6/2024
4.15.3	Form of Series J Warrant offered in September 2024	8-K	001-38677	4.3	9/6/2024
4.15.4	Form of Series K Warrant offered in October 2024	8-K	001-38677	4.1	10/25/2024
4.16	Form of Pre-Funded Warrant offered in September 2024	8-K	001-38677	4.4	9/6/2024
4.17	Form of Underwriters' Warrant offered in September 2024	S-1	333-279930	4.17	6/26/2024
4.18	Form of Warrant Agency Agreement dated as of September 3, 2024 entered into by and between the Registrant and Equiniti Trust Company, LLC	8-K	001-38677	4.5	9/6/2024
10.1	[omitted.]				
10.2+	2018 Form of Indemnification Agreement between the Registrant and directors and executive officers.	S-1	333-226191	10.2	8/24/2018
10.3+	Ra Medical Systems, Inc. 2018 Stock Compensation Plan and Forms of Award Agreement thereunder.	S-1	333-226191	10.3	7/16/2018
10.4+	Ra Medical Systems, Inc. 2018 Equity Incentive Plan and Forms of Award Agreement thereunder, as amended.	8-K	001-38677	99.1	10/13/2020
10.5	[omitted.]				
10.6	[omitted.]				
10.7	[omitted.]				
10.8	[omitted]				
10.9	[omitted.]				
10.12	[omitted.]				
10.13	[omitted.]				
10.14	[omitted.]				
10.16	Corporate Integrity Agreement, between the Company and the Office of Inspector General of the Department of Health and Human Services, dated December 28, 2020.	10-K	001-38677	10.20	3/17/2021
10.16.1	Notice of Suspension of Corporate Integrity Agreement, dated January 11, 2023.	10-K	001-38677	10.16.1	3/28/2023
10.17	[omitted.]				
10.18	[omitted.]				
10.19	[omitted.]				
10.20	[omitted.]				
10.21	[omitted.]				
10.22	[omitted.]				
10.23	Warrant Inducement Offer Letter dated July 22, 2022.	8-K	001-38677	10.1	7/22/2022

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.25	Registration Rights Agreement, dated January 9, 2023.	8-K	001-38677	10.5	1/13/2023
10.27.1	Debt Settlement Agreement and Release including certain royalty rights with David A. Jenkins, dated January 9, 2023.	10-K	001-38677	10.27.1	3/28/2023
10.27.2	Debt Settlement Agreement and Release including certain royalty rights with Daniel C. Stanzione, Sr. Irrevocable Trust Dated December 31, 2007, dated January 9, 2023.	10-K	001-38677	10.27.2	3/28/2023
10.27.3	Debt Settlement Agreement and Release including certain royalty rights with Fatboy Capital, L.P., dated January 9, 2023.	10-K	001-38677	10.27.3	3/28/2023
10.28.1	LockeT Royalty Agreement with Auston Locke.	10-K	001-38677	10.28	3/28/2023
10.28.2	Assignment and Agreement from Auston Locke in relation to LockeT dated July 15, 2022	S-1	333-279930	10.28.2	6/4/2024
10.28.3	Assignment and Agreement from David A. Jenkins in relation to LockeT dated January 24, 2023	S-1	333-279930	10.28.3	6/4/2024
10.28.4	Invention Assignment and Royalty Agreement with Auston Locke in relation to LockeT dated May 28, 2024	8-K	001-38677	10.1	6/3/2024
10.30.1	Lease with respect to Fort Mill facility.	10-K	001-38677	10.30.1	3/28/2023
10.31	[omitted.]				
10.31.1	[omitted.]				
10.31.2+	2023 Equity Incentive Plan	DEF 14A	001-38677	Annex C	11/25/2024
10.31.3+	2023 Form of Nonstatutory Stock Option Agreement for Non-Employee Directors Under 2023 Equity Incentive Plan	10-K	001-38677	10.31.3	4/1/2024
10.31.4+	2023 Form of Nonstatutory Stock Option Agreement for Employees Under 2023 Equity Incentive Plan	10-K	001-38677	10.31.4	4/1/2024
10.31.5+	2023 form of Incentive Stock Option Agreement Under 2023 Equity Incentive Plan	10-K	001-38677	10.31.5	4/1/2024
10.31.6+	Notice of Stock Option Award granted March 13, 2021 to Margrit Thomassen under Old Catheter's 2009 Equity Incentive Plan	10-K	001-38677	10.31.6	4/1/2024
10.31.7+	Non-plan Stock Option Award granted May 1, 2024 to Marie-Claude Jacques	S-1	333-279930	10.31.7	6/4/2024
10.31.8+	Non-plan Stock Option Award granted January 6, 2025 to Philip Anderson	10-K	001-38677	10.31.8	3/31/2025
10.31.9+	Offer Letter to Philip Anderson dated January 3, 2025	10-K	001-38677	10.31.9	3/31/2025
10.31.10+	Offer Letter to Marie-Claude Jacques dated April 24, 2024	10-K	001-38677	10.31.10	3/31/2025
10.32	Software and Technology License Agreement dated May 1, 2016, with Peacs BV.	10-K	001-38677	10.32	3/28/2023
10.32.1	Settlement and Amendment Agreement dated May 24, 2021 with Peacs BV.	10-K	001-38677	10.32.1	3/28/2023

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.33	Warrant Inducement Letter Dated October 24, 2024	8-K	001-38677	10.1	10/25/2024
10.33.2	Waiver Agreement Dated October 29, 2024	8-K	001-38677	10.1	10/30/2024
10.33.3	[omitted.]				
10.33.4	[omitted.]				
10.33.5	Promissory Note dated May 30, 2024	8-K	001-38677	10.2	6/3/2024
10.33.6	Promissory Note dated June 25, 2024	8-K	001-38677	10.1	6/26/2024
10.33.7	Promissory Note dated July 1, 2024	8-K	001-38677	10.1	7/1/2024
10.33.8	Promissory Note dated July 18, 2024	8-K	001-38677	10.1	7/23/2024
10.33.9	Promissory Note dated July 25, 2024	8-K	001-38677	10.1	7/30/2024
10.34	Quality Agreement with Zien Medical Technologies, Inc. related to LockeT Manufacture, dated March 20, 2023	S-1	333-279930	10.34	6/4/2024
10.35	First Amendment to Promissory Note dated May 30, 2024	S-1	333-279930	10.33.5	8/27/2024
10.36	First Amendment to Promissory Notes dated June 25, 2024, July 1, 2024 and July 18, 2024	S-1	333-279930	10.33.6	8/27/2024
10.37	First Amendment to Promissory Note dated July 25, 2024	S-1	333-279930	10.33.7	8/27/2024
16.1	Letter re change in certifying accountant	8-K	001-38677	16.1	6/26/2023
19.1	Insider Trading Policy dated March 21, 2025	10-K	001-38677	19.1	3/31/2025
21.1	Subsidiaries of the Registrant	10-K	001-38677	21.1	3/31/2025
23.1	Consent of WithumSmith+Brown, PC, Independent Registered Public Accounting Firm.	10-K	001-38677	23.1	3/31/2025
31.1	Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	10-K	001-38677	31.1	3/31/2025
31.2	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	10-K	001-38677	31.2	3/31/2025
31.3*	Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.4*	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1^	Certifications of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	10-K	001-38677	32.1	3/31/2025
32.2^	Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	10-K	001-38677	32.2	3/31/2025
97.1	Policy Relating to the Recovery of Erroneously Awarded Compensation	10-K	001-38677	97	4/1/2024
101.INS*	Inline XBRL Instance Document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				

* Filed herewith.

^ The information in this exhibit is furnished and deemed not filed with the Securities and Exchange Commission for purposes of section 18 of the Exchange Act of 1934, as amended (Exchange Act), and is not to be incorporated by reference into any filing of Ra Medical Systems, Inc. under the Securities Act of 1933, as amended (Securities Act), or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

\+ Indicates a management contract or compensatory plan.

SIGNATURES

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

CATHETER PRECISION, INC.

Date: April 30, 2025

By: /s/ Philip Anderson
Philip Anderson
Chief Financial Officer