UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended April 30, 2025

OR

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

Commission File Number: 001-42549

Kestra Medical Technologies, Ltd.

(Exact Name of Registrant as Specified in its Charter)

Bermuda	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3933 Lake Washington Blvd NE, Suite 200	
Kirkland, WA	**98033**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (425) 279-8002

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, par value $1.00 per share	KMTS	The Nasdaq Stock Market LLC

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 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 an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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 ☒

As of October 31, 2024, the last business day of the Registrant's most recently completed second fiscal quarter, there was no established public market for the Registrant's Common Shares. Therefore, the aggregate market value of the Registrant's voting and non-voting common equity held by non-affiliates of the Registrant cannot be calculated. The Registrant's Common Shares began trading on the Nasdaq Global Select Market on March 6, 2025.

The number of shares of the Registrant's Common Shares outstanding as of July 16, 2025 was 51,348,656.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Annual Report, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting to be held in 2025, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report relates (the "Proxy Statement").

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Explanatory Note

On March 7, 2025, Kestra Medical Technologies, Ltd. completed its initial public offering of its Common Shares, par value $1.00 per share (the "Common Shares"). Kestra Medical Technologies, Ltd. was formed solely for the purpose of completing the initial public offering and prior to the consummation of the initial public offering, did not engage in any business or activities other than those incidental to its formation, the organizational transactions consummated in connection with the initial public offering and the preparation of the prospectus and registration statement in connection with the initial public offering. Prior to the consummation of the initial public offering, the Company's business was conducted through West Affum Intermediate Holdings Corp. In connection with the initial public offering, certain organizational transactions were completed, pursuant to which West Affum Intermediate Holdings Corp. became a wholly owned subsidiary of Kestra Medical Technologies, Ltd. West Affum Intermediate Holdings Corp. is the predecessor to Kestra Medical Technologies, Ltd. for financial reporting purposes.

Except as otherwise indicated or the context requires, "Kestra," the "Company," "we," "our," "us" and other similar terms refer collectively to West Affum Intermediate Holdings Corp. and its consolidated subsidiaries for periods prior to the consummation of the initial public offering, and to Kestra Medical Technologies, Ltd. and its consolidated subsidiaries for periods following the consummation of the initial public offering.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking" statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the section captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, technology developments, financing and investment plans, dividend policy, competitive position, industry and regulatory environment, potential growth opportunities and the effects of competition. Forward looking statements include statements that are not historical facts and can be identified by terms such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "will" and "would," or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Important factors that could cause actual results, performance or achievements to differ materially from our expectations are described in Part I, Item 1A, "Risk Factors" and elsewhere in this Annual Report on Form 10-K, and include, but are not limited to, the following:

- our ability to continue to expand the commercialization of our ASSURE WCD, including associated products and services as part of our Cardiac Recovery System platform, or to commercialize any future product candidates and begin generating revenue;
- our ability to maintain regulatory approvals for our ASSURE WCD and to obtain new regulatory approvals necessary to distribute our ASSURE WCD in new markets or to distribute additional products we develop in the future;
- the rate and degree of market acceptance of our ASSURE WCD or any future product candidates that receive the necessary marketing and other regulatory approvals;
- the availability of reimbursement for our products;
- our ability to scale the manufacturing of our ASSURE WCD, obtain sufficient and timely supplies of components necessary to manufacture our ASSURE WCD and effectively manage inventory and distribution;
- our ability to hire and retain qualified personnel, including senior management and sales professionals;
- estimates of our total addressable market and near-term achievable market for our products;
- the timing or likelihood of regulatory filings and approvals or clearances;
- our growth plans, including our plans to enter into new markets;
- our ability to establish and maintain intellectual property protection for our products or defend ourselves against claims of infringement;
- the progress, timing, costs and results of our clinical trials;
- changes and developments relating to our regulatory landscape;
- our financial performance and changes in market trends;
- the increased expenses associated with being a public company; and
- changes and developments relating to our competitors and our industry.

We caution you that the foregoing list does not contain all of the forward-looking statements made in this Annual Report.

These risks are not exhaustive. Investors should also carefully read the factors described under Part I. Item 1A. "Risk Factors" in this Annual Report for a description of certain other risks that could, among other things, harm our business and financial performance and cause our actual results to differ from those expressed in forward-looking statements. We operate in a very competitive and rapidly changing environment where new risk factors may emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. These forward-looking statements speak only as of the date of this Annual Report. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments. We intend the forward-looking statements contained in this Annual Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

You should read this Annual Report and the documents that we reference in this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Annual Report by these cautionary statements.

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SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part I. Item 1A. "Risk Factors" in this Annual Report. You should carefully consider these risks and uncertainties when investing in our common shares. The principal risks and uncertainties affecting our business include the following:

- we have a limited operating history, which may make it difficult for you to evaluate our current business and its likelihood of success and viability. If we are unable to manage our business and any fluctuations in our business effectively, our business and growth prospects could be materially and adversely affected;

- we have a history of net losses, and there is no assurance as to when we will achieve profitability, if at all, even as we continue to grow and scale our business. As part of such continued growth, we may need to raise equity or debt financing in the future. If we are unable to raise capital when needed, we may be forced to delay or scale back our growth plans, which could materially and adversely affect our results of operations and prospects;

- we generate revenue primarily from the lease of our ASSURE WCD as part of our Cardiac Recovery System platform, and we are therefore highly dependent on our ASSURE WCD for our continued success;

- our business is dependent upon healthcare providers, hospitals and patients adopting our solutions, and if we fail to obtain and maintain broad adoption, our business would be adversely affected;

- our commercial success depends in part on the extent to which governmental authorities and health insurers provide coverage and adequate reimbursement levels. Failure to obtain and maintain coverage and adequate reimbursement for our products could limit our ability to market those products and make it difficult for us to operate profitably;

- if we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed;

- our clinical study initiatives may be complex, lengthy, expensive and carry uncertain outcomes. Future trials and studies by us or others may fail to replicate positive results observed to date;

- we depend on a limited number of third-party suppliers and contract manufacturers to manufacture and recondition our ASSURE WCD and its components, which could make us vulnerable to supply shortages and price fluctuations that could harm our business;

- billing for our products is complex, and we must dedicate substantial time and resources to the billing process;

- if our competitors are able to develop or market products and services that are more effective, or gain greater acceptance in the marketplace, than any products and services we develop, our commercial opportunities will be reduced or eliminated;

- we have identified material weaknesses in our internal control over financial reporting, and may identify additional material weaknesses. If our remediation of material weaknesses in our internal control over financial reporting is not effective, or we fail to develop and maintain effective internal control over financial reporting, our ability to produce timely and accurate financial statements could be impaired, which could harm our business and negatively impact the value of our common shares;

- third parties may assert that we are employing their intellectual property and other proprietary technology without authorization, and we may become a party to litigation or administrative proceedings related to intellectual property that could be costly, time-consuming, or unsuccessful and could hinder our ability to commercialize our existing or future products;

- our efforts to obtain intellectual property protection and the intellectual property rights we obtain may be inadequate, and our business may be adversely affected as a result;

- we may be subject to claims challenging the inventorship of our patents and other intellectual property; changes in the regulatory environment may make it more difficult and costly for us to manufacture, market or distribute our products, or to obtain approval for any future products;

- if we fail to comply with healthcare and other governmental regulations, we could face substantial penalties and our business, results of operations and financial condition could be adversely affected; and

- Bain Capital controls us, and its interests may conflict with ours or yours.

Industry and Market Data

Certain industry data and market data included in this Annual Report were obtained from independent third-party surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. Management's estimates presented herein are based upon management's analysis of internally compiled data, independent third-party surveys and industry publications prepared by a number of sources and other publicly available information. We obtained the industry and market data set forth in this Annual Report from our own internal estimates and research, as well as from academic and industry publications, research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on our knowledge of the industry and market, which we believe to be reasonable. We believe that the information from academic and industry publications, research, surveys and studies conducted by third parties included in this Annual Report is reliable.

Additionally, our estimated total addressable market is based on epidemiology data regarding cardiac patient populations with low ejection fractions, payor data on WCD reimbursement rates, the average initial prescription duration for our ASSURE WCD and our estimates of the industry average initial prescription duration for WCDs generally. Our total addressable market in the United States is based on epidemiology data from third-party sources including the American Heart Association and the Heart Failure Society of America and the Medicare reimbursement rate for WCDs as of January 2025 as published in the Centers for Medicare and Medicaid Services DMEPOS Fee Schedule. Our estimated total addressable market outside the United States is based on estimated average reimbursement rates and initial prescription durations for WCDs derived from internally collected data from industry sources and market participants and our internal estimates based on such data, as well as epidemiology data from third-party sources including PubMed, UptoDate, Statistica and the European Society of Cardiology in the following select international markets: Japan, Germany, United Kingdom, France, Italy, Spain, Canada, Poland, Australia, Romania, Netherlands, Belgium, Czech Republic, Sweden, Hungary, Austria, Switzerland and Denmark. These international markets were selected because they have already adopted WCD therapy or have a history of ICD utilization.

PART I

Item 1. Business.

Overview

We are a commercial-stage, wearable medical device and digital healthcare company focused on transforming patient outcomes in cardiovascular disease using monitoring and therapeutic intervention technologies that are intuitive, intelligent, and connected. We have developed and are commercializing our Cardiac Recovery System platform, a comprehensive and advanced system that integrates monitoring, therapeutic treatment, digital health, and patient support services into a single, unified solution. The cornerstone of our Cardiac Recovery System platform is the ASSURE WCD, a next generation wearable cardioverter defibrillator ("WCD") used to protect patients at an elevated risk of sudden cardiac arrest ("SCA"), a major public health problem that accounts for approximately 50% of all cardiovascular deaths in the U.S. The ASSURE WCD automatically monitors elevated risk patients and, if needed, delivers a defibrillation shock to return the patient's heart to normal rhythm. The ASSURE WCD was purpose-built to enhance patient comfort and compliance and directly address the key barriers to adoption associated with the only other commercially available WCD. We believe the ASSURE WCD offers significant clinical and functional advantages, including greater patient compliance as a result of a major reduction in false alarms and enhanced comfort and wearability. In addition to the ASSURE WCD, our Cardiac Recovery System platform includes a comprehensive suite of fully integrated digital solutions and services that enable enhanced patient and provider engagement and oversight, with the objective of improving patient outcomes. We believe our Cardiac Recovery System platform addresses serious unmet needs in the cardiac patient population and has the potential to disrupt and grow the market which has been limited to a single solution for more than 20 years. Active prescriptions represent hospitals that have prescribed the ASSURE WCD within the last six months. Additionally, our ASSURE WCD has been worn by over 20,000 patients since it was fully commercially launched.

SCA is a life-threatening emergency characterized by the abrupt cessation of the heartbeat caused by an electrical malfunction in the heart. This is typically triggered by ventricular arrhythmias, such as ventricular fibrillation ("VF"), and leads to a loss of consciousness and potentially death within minutes if not promptly treated. The American Heart Association ("AHA") estimates that SCA causes approximately 436,000 deaths per year, making it the third leading cause of death in the U.S. Defibrillation, or an electrical shock, is the only way to restore a fibrillating heart to a normal rhythm. Each minute of delay in restoring the heart to a normal rhythm reduces a patient's chance of survival by 7% to 10%. The average time for Emergency Medical Services ("EMS") arrival is 7 minutes from the time of a 911 call, and often longer in rural communities. The most common location of a SCA in adults is at a home or residence, representing approximately 73% of SCAs. In addition, approximately 50% of all SCAs are unwitnessed.

A WCD is a wearable, non-invasive miniaturized automated external defibrillator and is worn underneath regular clothing. The device continuously monitors a patient's heart rhythm and is capable of delivering a defibrillation shock. Wires connect electrodes inside the garment to the monitor, which is carried in a small pack or shoulder bag. The electrodes continuously acquire a patient's heart rate and rhythm for evaluation by the automated external defibrillator. If the monitor detects a potentially life-threatening arrhythmia, the WCD first alerts the patient via an audible alarm and then administers a shock, if needed.

The WCD is indicated for use in patients who are at risk for SCA and are not candidates for, or refuse, an ICD. WCDs are typically prescribed to patients immediately following an MI or heart failure diagnosis and serve as a bridge to recovery between the cardiac event and a longer-term treatment regimen. During this period, healthcare providers will adjust the medications prescribed for the patient and observe whether the patient's LVEF improves. The expected wear duration of the WCD varies based on the patient's indication, with the majority of our patients being prescribed the WCD for three months or longer.

For over 20 years, WCDs have been used to protect patients at elevated risk of SCA. However, until the ASSURE WCD received Food and Drug Administration ("FDA") approval in July of 2021, the market was limited to a single solution. Since the approval of the first WCD in 2001, global WCD revenues have grown to $1.3 billion in 2023, with approximately 85% of the revenues generated in the U.S. based on our analysis of third-party claims data and estimated average WCD wear prescription lengths and average reimbursement rates in the U.S. and in select international markets derived from industry data and internal estimates. The volume of patients prescribed a WCD in the U.S. grew at roughly 6% annually between 2021 and 2023, and we expect WCD revenues to continue growing.

Despite being proven as safe and effective in treating dangerous cardiac rhythms when worn, WCD therapy remains underutilized, reaching just 14% of the eligible U.S. patient population in 2023 based on data on patients indicated for a WCD and WCD prescription data from industry sources. We believe that the low penetration of WCD therapy is largely due to the limitations of the incumbent commercially available device. In feedback we have collected through directly engaging with patients and providers and customer feedback on public platforms, commonly cited reasons for patients or providers failing to use the competitor device include high false alarm frequency, poor wearability and patient discomfort, a unisex-only garment, low utility data and limited connectivity with patients. In the U.S., we estimate that there are approximately 800,000 cardiac patients each year who have experienced an MI or are diagnosed with heart failure and have low LVEF, therefore making them eligible for WCD therapy. Additionally, approximately 50,000 patients each year either have documented VT or VF, an inherited genetic condition, or have had their ICD temporarily explanted, and are also indicated for WCDs. Based on an average WCD wear prescription length of 3.4 months per patient and an average Medicare reimbursement rate of $3,519 per patient per month, we believe this represents an approximately $10 billion annual addressable market as of 2024. In select international markets, we estimate based on patient population data collected by various third-party industry sources that there are approximately 3.7 million people each year who experience an MI, are diagnosed with heart failure, have documented VT or VF, have an inherited genetic condition, or have had their ICD temporarily explanted. Among these patients, based on the same third-party industry sources, we estimate that approximately 1.8 million patients meet the indications for WCD therapy. Based on estimated average WCD wear prescription length in these international markets of 2.5 months per patient and estimated average reimbursement rate of $3,000 per patient per month derived from industry data and internal estimates, we believe this represents an approximately $14 billion total annual market opportunity outside the U.S. For a description of the international markets covered by this estimated market opportunity, see "Industry and Market Data."

The ASSURE WCD is the next generation of WCD therapy, delivering a safe and effective solution for patients with a design that enhances patient comfort and compliance. In addition to the ASSURE WCD, the various digital solutions and services of our Cardiac Recovery System platform include the ASSURE patient application, Kestra CareStation remote patient data platform, Heart Alert Services, and ASSURE Assist services. The ASSURE patient application engages patients with real-time mobile updates to promote compliance, while the Kestra CareStation remote patient data platform equips healthcare providers with actionable insights to support timely and informed care decisions. Heart Alert Services and ASSURE Assist services work together to enhance safety and are designed to provide critical alerts to healthcare providers for significant arrhythmias and notify emergency services when therapy is administered. This post-therapy EMS support is critical as a range of injuries, such as head injuries, soft tissue damage and bone fractures, can result from falling down after a SCA. In addition, the ASSURE wearable ECG as part of our Cardiac Recovery System platform provides monitoring and connectivity for patients no longer indicated for a WCD but who still require ongoing support while their heart continues to remodel. We believe we offer the most comprehensive and cohesive platform, with digital solutions and services that are seamlessly integrated with our ASSURE WCD, meaningfully differentiating our Cardiac Recovery System platform from the only other commercially available WCD and offering the following benefits:

- ***Modern and advanced design improves comfort, performance and maximizes wearability.*** The garments were developed with an athletic and sportswear designer and are tailored for body inclusivity, offering two styles and a wide range of sizes. We believe that having separate, gender-specific designs is particularly important given women make up approximately 40% of SCA patients. Overall wearability is further supported by the results of our active surveillance post-approval study, ACE-PAS, which demonstrate a median wear time of greater than 23 hours per day. In addition to improving comfort and wearability, our unique garment design incorporates cushioned electrodes that are embedded in the fabric to improve electrode contact and, ultimately, improve electrocardiogram ("ECG") signal quality.

- ***High fidelity ECG leading to fewer false alarms.*** The ASSURE WCD is designed to minimize false alarms. The overall level of noise is reduced through use of resistive ECG electrodes that are cushioned and securely bonded to the fabric, custom shielded cables, and isolation circuitry. The ASSURE WCD also utilizes four channels of high-quality ECG, combined with Adaptive Patient Intelligence ("API"), a proprietary technology that adapts to the patient heart rhythm to filter out artifacts and improve performance even in a noisy environment. Our most recent FDA submission from ACE-PAS from July 2024, which includes data from 5,929 patients, reported a low false alarm rate with only 6% of our patients experiencing a false alarm. This is compared to 46% of patients for the competitor's device, as reported in the Journal of Interventional Cardiac Electrophysiology Study. Reduction in false alarms may lead to lower patient anxiety, improved patient satisfaction and increased patient compliance.

- ***Product innovations and integrated digital solutions and services supporting the patient throughout the cardiac care continuum.*** Our Cardiac Recovery System platform is a comprehensive suite of proprietary wearable and fully integrated digital solutions and services for monitoring, diagnosing, and protecting patients through their cardiac recovery journey. We believe our Cardiac Recovery System platform represents a competitive advantage, with the goal of ultimately improving the prescriber and patient experience, maximizing patient comfort and compliance, and increasing adoption of our system. In addition, our Cardiac Recovery System platform's capabilities allow healthcare providers to identify other clinically significant arrhythmias.

- ***Improved energy delivery to enhance efficacy and safety.*** The ASSURE WCD delivers a 170 joule shock to better serve patients with higher defibrillation thresholds, compared to the competitor device which delivers a 150 joule shock. In addition, our system has a minimum defibrillation capacity of 25 shocks, providing a significant safety buffer for patients experiencing multiple cardiac events within a short time period, such as a VT storm, where a patient experiences multiple episodes of sustained VT within a short period of time.

We are building a body of clinical evidence supporting the safety, efficacy, and benefits of the ASSURE WCD, with eight publications completed to date. This growing portfolio includes our pivotal trials—the ASSURE WCD Clinical Evaluation—Detection and Safety Study ("ACE-DETECT") and the ASSURE WCD Clinical Evaluation—Conversion Efficacy Study ("ACE-CONVERT")—which served as the basis for our premarket approval ("PMA"). In addition, we are conducting the ACE-PAS as part of a broader ongoing ASSURE Patient Registry (the "Registry"). All patients prescribed the ASSURE WCD in the United States after August 5, 2022 are included in the Registry. As of April 30, 2025, our ongoing registry has enrolled over 20,000 patients, and its findings further validate the results of ACE-DETECT and ACE-CONVERT. Our most recent FDA submission from ACE-PAS from July 2024, which includes data from 5,929 patients, reported first shock conversion efficacy of approximately 96%, a median daily use of 23.2 hours and a low false alarm rate with only 6% of our patients experiencing a false alarm, compared to 46% for the competitor's device. These results underscore the ASSURE WCD's competitive advantages in wearability, usability, and patient compliance, providing strong support for continued adoption. We believe this collection of real-world evidence will generate additional publications, continue to increase awareness of WCDs as a proven therapy for elevated risk cardiac patients and further demonstrate the clinical differentiation of our ASSURE WCD.

We have made material investments in infrastructure to support rapid growth and scalability, specifically in our commercial organization, distribution and supply chain capabilities, as well as revenue cycle management capabilities. In the U.S., as of April 30, 2025, we have built a commercial sales team of approximately 80 direct sales representatives and more than 40 sales and clinical support professionals with deep expertise in cardiac rhythm management and established relationships in the cardiology and electrophysiology fields. This team is responsible for developing sales territory business plans, targeting and opening new accounts, and processing prescriptions of our ASSURE WCD. Our direct sales team is supported by a contracted team of over 300 APSs who assist patients with fitting and training as of April 30, 2025. At fitting, we deliver our ASSURE WCD from our distribution network to the patient. We utilize a lease business model, and when a patient's wear time has concluded, the device is returned for reprocessing and reintroduction into the distribution network. To support our growth, we have developed a highly scalable supply chain in collaboration with experienced, top-tier medical technology suppliers. Our substantial investment in a fleet of devices, each with a capacity for approximately three patient wears per year, are reprocessed through efficient reconditioning, which enables the business to scale with an attractive unit economic profile. Finally, our revenue cycle management capabilities streamline reimbursement processes by ensuring claims are accurately prepared and submitted according to individual payor requirements, facilitating timely collections. These capabilities are a critical asset in driving operational efficiency and supporting both patient and prescriber satisfaction. We believe our significant investments in infrastructure create a high barrier to entry that will help us protect and grow our market share.

Over a decade of investment in our research and development capabilities has resulted in a highly experienced and capable innovation engine. Designed to be scalable, our Cardiac Recovery System platform supports future extensions and enhancements, enabling the integration of new therapeutic and diagnostic capabilities to support our existing fleet of ASSURE WCDs. The platform also enables data collection from patients that we believe will support training of future automated algorithms to detect and predict clinically relevant events. Moreover, we have a robust patent and trade secrets portfolio, with more than 365 pending and issued patents worldwide as of April 30, 2025. We believe the combination of our intellectual property portfolio and upgradeable product design creates significant opportunities for efficient innovation.

WCD therapy in the U.S. has well-defined reimbursement codes, steadily increasing Medicare payment rates and broad coverage from major U.S. payors. Reimbursement rates continue to rise, reflecting growing recognition and support for this life-saving therapy. Strong prescriber demand and patient preference for the ASSURE WCD have driven broad payor coverage for the ASSURE WCD, with over 285 million U.S. lives being currently covered via insurance contracts as of April 30, 2025, representing approximately 90% of the total available lives, including traditional Medicare, select state Medicaid programs, and national commercial insurers. Based on feedback from our payors, we believe that this reflects payors' desire for a second choice to the competitor product, our solution addressing an unmet need with a female-specific garment and the overall patient compliance benefits of the ASSURE WCD. Our established payor relationships reduce our administrative burden in authorization and billing for our ASSURE WCD.

We have experienced rapid growth since our full commercial launch, expanding our headcount from 66 team members in October 2020 to over 330 team members as of April 30, 2025. For the fiscal year ended April 30, 2025, we generated revenue of $59.8 million, compared to revenue of $27.8 million for the fiscal year ended April 30, 2024, representing 115% year-over-year growth. For the fiscal year ended April 30, 2025, we recognized a net loss of $113.8 million, compared to a net loss of $94.1 million for the fiscal year ended April 30, 2024. As of April 30, 2025 and 2024, we had an accumulated deficit of $520.2 million and $406.4 million, respectively. For the year ended April 30, 2025, we recognized a gross profit of $24.2 million compared to a gross profit of $0.4 million for the year ended April 30, 2024.

Our Success Factors

We believe the continued growth of our company will be driven by the following success factors:

- ***Large, growing, and underpenetrated WCD market with a single competitor.*** For over 20 years, WCDs have been used to protect patients at an elevated risk of SCA. However, until the ASSURE WCD received FDA approval in July of 2021, the market was served by a single supplier. Since the approval of the first WCD in 2001, global WCD revenues have grown to $1.3 billion in 2023, with approximately 85% of the revenues generated in the U.S. based on our analysis of third-party claims data and estimated average WCD wear prescription lengths and average reimbursement rates in the U.S. and in select international markets derived from industry data and internal estimates. The volume of patients prescribed a WCD in the U.S. grew at roughly 6% annually between 2021 and 2023, and we expect WCD revenues to continue growing. Despite being proven as safe and effective in treating dangerous cardiac rhythms when worn, WCD therapy remains underutilized, reaching just 14% of the eligible U.S. patient population in 2023 based on data on patients indicated for a WCD and WCD prescription data from industry sources. This low penetration is attributed largely to poor patient compliance, a challenge stemming from the limitations of the competitor device. As a next-generation WCD therapy, our ASSURE WCD, as part of our broader comprehensive Cardiac Recovery System platform, is aiming to solve this issue by providing a solution that is intended to enhance patient comfort and compliance. In the U.S., we estimate that there are approximately 800,000 cardiac patients each year who have experienced an MI or are diagnosed with heart failure and have low LVEF, therefore making them eligible for WCD therapy. Additionally, approximately 50,000 patients each year either have documented VT or VF, an inherited genetic condition, or have had their ICD temporarily explanted, and are also indicated for WCDs. Based on an average WCD wear prescription length 3.4 months per patient and an average Medicare reimbursement rate of $3,519 per patient per month, we believe this represents an approximately $10 billion annual addressable market as of 2024. While our current commercial efforts are focused on the U.S., international markets represented approximately 15% of global WCD revenues in 2023, primarily concentrated in several large countries in western Europe. In select international markets, we estimate based on patient population data collected by various third-party industry sources that there are approximately 3.7 million people each year who experience an MI, are diagnosed with heart failure, have documented VT or VF, have an inherited genetic condition, or have had their ICD temporarily explanted. Among these patients, based on the same third-party industry sources, we estimate that approximately 1.8 million patients meet the indications for WCD therapy. Based on estimated average WCD wear prescription length in these international markets of 2.5 months per patient and estimated average reimbursement rate of $3,000 per patient per month derived from industry data and internal estimates, we believe this represents an approximately $14 billion total annual market opportunity outside the U.S. as of 2024. For a description of the international markets covered by this estimated market opportunity, see “Industry and Market Data.”

- ***Highly innovative Cardiac Recovery System platform designed to protect patients from SCA and improve patient compliance and healthcare provider adoption.*** With improved patient compliance and superior clinical efficacy as our main objectives, we purpose-built our ASSURE WCD from the ground up. The ASSURE WCD is the cornerstone of our Cardiac Recovery System platform, a comprehensive and advanced system that integrates monitoring, therapeutic treatment, digital health, and patient support services into a single, unified solution. The ASSURE WCD directly addresses known barriers by prioritizing comfort, usability, and diagnostic utility, positioning it to drive broader adoption and improve outcomes for elevated risk cardiac patients. The wearable garments—developed with an athletic and sportswear designer—incorporate advanced electronics, mobile technology, signal processing and performance fabrics to deliver superior wearability. Available in gender-specific styles and a wide range of sizes, the garments feature cushioned integrated sensors, ensuring comfort and body inclusivity. This design is proven out by results from our post-approval study, which demonstrate a median wear time of over 23 hours per day. The ASSURE WCD minimizes false alarms using advanced, custom electrical engineering techniques to reduce motion-induced noise. The ASSURE WCD utilizes four channels of high-quality ECG, combined with API, a proprietary technology that adapts to the patient heart rhythm, to filter out artifacts and improve performance even in a noisy environment. Our most recent FDA submission from ACE-PAS from July 2024, which includes data from 5,929 patients, reported a low false alarm rate with only 6% of our patients experiencing a false alarm. This is compared to 46% of patients for the competitor's device, as reported in the Journal of Interventional Cardiac Electrophysiology Study. This reduction lowers patient anxiety and improves satisfaction. With a patient-centered design, advanced ECG fidelity, and integrated digital platform, the ASSURE WCD is a differentiated solution that protects patients, empowers healthcare providers with actionable insights, and improves outcomes across the cardiac care continuum.

- ***Comprehensive and fully integrated suite of mission critical digital solutions and services for driving patient and healthcare provider engagement.*** Designed to enhance both patient and provider experiences, our Cardiac Recovery System platform is a unified, patient-centered solution that addresses known barriers to adoption and improves patient care. The various digital solutions and services of the Cardiac Recovery System platform include the ASSURE patient application, Kestra CareStation remote patient data platform, Heart Alert Services, and ASSURE Assist services. The ASSURE patient application engages patients with real-time mobile updates to promote compliance, while the Kestra CareStation remote patient data platform equips healthcare providers with actionable insights to support timely and informed care decisions. Heart Alert Services and ASSURE Assist services work together to enhance safety and are designed to provide critical alerts to healthcare providers for significant arrhythmias and notify emergency services when therapy is administered. We believe we offer the most comprehensive and cohesive platform, with digital solutions and services that are seamlessly integrated with our ASSURE WCD, meaningfully differentiating our Cardiac Recovery System platform.

- ***Material investments in infrastructure to support rapid growth and scale.*** We have made material investments in infrastructure to support rapid growth and scalability, specifically in our commercial organization, distribution and supply chain capabilities, and revenue cycle management capabilities. In the U.S., we have built a commercial sales team of approximately 80 direct sales representatives and more than 40 sales and clinical support professionals with deep expertise in cardiac rhythm management and established relationships in the cardiology and electrophysiology fields. Our team is further supported by a contracted network of over 300 patient specialists who assist with onboarding, fitting, and training patients, ensuring a scalable and seamless adoption process. To support our growth, we have developed a highly scalable supply chain in collaboration with experienced, top-tier medical technology suppliers. Our substantial investment in a fleet of devices, each with a capacity for approximately three patient wears per year, are reprocessed through efficient reconditioning, which enables the business to scale with an attractive unit economic profile. Finally, our revenue cycle management capabilities streamline reimbursement processes by ensuring claims are accurately prepared and submitted according to individual payor requirements, facilitating timely collections. These capabilities are a critical asset in driving operational efficiency and supporting both patient and prescriber satisfaction. We believe our significant investments in infrastructure create a high barrier to entry that will help us protect and grow our market share.

- ***Established reimbursement and favorable payor coverage.*** WCD therapy in the U.S. has well-defined reimbursement codes, steadily increasing Medicare payment rates and broad coverage from major U.S. payors. Reimbursement rates continue to rise, reflecting growing recognition and support for this life-saving therapy. From 2021 to 2025, published Medicare reimbursement rates have increased at a CAGR of 4.7%. Strong prescriber demand and patient preference for the ASSURE WCD have driven broad payor coverage for the ASSURE WCD, with over 285 million U.S. lives being covered as of April 30, 2025 via insurance contracts, representing approximately 90% of the total available lives, including traditional Medicare, select state Medicaid programs, and national commercial insurers. Based on feedback from our payors, we believe that this rapid payor coverage adoption reflects payors' desire for a second choice to the competitor product, our solution addressing an unmet need with a female-specific garment and the overall patient compliance benefits of the ASSURE WCD.

- ***Strong and compelling body of clinical evidence.*** We are building a body of clinical evidence supporting the safety, efficacy, and benefits of the ASSURE WCD, with eight publications completed to date. This growing portfolio includes our pivotal trials—ACE-DETECT and ACE-CONVERT—which served as the basis for our PMA approval. ACE-DETECT confirmed detection of arrhythmias and demonstrated a significantly lower false-positive shock alarm rate compared to the existing commercial device with no missed events, low patient-reported discomfort, and no serious adverse events over a 30-day wear period in ambulatory patients at elevated risk of SCA. ACE-CONVERT showed a cumulative first- and second-shock conversion efficacy of 100% for induced VT/VF, highlighting the system's reliability in life-threatening scenarios. In addition, we are continuing our active enrollment of patients in ACE-PAS, our real-world post-approval patient registry. All patients prescribed the ASSURE WCD in the United States after August 5, 2022 are included in the Registry. As of April 30, 2025, our ongoing registry has enrolled over 20,000 patients, and its findings further validate the results of ACE-DETECT and ACE-CONVERT. Our most recent FDA submission from ACE-PAS from July 2024, which includes data from 5,929 patients, reported first shock conversion efficacy of approximately 96%, a median daily use of 23.2 hours and a low false alarm rate with only 6% of our patients experiencing a false alarm, compared to 46% for the competitor's device. These results underscore the ASSURE WCD's competitive advantages in wearability, usability, and patient compliance, providing strong support for continued adoption. Looking ahead, we remain committed to expanding our clinical data and evidence to reinforce the value of our solutions, drive further market adoption, and strengthen evidence of the system's clinical utility.

- ***Broad research and development capabilities and a robust intellectual property portfolio.*** Over a decade of investment in our research and development capabilities has resulted in a highly experienced and capable innovation engine. Designed to be scalable, our Cardiac Recovery System platform supports future extensions and enhancements, enabling the integration of new therapeutic and diagnostic capabilities to support our existing fleet of ASSURE WCDs. The platform also enables data collection from patients that will support training of future automated algorithms to detect and predict clinically relevant events. Moreover, we have a robust patent and trade secrets portfolio, with more than 365 pending and issued patents worldwide. We believe the combination of our IP portfolio and upgradeable product design create significant opportunities for future innovation.

- ***Highly experienced management team and board with proven commercial growth success.*** Our leadership team brings over 350 years of combined experience spanning enterprise strategy, finance, operations, research and development, and regulatory affairs. Our team also has deep experience and expertise in external defibrillation technologies. With a proven track record of successfully scaling medical technology businesses, the team guided the ASSURE WCD from concept through commercial launch. This expertise is further bolstered by an experienced board and world-class investors with deep industry knowledge and recognized leadership in healthcare, medical technology, and adjacent, relevant industries.

Our Growth Strategies

To fully achieve our mission of providing innovative, intuitive medical technologies to protect and support at-risk patients, we intend to pursue the following growth strategies:

- ***Continue to capture share of the current WCD prescriptions in the U.S.*** In 2023, approximately 120,000 U.S. patients received a WCD, generating over $1 billion in revenues. Since its full commercial launch in August 2022, the ASSURE WCD has been worn by more than 20,000 patients, demonstrating its potential to address unmet clinical needs and disrupt the market. To build on this momentum, we are expanding our commercial organization, currently comprised of approximately 80 team members as of April 30, 2025, including regional sales leaders, territory managers, associate sales representatives, and clinical care specialists. This strategic expansion will enhance territory coverage, accelerate entry into new markets, and strengthen our ability to reach more patients. We see additional opportunities to drive compliance by prioritizing patient comfort and leveraging greater connectivity to prevent lapses in usage. To further advance utilization, we are responsibly fostering advocacy through collaborations with key opinion leaders, medical societies, and clinical advisory boards. Peer-to-peer education, supported by our medical consultants, plays a critical role in ensuring the ASSURE WCD's unique benefits are widely recognized and embraced within the medical community.

- ***Expand adoption of our Cardiac Recovery System platform in the U.S. to increase the penetration of the U.S. total addressable WCD market.*** Despite its established efficacy, WCD therapy remains underutilized in the U.S., primarily due to the limitations of the legacy device and gaps in awareness by healthcare providers of its broader diagnostic utility. As a result, many indicated patients do not receive a prescription and some choose not to wear the device. Additionally, many healthcare providers—even those familiar with WCD therapy—may not fully recognize the breadth of patients who could benefit from this life-saving technology. This underutilization highlights significant opportunities to expand awareness and adoption. To close this gap, we are implementing a targeted market-shaping strategy to emphasize the differentiated, clinically meaningful advantages of our Cardiac Recovery System platform. A key focus is educating healthcare providers on the benefits of WCD therapy for newly diagnosed heart failure patients in parallel to receiving guideline-directed medical therapy ("GDMT"). These efforts include direct engagement with healthcare providers to broaden awareness of eligible patient populations and position WCDs as integral to comprehensive, longer-term cardiac care. We are further advancing adoption through conference and tradeshow participation, developing key opinion leader partnerships to build advocacy, and increasing brand awareness with programmatic and industry-specific advertising.

- ***Build upon our strong base of clinical evidence.*** We are committed to building upon our strong foundation of clinical evidence demonstrating the efficacy of our ASSURE WCD and our broader Cardiac Recovery System platform. The ASSURE Patient Registry serves as a cornerstone for generating real-world evidence on our ASSURE WCD's performance, and we anticipate that it will support a robust cadence of publications. We believe our ongoing clinical initiatives will further validate the benefits of our system and may support stronger guideline recommendations for WCD therapy.

- ***Continue our payor engagement to broaden coverage and increase reimbursement.*** After successfully contracting with national payors, we are now focusing on state and smaller regional plans. Using historical data, we are identifying health plans with the highest volume of out-of-network referrals and patient fittings, prioritizing those with the greatest potential to increase our in-network coverage in the geographies that we serve. This targeted approach aims to shift a larger proportion of our business to in-network fittings, driving greater efficiency and accessibility for patients and providers. We are also engaging with payors to educate them of the benefits of our Cardiac Recovery System platform and to optimize reimbursement.

- ***Innovate our system and bolster our digital healthcare platform and data management capabilities.*** Our research and development initiatives are focused on introducing enhancements, new features, and improvements to our ASSURE WCD as well as our broader suite of digital solutions. We are continuously innovating to improve our WCD in order to expand utility to broader patient populations and to ensure greater reliability and patient confidence. From a regulatory perspective, our digital healthcare platform is separate from the ASSURE WCD and is treated as an FDA Class I 510(k)-exempt device, which allows us to rapidly innovate and upgrade the digital capabilities of our Cardiac Recovery System platform. As a robust digital health platform, our system is designed to provide data transparency, diagnostic flexibility, and workflow efficiencies. With features like configurable notifications and on-demand reporting, our system empowers healthcare providers to deliver more informed care. Through the ASSURE Patient Registry, we are maximizing the utility of this system to collect and leverage aggregated, de-identified data to build clinical evidence and support innovations in prediction, prevention, and therapy. For example, we seek to identify opportunities to develop advanced capabilities to deliver personalized clinical decision support. Our efforts to continuously innovate reflect our vision of leveraging our unique capabilities to deliver smarter, more effective solutions for cardiac patients.

- ***Drive gross profit expansion and operating leverage.*** Our gross profit has expanded significantly through our commercial launch with improvements in realized per-patient reimbursement and a lower cost per patient due to the increased number of patients we served. Rapid commercial payor contracting uptake has resulted in increased reimbursement from a higher mix of in-network patients. The reduction in cost of revenues per patient has come from volume increases in the number of fittings, re-use of our WCD fleet, our preventative maintenance program and manufacturing process enhancements. As the number of patients we serve increased, the cost of fitting per patient has decreased. In addition to improving gross profits, we believe our business model enables us to drive operating leverage. The operating cost to commercialize and service the ASSURE WCD is highly efficient with case coverage support and streamlined provider referral processes, including direct electronic medical record selection of the ASSURE WCD. We believe that this, coupled with expected gross profit expansion, will enable us to drive profitability as the company grows.

- ***Pursue expansion in international markets.*** While our current commercial focus remains on the U.S., international markets accounted for approximately 15% of the global $1.3 billion in WCD revenues in 2023. In select international markets, we estimate based on patient population data collected by various third-party industry sources that there are approximately 3.7 million people each year who experience an MI, are diagnosed with heart failure, have documented VT or VF, have an inherited genetic condition, or have had their ICD temporarily explanted. Among these patients, based on the same third-party industry sources, we estimate that approximately 1.8 million patients meet the indications for WCD therapy. Based on estimated average WCD wear prescription length in these international markets of 2.5 months per patient and estimated average reimbursement rate of $3,000 per patient per month derived from industry data and internal estimates, we believe this represents an approximately $14 billion total annual market opportunity outside the U.S. For a description of the international markets covered by this estimated market opportunity, see "Industry and Market Data." As of the date of this Annual Report, we have not received any regulatory approvals to commercialize our products outside of the U.S. and have not submitted any applications to obtain such regulatory approvals. However, we are currently planning to pursue CE Mark approval in Europe and, in the future, intend to strategically commercialize in select international countries. We anticipate Western Europe to be our initial focus due to favorable market dynamics and our goal is to obtain regulatory approvals to begin distributing our ASSURE WCD in certain markets in Western Europe within the next three years.

- ***Strategically pursue adjacent markets with new products offerings and differentiated services.*** The initial focus of our Cardiac Recovery System platform is to serve high-acuity patients who require both continuous monitoring and therapy. Beyond this, we are strategically positioned to expand our offerings to address a broader spectrum of cardiac patients, including those with atrial fibrillation, advanced hypertension, and other conditions, many of whom may remain undiagnosed without advanced monitoring solutions. Our long-term vision is to enable seamless transitions in monitoring, diagnostics, and therapy as patients' health conditions evolve. The launch of our ASSURE wearable ECG marks the first step in this expansion, providing monitoring and connectivity for patients no longer indicated for a WCD but who still require ongoing support. We received FDA approval for our ASSURE wearable ECG in May 2024 and began its limited commercial launch in September of 2024 in certain strategic U.S. markets.

Market Overview

Our Market Opportunity

SCA is a major public health problem and accounts for approximately 50% of all cardiovascular deaths in the U.S. For more than two decades, healthcare providers have prescribed WCDs to protect their patients at an elevated risk of SCA. Until the ASSURE WCD was approved by the FDA in July of 2021, the WCD market was served by a single competitor.

Since the approval of the first WCD in 2001, global WCD revenues have grown significantly, reaching over $1.3 billion in 2023, with approximately 85% of the revenues coming from the U.S. based on our analysis of third-party claims data and estimated average WCD wear prescription lengths and average reimbursement rates in the U.S. and in select international markets derived from industry data and internal estimates. Between 2021 and 2023, the volume of patients prescribed a WCD in the U.S. grew roughly 6% annually. We expect further penetration and growth of the WCD market, driven by increased awareness and education about WCD therapy, the expanded launch of our innovative and comprehensive solution, and the rapidly growing heart failure population, which will likely expand the number of patients at elevated risk of SCA and indicated for a WCD. Despite being available for over 20 years and proven effective in treating dangerous cardiac rhythms when worn by patients, the therapy has reached just 14% of eligible U.S. patients in 2023 based on data on patients indicated for a WCD and WCD prescription data from industry sources, highlighting a significant opportunity for growth. We attribute this low penetration to poor patient compliance, driven by the limitations of our competitor's device. The ASSURE WCD, as part of our broader Cardiac Recovery System platform, is designed to prioritize patient comfort and compliance, addressing common barriers to acceptance experienced by the only other commercially available WCD.

The WCD is indicated for use in patients who are at risk for SCA and are not candidates for, or refuse, an ICD. Medical guidelines recommend WCD use in those patients with a low LVEF and a recent MI, recent revascularization procedure or newly diagnosed nonischemic cardiomyopathy with heart failure symptoms. In addition, patients with documented VT or VF or an inherited genetic condition that places them at high risk for SCA, or patients who have had their ICD temporarily explanted are also indicated for WCDs. According to the AHA, approximately 1.8 million people in the U.S. each year experience a serious cardiac event, such as an MI, or are diagnosed with heart failure. Among these patients, around 800,000 patients have low LVEF, placing them at an elevated risk of SCA. Additionally, approximately 50,000 patients each year either have documented VT or VF, an inherited genetic condition, or have had their ICD temporarily explanted. Based on the foregoing annual incidences, the current Medicare reimbursement rate of $3,519 per patient per month as published in the CMS DMEPOS Fee Schedule in January 2025, and our average initial WCD prescription length of 3.4 months, we believe the total, annual addressable market in the U.S. for the ASSURE WCD is approximately $10 billion.

While our current commercial focus is on the U.S., approximately 15% of the global WCD revenues in 2023 were generated internationally, representing approximately $200 million, and that has primarily been concentrated in western Europe where the market has been most developed, as well as in Japan. In select international markets, we estimate based on patient population data collected by various third-party industry sources that there are approximately 3.7 million people each year who experience an MI, are diagnosed with heart failure, have documented VT or VF, have an inherited genetic condition, or have had their ICD temporarily explanted. Among these patients, based on the same third-party industry sources, we estimate that approximately 1.8 million patients meet the indications for WCD therapy. Based on estimated average WCD wear prescription length in these international markets of 2.5 months per patient and estimated average reimbursement rate of $3,000 per patient per month derived from industry data and internal estimates, we believe this represents an approximately $14 billion total annual market opportunity outside the U.S. For a description of the international markets covered by this estimated market opportunity, see "Industry and Market Data." As of the date of this Annual Report, we have not received any regulatory approvals to commercialize our products outside of the U.S. and have not submitted any applications to obtain such regulatory approvals. However, we are currently planning to pursue CE Mark approval in Europe and, in the future, intend to strategically commercialize in selected international countries. We anticipate Western Europe to be our initial focus due to favorable market dynamics and our goal is to obtain regulatory approvals to begin distributing our ASSURE WCD in certain markets in Western Europe within the next three years.

WCD Therapy for Patients at Elevated Risk of SCA

A WCD is a wearable, non-invasive monitor and miniaturized automated external defibrillator intended to perform the same tasks as an ICD without the need for an invasive surgical procedure. WCDs can automatically detect SCA and, if needed, safely deliver a defibrillation shock to return the patient's heart rhythm to normal, even when a patient is alone. A WCD is composed of a garment that is worn underneath regular clothing and a portable miniaturized automated defibrillator. Wires connect electrodes inside the garment to the monitor, which is carried in a small pack or shoulder bag. The electrodes continuously acquire a patient's heart rate and rhythm for evaluation by the automated defibrillator. If the monitor detects a potentially life-threatening arrhythmia, the WCD first alerts the patient via an audible alarm and then administers a shock, if needed.

WCDs are proven to work when worn. The Vest Prevention of Early Sudden Death ("VEST") trial, a randomized controlled trial sponsored by the National Institutes of Health and ZOLL Medical Corporation ("ZOLL"), evaluated the survival benefit of WCD therapy in post-MI patients with an LVEF of 35% or less. This trial compared the competitor WCD with GDMT versus GDMT alone. Although the initial intention-to-treat analysis of the WCD therapy in the VEST study published in 2018 did not indicate a statistically significantly lower rate in sudden arrhythmic death when compared to GDMT alone, the as-treated analysis showed a significantly lower percentage of patients died when they were wearing the WCD than when they were not. This suggested that poor patient compliance with wearing the WCD was a primary driver of the intention-to-treat-results in which 75% percent of patients were not wearing the WCD at time of death. In addition, to assess the impact of early discontinuation of the WCD, investigators performed a subsequent per-protocol analysis which censored patients after they stopped wearing the WCD. This per-protocol analysis published in 2020 demonstrated a significant reduction in arrhythmic death (62%, $p=0.02$) and all-cause death (75%, $p<0.001$) when comparing those patients who wore the WCD with those who did not wear the WCD. Similarly, registry studies have shown a survival rate of over 90% for SCA patients wearing a WCD after an appropriate shock.

WCDs are typically prescribed to patients immediately following an MI or heart failure diagnosis and serve as a bridge to recovery between the cardiac event and a longer-term treatment regimen. During this period, healthcare providers will optimize the patient's medical therapy while also waiting to see if the patient's LVEF improves. The expected wear duration of the WCD varies based on the patient indication, with the majority of our patients being prescribed the WCD for three months or longer.

The average age of our patients prescribed a WCD is 65 years. The population of patients indicated and eligible for receiving WCDs can be split into three main groups:

- ***Newly diagnosed heart failure with low LVEF.*** These patients represent approximately 56% of the addressable market at elevated risk for SCA. Current guidelines require a waiting period of three months before this patient population is eligible to be evaluated for an ICD. During this period, patients are typically treated with GDMT, which consists of a combination of up to four main drug classes. After three months, the patient's LVEF should be reassessed. If the patient's LVEF improves above 35%, neither the WCD nor an ICD is indicated. If the patient's LVEF remains at or below 35%, the patient may receive an ICD (per the current guidelines), or their healthcare provider may decide to continue with GDMT and the WCD while their heart continues to remodel. The expected WCD wear duration for patients in this population is three months or greater. According to the Heart Failure Society of America, approximately 6.7 million Americans over 20 years of age have heart failure, and the prevalence is expected to continue to rise. Of the newly diagnosed heart failure patients each year, approximately 50% have a low LVEF.

- ***Post MI with low LVEF.*** These patients represent approximately 38% of the addressable market at elevated risk for SCA. Current guidelines require an ICD waiting period of 40 days post MI or 90 days post coronary revascularization. Coronary revascularization includes procedures such as percutaneous coronary intervention, which is a minimally invasive procedure that restores blood flow from the inside using balloon catheters or stents, or coronary artery bypass grafting, which is a surgery where a provider creates a bypass around a blocked section of an artery. The expected WCD wear duration for patients in this population is 40 days or greater.

- ***Other.*** These patients represent approximately 6% of the addressable market and include patients with documented VT/VF, those indicated for an ICD but who have a contraindication to immediate placement, such as an infection or extraction, and patients with an inherited genetic condition. As there is no waiting period mandated by current guidelines for these indications, the expected WCD wear duration for patients in this population is variable, but likely less than 60 days.

Limitations of the Legacy, Commercially Available WCD

The WCD is indicated for use in patients who are at risk for SCA and are not candidates for, or refuse, an ICD. However, limitations of the only other commercially available WCD, such as patient comfort and false alarm rate, as well as gaps in awareness by healthcare providers of its broader diagnostic utility have led to underutilization of the therapy. Many indicated patients do not receive a prescription and some choose not to wear a WCD. Patients who choose not to wear a WCD are often left reliant on first responders or EMS in the event of a SCA. This reliance poses a significant risk, as only 16% of sudden cardiac events occur in public places where an automated external defibrillator might be available according to the American Heart Association. Based on data from the American Medical Association, the average time for EMS arrival is 7 minutes from the time of a 911 call, and often longer in rural communities. During this critical time, survival rates decline by 7% to 10% for every minute that passes.

This underutilization is reflected in the findings of the VEST trial, where 34% of patients had a median daily wear time of zero hours—indicating patients fully opted out of potentially life-saving therapy rather than wear the product. These results highlight the critical impact of patient compliance on WCD therapy and underscore the need for solutions that address the barriers preventing consistent wear. In feedback we have collected through directly engaging with patients and providers and customer feedback on public platforms, commonly cited reasons for patients or providers failing to use the LifeVest WCD on a consistent basis include:

- ***High frequency of false positive shock alarms.*** Prior to delivering a therapeutic shock, a WCD sounds an alarm that alerts the patient that a shock is about to be delivered. A false positive shock alarm occurs when the device detects a signal and mistakenly classifies it as a shockable rhythm. For the LifeVest WCD, this may occur due to noisy ECG channels resulting from a poor fit or from very fast non-shockable rhythms. False alarms are common with the LifeVest WCD and typically contribute to added anxiety for patients, sleep disturbances and restriction of daily routines. High false alarms also lead to patient frustration that may result in unnecessary calls to the prescribing provider. Even after recent algorithm design updates, the competitor reported that 46% of patients wearing their WCD still experienced false alarms. In addition, we believe that the interface of the LifeVest WCD is cumbersome, requiring the user to locate the monitor and press two buttons simultaneously to divert a shock during a false alarm event.

- ***Discomfort and unisex-only garment.*** The LifeVest WCD only comes in one style, intended to fit both genders, which has been reported to cause significant discomfort, especially for women given many must wear a bra over the garment, based on feedback we have collected through directly engaging with patients and providers and customer feedback on public platforms. Additionally, poorly fitting garments combined with ECG sensors attached by Velcro fasteners can lead to the electrodes digging into the patient's skin or flipping over, exacerbating discomfort and poor ECG contact.

- ***ECG noise and low utility data.*** Poor fit and ECG contact with only two channels may result in noisy ECG data, which in turn may contribute to false alarms and may limit the diagnostic utility of the LifeVest WCD remote monitoring functionality.

- ***Limited connectivity with patient.*** Patient connectivity is critical because it fosters ongoing engagement with the patient to improve compliance and ensures clinically-actionable data is transferred to healthcare providers in a consistent, timely, and easy manner. According to the LifeVest 5100 WCD operating manual, although the monitor contains a cell phone module for data transmission, patient data is generally only uploaded once per day, potentially reducing the diagnostic utility of patient data.

Our Solution

The ASSURE WCD is the cornerstone of our Cardiac Recovery System platform, a robust and extensible system integrating therapy, monitoring, and digital health solutions that represents the future of cardiac care. As a next generation of WCD therapy, the ASSURE WCD delivers a safe and effective solution for patients and was intentionally designed to enhance patient comfort and compliance and successfully resolve the key barriers to adoption associated with the only other commercially available WCD. The ASSURE WCD received FDA approval on July 27, 2021 for adult patients at elevated risk of SCA who are not candidates for, or decline, an ICD. As of April 30, 2025, the ASSURE WCD has been worn by over 20,000 patients.

In addition to the ASSURE WCD, our Cardiac Recovery System platform includes fully integrated digital solutions and services such as the ASSURE patient application, Kestra CareStation remote patient data platform, Heart Alert Services, and ASSURE Assist services, as well as the recently launched ASSURE wearable ECG. Cleared by the FDA on May 7, 2024, the ASSURE wearable ECG provides extended monitoring and valuable insights into a patient's heart function after they are no longer indicated for a WCD. This non-therapeutic platform supports cardiac recovery monitoring using many of the same familiar features as the ASSURE WCD, ensuring continuity and ease of use for both patients and clinicians.

The following paragraphs describe the several components of the ASSURE WCD, ASSURE wearable ECG and digital solutions and services that are all integrated and included as part of our Cardiac Recovery System platform.

Wearable Components

- ***SensorFit Garment.*** A breathable, lightweight fabric garment with embedded, non-adhesive, cushioned ECG sensors designed to move with the patient and capture high fidelity ECG signals. The SensorFit Garment was developed with an athletic and sportswear designer and is available in two styles and multiple sizes, intentionally designed to fit different gender and body types. The SensorFit Garment can be worn with both the ASSURE WCD and the ASSURE wearable ECG.

- ***Monitor.*** The primary electronic component that controls overall system operation and delivers 170J biphasic defibrillation therapy. The monitor leverages four channels of high-fidelity ECG signals—an industry first—to detect heart arrhythmia and, if needed, quickly and autonomously deliver appropriate electric defibrillation therapy to restore normal heart rhythm. It is powered by a rechargeable lithium-ion battery pack with two batteries, each having a minimum runtime of 24 hours. The ASSURE wearable ECG includes a separate compact monitor that fits into the existing SensorFit Garment.

- ***Therapy Cable.*** The ASSURE WCD includes a custom reusable cable that securely connects the garment to the monitor. This cable facilitates the integration of three defibrillation pads, which snap into conductive mesh pockets in the garment and release a defibrillation gel onto the patient's skin to prepare for the delivery of a defibrillation shock. Additionally, the system features the HeartPoint Alert Button, which attaches to the left or right shoulder strap of the garment. This button provides both tactile and audible feedback, allowing patients to check device status or divert a shock from an ergonomic location. Patients can also use the button to trigger a recording of their heart rhythm when experiencing symptoms like VT induced rapid heartrate, with the data becoming accessible to their care teams via the Kestra CareStation remote patient data platform. The ASSURE wearable ECG is equipped with a separate cable that connects the ECG front-end monitor to the portable battery pack. Both components fit seamlessly into the existing pockets of the SensorFit Garment, ensuring ease of integration and usability.

Accessories for the Patient

- ***Charger.*** Table-top charging station for the monitor's lithium-ion batteries. Also includes a USB port and a stand for charging mobile devices.

- ***Carry Pack.*** A wearable case designed to hold the monitor that can be worn easily clipped to a belt, around the waist, or over the shoulder to adapt to the patient's lifestyle.

Provider and ASSURE Patient Specialist Tools

- ***Programming Tablet.*** Used by our ASSURE patient specialist during the fitting and training process to program our ASSURE WCD for patient use. Wirelessly connects to the monitor to configure the system according to the patient's prescription and receives patient physiological data collected by the ECG electrodes to assess real-time electrode contact. This technology is a key tool used to ensure proper patient application during the fitting process.

Integrated Digital Solutions and Services

- ***Downloadable ASSURE Patient App.*** Transmits key patient data to the Company and care teams automatically and enables patients to track their physical activity and usage, record symptoms, watch educational videos, and access troubleshooting assistance.

- ***Kestra CareStation Remote Patient Data Platform.*** Available to healthcare professionals who follow patients wearing our ASSURE WCD and ASSURE wearable ECG. The Kestra CareStation remote patient data platform is a cloud-based monitoring platform that summarizes relevant patient data for healthcare providers, enabling them to conveniently track patient progress, receive configured alerts and notifications, and to bill Remote Physiologic Monitoring CPT codes.

- ***ASSURE Assist Services.*** Provides additional support for patients who experience a life-threatening heart rhythm by sending an alert via the ASSURE patient application to an EMS operator after a defibrillation shock or a high-rate heart event. The EMS operator attempts to contact the patient to determine if additional help is required and, if needed, may dispatch EMS to the patient's location.

- ***Heart Alert Services.*** Remote cardiac patient monitoring that enables timely identification of clinically significant arrhythmias, physiologic trends and other device alerts that may warrant intervention. This service is administered by a team of our cardiac device specialists utilizing the Kestra CareStation remote patient data platform.

Key Benefits of Our Solution

Our Cardiac Recovery System platform offers notable benefits and an improved user-experience that differentiates it from the only other commercially available WCD. These benefits include:

- ***Modern and advanced design to improve comfort, performance and maximize wearability.*** The design of our garments incorporates advancements in electronics, mobile technology, signal processing techniques, and fabrics. The garments were developed with an athletic and sportswear designer and are tailored for body inclusivity, offering two styles and a wide range of sizes. We believe that having separate, gender-specific designs is particularly important given women make up approximately 40% of SCA patients. Overall wearability is further supported by the results of our post-approval study which demonstrates a median wear time of greater than 23 hours per day. In addition to improving comfort and wearability, our unique garment design incorporates cushioned electrodes that are embedded in the fabric to improve electrode contact and, ultimately, improve ECG signal quality.

- ***High fidelity ECG leading to fewer false alarms.*** The ASSURE WCD is designed to minimize false alarms. The overall level of noise is reduced through use of resistive ECG electrodes that arrhythmias are cushioned and securely bonded to the fabric, custom shielded cables, and isolation circuitry. The ASSURE WCD also utilizes four channels of high-quality ECG, combined with API, a proprietary technology that adapts to the patient heart rhythm to filter out artifacts and improve performance even in a noisy environment. Our most recent FDA submission from ACE-PAS from July 2024, which includes data from 5,929 patients, reported a low false alarm rate with only 6% of our patients experiencing a false alarm. This is compared to 46% of patients for the competitor's device, as reported in the Journal of Interventional Cardiac Electrophysiology Study. Reduction in false alarms may lead to lower patient anxiety, improved patient satisfaction and increased patient compliance.

- ***Product innovations and integrated digital solutions and services supporting the patient throughout the cardiac care continuum.*** Our Cardiac Recovery System platform represents a comprehensive suite of proprietary wearable and fully integrated digital solutions and services for monitoring, diagnosing, and protecting patients through their cardiac recovery journey. We believe our Cardiac Recovery System platform represents a competitive advantage, with the goal of ultimately improving the prescriber and patient experience, maximizing patient comfort and compliance, and increasing adoption of our system. In addition, our Cardiac Recovery System platform's capabilities allow healthcare providers to identify other clinically significant arrhythmias.

- ***Improved energy delivery to enhance efficacy and safety.*** The ASSURE WCD delivers a 170 joule shock to better serve patients with higher defibrillation thresholds, compared to the competitor device which delivers a 150 joule shock. In addition, our system has a minimum defibrillation capacity of 25 shocks, providing a significant safety buffer for patients experiencing multiple cardiac events within a short time period, such as a VT storm, where a patient experiences multiple episodes of sustained VT within a short period of time.

Treatment with the ASSURE WCD

WCDs are generally prescribed by a general cardiologist, interventional cardiologist, cardiac electrophysiologist, cardiothoracic surgeon, hospitalist, nurse practitioner or physician's assistant. The healthcare provider determines the prescription length of a WCD. Once prescribed, we are responsible for the product delivery and can support fitting and training of the patient within 24 hours of the prescription.

The ASSURE WCD is intended to be continuously worn (except when bathing or showering), and can be easily removed and put back on by the patient. Patients receive two batteries for the monitor with a minimum runtime of approximately 24 hours. Patients are instructed to always charge one battery, replacing the monitor's battery at the end of each day. The patient is also typically provided two SensorFit Garments so they can remain protected while washing one of the garments. Our ASSURE WCD is designed to detect life-threatening rapid heart rhythms, specifically VF and VT, above a heart rate threshold programmable by the clinician. If the system determines a shock is needed to correct a heart rhythm, it will first vibrate and emit an audible alert notifying the patient they are about to receive a shock. If the patient does not respond by pressing the HeartPoint Alert Button, gel is released from the defibrillation pads onto the patient's back and chest, and a shock is delivered to restore a normal heart rhythm without further interaction required from the patient or bystander. The ASSURE WCD will continue to analyze the patient's heart rhythm and administer additional shocks, if needed. After a shock is delivered, we offer an additional layer of support for the patient through our ASSURE Assist services, which enables us to connect with the patient, a designated caregiver, or 911 emergency services. Our ASSURE WCD also analyzes the patient's heart rate for very slow rhythms. When certain non-shockable rhythms are detected, the rhythm is recorded, and an alert sequence is initiated to attract bystander attention, instructing them to call 911 and perform cardiopulmonary resuscitation.

At the conclusion of the wear period, the patient returns all components of the ASSURE WCD in a pre-paid shipping box that we supply.

Our Clinical Results and Studies

We are committed to generating clinical evidence to support the safety, efficacy and benefits of the ASSURE WCD, and we will continue to invest in developing clinical evidence to further demonstrate the advantages of our system. Preclinical and human clinical safety and effectiveness data provided the basis for PMA approval of the ASSURE WCD on July 27, 2021. The evidence included an extensive series of engineering verification tests and statistically robust animal studies, followed by two investigational device exemption ("IDE") human trials, ACE-DETECT and ACE-CONVERT. These combined studies evaluated 143 elevated risk SCA patients in the U.S. Currently, we are conducting the ACE-PAS as part of a broader on-going ASSURE Patient Registry. The real-world evidence in connection with ACE-PAS is collected by demographic and clinical characteristics being abstracted from medical history records provided with the Durable Medical Equipment order for the ASSURE WCD. The detected arrhythmias are automatically stored by the ASSURE WCD and then adjudicated by clinical experts in electrophysiology to assess rhythm and shock efficacy, if applicable. Device usage, which is measured by minutes worn, is automatically stored by the ASSURE WCD. We believe this collection of real-world evidence will generate additional publications, continue to increase awareness of WCDs as a proven therapy for elevated risk cardiac patients and further demonstrate the clinical differentiation of our ASSURE WCD.

Overview of Our Sponsored Clinical Trials

ACE-DETECT Trial

The ASSURE WCD Clinical Evaluation—DETECTion and Safety Study (ACE-DETECT—NCT03887052) was a multi-center, prospective, nonrandomized study at 10 sites across the U.S. The study's primary purpose was to evaluate the false positive shock alarm rate in patients at elevated risk for SCA. Eligible patients were adults (≥18 years old) with LVEF ≤40% and an active ICD. Complete study design and results of ACE-DETECT were published by Poole et al. in the Journal of Cardiovascular Electrophysiology (2022), *A Wearable Cardioverter Defibrillator with a Low False Alarm Rate.*

A total of 130 patients were enrolled in the ACE-DETECT study. The mean age was 61.2 ± 11.4 years and a majority were male (69%). All patients had been diagnosed with a cardiomyopathy, most having severely reduced LVEF. A history of atrial fibrillation, atrial flutter or atrial tachycardia was present in nearly half of the patients and approximately half of the patients had VF/VT previously detected by their ICD.

WCD shock therapy and shock alarms were disabled, but shock alarm markers were recorded. WCD parameters were programmed to nominal settings and ICD parameters were left to the discretion of the investigator. Patients were asked to wear the ASSURE WCD as much as possible for 30 days with exceptions allowed for showering or bathing. Clinical follow-ups were conducted weekly via phone; patients returned for final follow-ups at the end of the 30-day period. Both the WCD and ICD were interrogated to collect all stored arrhythmia episodes. WCD data also captured minutes of wear per day. Patients separately reported their perceived discomfort for eight anatomical regions on the torso at baseline and final follow-up. Relative comfort and ease of use were assessed after wear by patients who had prior experience wearing the LifeVest WCD.

The primary endpoint was the false positive alarm rate compared to a pre-specified objective performance goal of 0.29 per patient-day. False positive alarms were defined as a WCD shock alarm event marker associated with a rhythm other than VF/VT. Other outcome measures included a summary of WCD and ICD detected episodes, patient use compliance and adverse events determined to be at least possibly related to the device. Other detected episode types included true positive alarms, true positive detections and missed events.

Results

The primary endpoint performance goal was achieved. Three false positive alarms occurred in the cohort of 130 patients over a total of 3,501 patient-days, or 9.6 years, of device exposure. The observed false positive alarm rate was 0.00075 per patient-day or one false positive alarm every 1,333 days. This was well below the pre-specified performance goal of 0.29 per patient-day ($p<0.001$), equivalent to one false positive alarm every 3.5 days.

A total of 163 WCD episodes were recorded in 18 patients. Four of these episodes in three patients were adjudicated as VF/VT, true positive detections, and were also detected by the ICD. The remaining 159 WCD episodes in 17 patients were adjudicated as other rhythm with noise, uncertain rhythm with noise or atrial flutter without noise. Of the 159 WCD episodes, 156 closed before a shock alarm event marker was recorded because the noise was resolved, or the rhythm was determined to be non-shockable. In the remaining three episodes, a shock alarm event marker (false positive alarm) was recorded. Two of these episodes occurred during a ventricular paced rhythm in one patient and one during a sinus rhythm in another patient.

The ICDs detected a total of 106 episodes in 51 patients that were adjudicated as rhythm type VF/VT. These include the four WCD true positive detections discussed above, of which three received ICD therapy. The remaining 102 episodes were not detected by the WCD as they either did not have a duration of at least 20 seconds, or the rate was less than 170 bpm, which was below the programmed detection criteria.

Compliance

Patients were asked to wear our ASSURE WCD for a period of 30 days. Due to some patients returning our ASSURE WCD after the required 30-day period, patients wore our ASSURE WCD for a median of 31 days with a median daily use of 23 hours. Approximately 95% of patients had a median daily wear time of at least 22 hours. No significant differences were found in use by age or by sex.

Safety

None of the observed adverse events were classified as serious or unanticipated adverse effects. The most frequently reported events were mild skin irritation, followed by musculoskeletal-related complaints, such as muscle strain related to carrying the monitor. One patient reported severe musculoskeletal pain related to wearing the ASSURE WCD.

Comfort

Of the 130 patients enrolled, 127 completed the comfort survey at both the outset of the study, and at end of wear for eight anatomical regions on the torso. Of these 127, 89.0% reported no or slight discomfort at baseline, and 83.5% reported no or slight discomfort at end of wear.

Twenty-one of the 130 patients who participated in our ACE-DETECT clinical trial had previously worn the LifeVest WCD. Seventy-six percent (76%) of these patients reported that our ASSURE WCD was easier to use and more comfortable than the LifeVest WCD.

ACE-CONVERT Trial

The ASSURE WCD Clinical Evaluation – Conversion Efficacy Study (ACE-CONVERT- NCT04132466) was a prospective, nonrandomized study at two sites across the U.S. The trial was designed to evaluate shock conversion efficacy of the ASSURE WCD defibrillation waveform in humans. Eligible patients were adults (≥18 years old) undergoing electrophysiology procedures with planned induction of ventricular arrhythmias. Complete study design and results for ACE-CONVERT were published by Gleva et al. in the PLOS ONE journal (2023), *Defibrillation effectiveness and safety of the shock waveform used in a contemporary wearable cardioverter defibrillator: Results from animal and human studies.*

A total of 13 patients were enrolled in the ACE-CONVERT trial. The mean age was 55.3 ± 11.3 years and a majority were male (54%). All enrolled patients underwent new ICD implant or ICD replacement. Additionally, the enrolled patients had a mix of primary etiologies of cardiovascular disease, and all had comorbidities. The mean LVEF of enrolled patients was 46.8%.

VF was induced and the ASSURE WCD defibrillation shock was delivered on physician command. If the first shock was not successful, a second shock from the ASSURE WCD was delivered. If this second shock was not successful, the commercial external defibrillator was to be used to deliver a rescue shock.

The primary endpoint was cumulative first and second shock conversion rate with a performance goal of ≥ 94% based on prior studies. Other outcome measures included the first shock conversion rate and a summary of adverse events.

Results

The primary endpoint of cumulative first and second shock efficacy for conversion of ventricular fibrillation was 100%, exceeding the 94% pre-specified performance goal. On an intention-to-treat analysis, the first shock efficacy was 84.6%. A total of 15 shocks were delivered from the ASSURE WCD in 13 patients. No patient required rescue defibrillation.

Safety

Three adverse events occurred in three subjects (23.1%). All events were mild skin irritation from the adhesive defibrillation pads and all events resolved without further sequelae.

ASSURE Patient Registry and ACE-PAS

The ASSURE Patient Registry was established to enroll patients fitted with the ASSURE WCD after PMA approval. The primary goal of the registry was to cultivate a database to support endpoint analysis for our post-approval study, ACE-PAS (ACE-PAS, NCT05135403). The secondary goal of the registry was to provide data for observational studies and real-world evidence specifically related to performance of our ASSURE WCD under its intended use. All patients prescribed the ASSURE WCD in the United States after August 5, 2022 are included in the Registry. As of April 30, 2025, our ongoing registry has enrolled over 20,000 patients, and its findings further validate the results of ACE-DETECT and ACE-CONVERT.

Our latest FDA submission for ACE-PAS in July 2024 included 5,929 patients, of which 33% were female and the average age was 65. This real-world evidence demonstrated greater than 95% first-shock conversion efficacy. The percentage of patients experiencing one or more false positive alarms was only 6% (compared to 46% for the competitor's device) and median daily usage (excluding first and last wear day) was 23.2 hours per day.

Select Independent Group Studies

The Cleveland Clinic presented two abstracts at the AHA Scientific Sessions in November 2024. The abstracts are summarized below.

Abstract #1 Initial Real-World Experience with a Novel Wearable Cardioverter Defibrillator (Tanaka-Esposito et al.)

The first abstract evaluated patient compliance and efficacy in a cohort with balanced gender representation, as well as performance of the ASSURE WCD in minimizing noise artifact leading to false alarms and unnecessary shocks. The data was gathered through a medical chart review of 55 patients prescribed the ASSURE WCD at the Cleveland Clinic between January 2023 and April 2024 as part of a retrospective analysis. All device-detected arrhythmia episodes were manually adjudicated by a Board-Certified Electrophysiologist.

The median daily wear time was 22 hours per day. Female representation was 49%, significantly greater than prior reports of competitive WCD usage. Four episodes of sustained VF/VT were detected in four patients. A single shock terminated VF/VT in two, while asymptomatic VT was diverted by the other two patients who were only aware because of the device alerting of an imminent shock. One shock for hemodynamically unstable atrial fibrillation with heart rate >200bpm was delivered and deemed necessary. There were no unnecessary shocks and no deaths occurred while wearing the ASSURE WCD. A total of 10 patients experienced a median of one alarm during the WCD wear period. Nearly 97% of the alarms were associated with a significant tachyarrhythmia, with only 3% due to noise artifact.

Patient compliance with the ASSURE WCD was high in this real-world observational study with equal representation of both sexes. The ASSURE WCD effectively terminated sustained hemodynamically significant tachyarrhythmias, emitted few false alarms due to noise, and resulted in no unnecessary shocks.

Abstract #2 Clinical Impact of Ventricular and Supraventricular Arrhythmia Detection with a Novel Wearable Cardioverter Defibrillator (Tanaka-Esposito et al.)

The second abstract evaluated the occurrence of ventricular and atrial arrhythmia detected by the ASSURE WCD and the clinical consequences of these diagnoses. The data was gathered through a medical chart review of 55 patients prescribed the ASSURE WCD at the Cleveland Clinic between January 2023 and April 2024 as part of a retrospective analysis. Rhythm classification of all device-detected and patient-initiated episodes displayed with four independent ECG channels was manually adjudicated by a Board-Certified Electrophysiologist.

Four patients (7%) had sustained VF/VT detected by the ASSURE WCD and all received a secondary prevention ICD. Notably, two patients were asymptomatic and became aware of their condition only after the device alerted them to an imminent shock. Both patients showed significant recovery of EF >35% during the wear period. Moreover, had sustained VF/VT not been detected by the ASSURE WCD for these patients, neither would have met the indication for a preventative ICD. Additionally, six patients (11%) had AF/AFL recorded by the ASSURE WCD. In three patients, AF/AFL manifested in a paroxysmal pattern, which was a new diagnosis for each of them. All were at an elevated risk for stroke with median CHADS-VaSC ≥4.e

The authors concluded that in addition to its primary utility for preventing SCA, the ASSURE WCD can detect unnoticed yet clinically-significant arrhythmia. The detection of sustained ventricular arrhythmias in asymptomatic, elevated risk patients enabled secondary prevention of SCA. Similarly, documenting AF/AFL in high-risk patients could significantly reduce their risk.

Sales and Marketing

We generate revenue primarily from the lease of our ASSURE WCD as part of our Cardiac Recovery System platform. Patients are prescribed our ASSURE WCD by a healthcare provider for a specific length of time. Once an order is made, we fit the patient for the WCD in a hospital, clinic or home setting. We directly bill various third-party payors for the lease of our product for the duration of its use by patients.

Our commercial strategy and our direct sales force primarily target general cardiologists, interventional cardiologists, cardiac electrophysiologists, and advanced practice providers within hospitals and clinics in the U.S., as these represent the primary healthcare providers managing the care of patients at elevated risk of SCA and who typically make decisions regarding WCD prescriptions. Our sales, marketing and product education efforts are focused on capturing market share and driving adoption by offering healthcare providers an innovative, safe and effective WCD alternative.

Our commercial team is comprised of approximately 80 direct sales representatives as well as more than 40 sales and clinical support professionals as of April 30, 2025 with deep expertise in cardiac rhythm management as well as established relationships in the cardiology and electrophysiology fields. This team is responsible for developing sales territory business plans, targeting and opening new accounts, and driving adoption of our Cardiac Recovery System platform. Once a healthcare provider prescribes our ASSURE WCD to a patient, our direct sales team is supported by a contracted team of over 300 APSs who assist patients with fitting and training. These specialists assist with fitting patients with the appropriate size and gender-specific option of the ASSURE WCD and provide training on its proper wear and use. At fitting, we deliver our ASSURE WCD from our distribution network to the patient. When a patient's wear time has concluded, the device is returned for reprocessing and reintroduction into the distribution network.

Based on data from Definitive Healthcare and our internal estimates, we estimate that there are approximately 2,700 hospitals in the U.S. that actively prescribe WCDs as of November 30, 2024. We further estimate based on our internal analysis of the same data, that approximately 80% of U.S. WCD prescription volume is generated by approximately 30% of these hospitals. We have initially focused on establishing key customer accounts and expansion into high WCD-volume areas. We plan to continue to further scale our commercial team to reach a wider range of healthcare providers across the entire U.S. Our commercial team has been successful at driving adoption of the ASSURE WCD with hospitals ranging from top academic medical centers to community hospitals. As healthcare providers gain experience with our ASSURE WCD, we expect to capture more volume and further establish the WCD as the standard of care protection for patients at elevated risk of SCA.

Having established our commercial presence in the U.S., one of our future initiatives is to expand internationally where similar unmet patient needs remain. The prevalence of single payor health systems outside of the U.S. provides an opportunity to efficiently penetrate large pools of net new eligible lives. As of April 30, 2025, we have not received any regulatory approvals to commercialize our products outside of the U.S. and have not submitted any applications to obtain such regulatory approvals. However, we are currently planning to pursue CE Mark approval in Europe and, in the future, intend to strategically commercialize in select international countries. We anticipate Western Europe to be our initial focus due to favorable market dynamics and our goal is to obtain regulatory approvals to begin distributing our ASSURE WCD in certain markets in Western Europe within the next three years.

Third Party Coverage, Reimbursement and Payor Relations

We derive nearly all our revenue from the direct billing of various third-party payors, including Medicare, Medicaid, private payors and other healthcare-related organizations, for the lease of our ASSURE WCD to patients as part of our Cardiac Recovery System platform. Additionally, any costs associated with our solution that are not covered by third-party payors, such as co-payments, are billed directly to the patient by our team.

We have strong, established payor relationships, including some of the largest private payors in the U.S. Based on our estimates, we are contracted or enrolled as an in-network healthcare provider with payors currently covering over 285 million lives as of April 30, 2025. These contracts allow us to be an in-network healthcare provider for patients, enabling them to access our system at a competitive rate and copay. These established payor relationships reduce our administrative burden in authorization and billing for our ASSURE WCD. Our payor relationships are supported by our revenue cycle management platform, which streamlines reimbursement processes by ensuring claims are accurately prepared and submitted according to individual payor requirements, facilitating timely collections. These capabilities are an important element in our strategy to increase operational efficiency and support both patient and healthcare provider satisfaction.

WCDs are reimbursed as Durable Medical Equipment under the DMEPOS Fee Schedule and our ASSURE WCD is eligible for payment under the existing HCPCS code K0606. The ASSURE WCD is the only WCD officially code-verified by the Medicare PDAC. Code K0606 falls under the Capped Rental monthly reimbursement rate for lease payments. K0606 is a valid 2024 HCPCS code defined as an automated defibrillator, with integrated ECG analysis, garment type. The Medicare allowable for code K0606 is approximately $3,519 per month for months one to three and reduces 25% to $2,639 for months four to thirteen published in the CMS DMEPOS Fee Schedule in January 2025, while the maximum Medicare allowable over the course of their lease is approximately $36,950. The standard patient co-insurance is 20%. We have been issued a Medicare Provider Number by the CMS, which enables us to bill Medicare for reimbursement for our ASSURE WCD. Reimbursement rates for WCDs have shown favorable trends, with published Medicare reimbursement rates having increased at a CAGR of 4.7% from 2021 to 2025.

Private payor reimbursement rates are generally in line with Medicare rates and vary based on several factors, including but are not limited to, the payor, geographic location, and contract terms. Most large, national payors have established coverage policies in place to cover WCD therapy.

Outside the U.S., reimbursement levels vary by country and by region. Some countries or regions may require us to gather additional clinical data before granting coverage and reimbursement for our ASSURE WCD. We intend to work with payors to obtain coverage and reimbursement approval in countries and regions we intend to enter in the future, including select countries in Western Europe such as Germany and France. We estimate that these two countries include approximately 600,000 WCD-indicated patients, representing a sizeable opportunity for our international expansion.

Research & Development

We are committed to investing in research and development activities to advance our Cardiac Recovery System platform as well as develop and commercialize next-generation products. Over a decade of investment in our research and development capabilities has resulted in a highly experienced and capable innovation engine. Designed as a scalable platform, our Cardiac Recovery System platform supports future extensions and enhancements, enabling the integration of new therapeutic and diagnostic capabilities to support our existing fleet of ASSURE WCDs. The platform also enables data collection from patients that will support training of automated algorithms to detect and predict clinically relevant events. We also intend to leverage the Class I nature of our broader suite of digital solutions to continually enhance the digital capabilities of our Cardiac Recovery System platform, offering greater data transparency, diagnostic flexibility, and workflow efficiency.

Through the ASSURE Patient Registry, we are maximizing the utility of this system to collect and leverage aggregated, de-identified data to build clinical evidence and support innovations in prediction, prevention, and therapy. For example, we aim to develop advanced capabilities to deliver personalized clinical decision support. Our efforts to continuously innovate reflect our vision of leveraging our unique capabilities to deliver smarter, more effective solutions for cardiac patients.

In addition to serving high-acuity patient populations, we believe we are positioned to expand our offerings to a broader range of cardiac patients, including those with previously undiagnosed atrial fibrillation, advanced hypertension, and other cardiac conditions. Our long-term vision is to deliver a comprehensive and cohesive ecosystem of monitoring, diagnostics, and therapy that seamlessly supports patients as their health conditions evolve. The launch of our ASSURE wearable ECG is the first step in this effort, designed for patients no longer indicated for a WCD but who still require monitoring, patient support, and connectivity.

We have established a tenured and dedicated research and development team comprised of highly skilled engineers and program managers with extensive experience in external and implantable defibrillation, as well as more than a decade of experience creating our next generation wearable medical device. In addition, we have strong software development resources capable of innovating advanced algorithms, user interfaces, and connectivity solutions to enhance the functionality and user experience of our Cardiac Recovery System platform.

For the fiscal years ended April 30, 2025 and 2024, our research and development expenses were $15.7 million and $15.5 million, respectively.

Manufacturing and Supply

We utilize third-party manufacturing and supply partners to manufacture our ASSURE WCD and its components. We believe outsourcing the manufacture of our ASSURE WCD provides the expertise and capacity required to effectively and efficiently scale production based on the demand. We select our third-party partners to ensure that our ASSURE WCD and its components are of the highest quality and adhere to all applicable regulations. We employ a rigorous manufacturing and supplier partner assessment, qualification, and selection process to target partners that meet the requirements of the FDA and the International Organization for Standardization, as well as quality standards supported by internal policies and procedures. Our quality assurance program monitors and maintains manufacturing and supplier partner performance through qualification and periodic reviews and audits. Our tier one third-party manufacturing and supplier partners, which supply our SensorFit Garment and assemble our ASSURE WCD, are also independently audited by the FDA. We rely on a single or limited number of suppliers for certain components of our ASSURE WCD. We seek to manage single-source supplier risk by regularly assessing the quality and capacity of our partners, as well as by qualifying alternative partners and developing contingency plans for responding to disruptions.

Our third-party manufacturing and supplier partners inspect, test, and assemble our ASSURE WCD and its components under strict manufacturing processes supported by internal policies and procedures. Our third-party partners are all in compliance with current Good Manufacturing Practice regulations applicable to our ASSURE WCD. Both of our tier-one third-party manufacturing and supplier partners are headquartered in the U.S. and provide products from their facilities based in the U.S.

We utilize a lease business model where certain components of our ASSURE WCD are reused for multiple patients. At the end of a prescription, the patient ships our ASSURE WCD back to our third-party manufacturing partner, who disposes of the single-use items, such as our SensorFit Garment, and then inspects, tests, and recertifies the other components for use by another patient. The reusable nature of our ASSURE WCD allows each device to be deployed multiple times, thereby reducing the ongoing demand for new inventory. These reconditioning processes are validated and FDA approved. We also have preventative maintenance and repair processes that can further extend the life each ASSURE WCD.

We utilize an inventory distribution strategy where we pre-emptively deploy our ASSURE WCD and its components to a central distribution location, as well as 15 additional strategically-located third-party warehouses across the U.S. This is done to ensure our ASSURE WCD is available for immediate use no matter where a patient is located. Inventory stock is allocated based on historical ASSURE WCD utilization in that territory, as well as sales forecasting to account for growing demand. Using this strategy, ASSURE WCD components are typically replenished within a 24-hour window. We believe this distribution model optimizes the availability of our ASSURE WCD inventory, supports growth, and minimizes the impact of localized weather, transportation delays, or other disruptions.

Our tier-one third-party manufacturing and supplier partners also operate facilities in Asia and Europe, equipped with localized manufacturing and reconditioning capabilities. These facilities can leverage our proven systems and processes in the U.S. to support our future international needs.

Competition

We believe that our Cardiac Recovery System platform, including our ASSURE WCD and wearable ECG, provide us with an advantage relative to other competing solutions. However, our currently marketed products and any future products we commercialize will be subject to competition. The WCD market has historically been served by a single incumbent commercial product, the LifeVest WCD marketed by ZOLL. Most recently, a new market entrant received FDA approval for an adhesive-based external defibrillator.

We remain confident that our Cardiac Recovery System platform will continue to be advantaged in the market due to our differentiated and integrated features enabling superior patient comfort, compliance, connectivity and support.

We believe that the primary factors in developing a competitive WCD include:

- product safety and effectiveness;
- detection algorithm sensitivity, specificity and false alarm rate;
- patient physical and psychological comfort and ease of use;
- ability to integrate within the patient monitoring ecosystem;
- quality, breadth and ongoing generation of clinical evidence;
- technological innovation, product enhancements and speed of innovation;
- capital required to achieve PMA approval as well as to facilitate post-commercial initial inventory; and
- regulatory status and speed to market.

Additionally, we believe that the following factors are required to commercially compete in the WCD market:

- patient and healthcare provider connectivity and engagement;
- post-event monitoring and emergency support;
- effective marketing to and education of patients, physicians, other healthcare providers and hospitals;
- company, product and brand recognition;
- device reusability and durability;
- reimbursement and payor coverage;
- complexity in building up the RCM capabilities and logistics to support broad-based;
- commercialization and service levels; and

- recruitment and retention of a qualified and experienced sales force.

Intellectual Property

In order to remain competitive, we must develop and maintain protection for the proprietary aspects of our technologies. We rely on a combination of patent, copyright, trademark and trade secret laws, and confidentiality and invention assignment agreements to protect our intellectual property rights. The protection of intellectual property has been and remains a priority for us.

We rely on utility patent, design patent or other similar protection and registration mechanisms through various jurisdictions that relate to our ASSURE WCD. As of April 30, 2025, we have rights to 237 issued U.S. and foreign patents, consisting of 205 issued patents in the U.S., 16 issued patents in the European Union, 7 issued patents in Japan, 4 issued patents in Australia and 5 issued patents in China. Additionally, as of April 30, 2025, we had 130 pending published and unpublished U.S. and foreign patent applications, consisting of 117 pending published and unpublished patent applications in the U.S., 5 pending published patent applications in the European Union, 3 pending published patent applications in Japan, 2 pending published patent applications in Australia and 3 pending published patent applications in China. Assuming all required fees and other charges are paid, the earliest expiry date for issued patents owned or used by us is in July 2025.

We rely on trademarks, service marks, trade names and brand names, such as our registered or applied for trademarks for the marks ASSURE, CARDIAC RECOVERY SYSTEM, KESTRA and KESTRA CARESTATION to distinguish our products from the products of our competitors. We have registered or applied for the ASSURE mark in the United States and selected locations internationally, but we may be unable to obtain, maintain, protect or enforce our trademarks in the markets where we currently or may in the future operate.

We also rely upon trade secrets, know-how, continuing technological innovation, and licensing opportunities, to develop and maintain our competitive position. However, trade secrets and know how may be difficult to protect. We protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with third party contract manufacturers, suppliers, employees, consultants and others who may have access to proprietary information that we own or license for use.

There is no active litigation involving any of our patents or other intellectual property rights and we have not received any notices of patent infringement. We may be required to enforce or defend our intellectual property rights against third parties in the future. For additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us, see “Risk Factors—Risks Related to Our Intellectual Property.”

Government Regulation

Our products and our operations are subject to extensive and ongoing regulation by the FDA, the CMS and other federal and state authorities in the United States. Regulations cover virtually every critical aspect of a medical device company’s business operations, including research activities, product development, quality and risk management, contracting, reimbursement, medical communications, and sales and marketing. In addition, we are subject to regulation by CMS, state law, and private payor requirements as a DME supplier with respect to our product leasing and payor billing operations. In the United States, the Federal Food, Drug and Cosmetic Act (the “FDCA”) and the implementing regulations of the FDA govern, among other things, product design and development, pre-clinical and clinical testing, premarket notifications and clearance or approval, investigational device exemption, establishment registration and device listing, product manufacturing, quality systems, import and export, product labeling, product storage, medical device reporting, recalls and field safety corrective actions, advertising and promotion, revenues and distribution, and post-market surveillance (including complaint handling and adverse event reporting). Our business is subject to various federal, state and local regulations, including, but not limited to, ISO 13485, ISO 14971 and the FDA’s QSR contained in 21 CFR Parts 801, 803, 807, 812, 814, and 820.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a premarket notification under Section 510(k) of the FDCA or a PMA. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the QSR, establishment registration and product listing, reporting of adverse events, and truthful and non-misleading labeling, advertising and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, special labeling requirements, post-market surveillance, patient registries and FDA product-specific guidance documents.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device.

Devices deemed by the FDA to pose the greatest risks, such as life-sustaining or life-supporting devices, those that are of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury, are placed in Class III, requiring approval of PMA. The PMA process is more stringent, time-consuming and expensive than the 510(k) clearance process. Some pre-amendment devices are unclassified, but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed.

Our ASSURE WCD is a Class III device that has received a PMA. For the purpose of our PMA, our digital health platform is separate from our ASSURE WCD and is treated as a FDA Class I 510(k)—exempt device.

510(k) Clearance Marketing Pathway

The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or another commercially available device that was cleared through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. FDA collects user fees for certain medical device submission and annual fees and for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is not "substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirement as described below. After a device receives 510(k) clearance or *de novo* classification, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), *de novo* request or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained or a *de novo* request is granted. In these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

De Novo Classification Process

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a route to market for low-to-moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Pursuant to the Food and Drug Administration Safety and Innovation Act (the "FDASIA") manufacturers may request *de novo* classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not-substantially-equivalent determination. *De novo* classification requests are subject to the payment of user fees.

Under FDASIA, FDA is required to classify the device within 120 days following receipt of the *de novo* request, although the process may take significantly longer. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. If FDA grants the *de novo* request, the device may be legally marketed in the United States. However, the FDA may reject the request if the FDA identifies a legally marketed predicate device that would be appropriate for a 510(k) notification, determines that the device is not low-to-moderate risk, or determines that General Controls would be inadequate to control the risks and/or special controls cannot be developed. After a device receives *de novo* classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another *de novo* request or even PMA approval.

PMA Pathway

Class III devices require a PMA before they can be marketed, although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA application, the applicant must demonstrate that the device is safe and effective, and the PMA application must be supported by extensive data, including data from pre-clinical studies and human clinical trials. The PMA application must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. The PMA process is burdensome, and in practice, the FDA's review of a PMA application may take up to several years following initial application.

Following receipt of a PMA application, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA application, although in practice, the FDA's review often takes significantly longer, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be safe, effective, reliable or accurate to the FDA's satisfaction;
- the data from pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant, its clinical trial data and clinical sites, as well as its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with FDA requirements, including the Quality System Regulation, or QSR. PMA applications are also subject to the payment of user fees, which for fiscal year 2021 includes a standard application fee of $365,657.

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

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

Clinical Trials

Clinical trials are almost always required to support a PMA application and are sometimes required to support a 510(k) submission. We completed clinical trials for our ASSURE WCD in March 2020 and received our PMA for our ASSURE WCD on July 27, 2021 We are currently engaged in a post-approval clinical study of our ASSURE WCD and may in the future engage in additional clinical trials and other clinical initiatives to support additional indications and stronger guideline recommendations for WCD therapy and to obtain regulatory approvals to market our products in new markets. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements and obtain Institutional Review Board, or IRB approval when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an IRB for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient and does not require an IDE application, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. The FDA's approval of an IDE application allows clinical testing to go forward, but it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria. All clinical trials must be conducted in accordance with applicable FDA regulations including for example those that govern good clinical practices, IRB review, investigational device labeling, prohibitions on promotion, and recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. Clinical trials that meet certain requirements must be entered into the clinical trials registry at clinicaltrials.gov.

The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients, sponsor or study sites do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to the products that are part of our trial;
- IRBs and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- the sponsor or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;
- third-party clinical investigators have significant financial interests related to the sponsor or the study that the FDA deems to make the study results unreliable, or the company or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers and suppliers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process, as well as maintain various records;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for uncleared, unapproved or "off-label" uses and impose other restrictions on labeling;
- requirements related to promotional activities;
- FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;

- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of a supplement for certain modifications to PMA devices;

- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;

- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

- complying with the federal law and regulations requiring Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and

- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Additionally, the FDA may require us to conduct post-market surveillance studies or establish and maintain a system for tracking our products through the chain of distribution to the patient level. The FDA enforces regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors.

The FDA has broad regulatory compliance and enforcement powers. Failure to comply with applicable regulatory requirements can result in enforcement actions by the FDA and other regulatory agencies. These may include any of the following sanctions or consequences:

- warning letters or untitled letters that require corrective action;

- fines and civil penalties;

- unanticipated expenditures;

- delays in approving or refusal to approve future products;

- suspension or withdrawal of FDA 510(k) clearance or PMAs that have already been granted;

- product recall, withdrawal, administrative detention or seizure;

- interruption of production, including partial suspension or total shutdown;

- operating restrictions, including refusal to grant export approvals for devices being shipped to foreign markets;

- injunctions, consent decrees; and

- criminal prosecution.

We and our contract manufacturers, specification developers and some suppliers of components of our products, are also required to comply with current good manufacturing practice requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and it includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA evaluates compliance with the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes that we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down such manufacturing operations, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees.

Fraud and Abuse Laws

In addition to FDA restrictions, there are numerous federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs.

Federal Anti-Kickback and Self-Referral Laws

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything at less than its fair market value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a review of all its relevant facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of (or purchases, or recommendations related to) federal healthcare covered business, the Anti-Kickback Statute has been implicated and potentially violated.

The penalties for violating the federal Anti-Kickback Statute include imprisonment for up to five years, fines of up to $25,000 per violation and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which do not have the same exceptions and apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs. Further, the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act ("PPACA"). Specifically, under the Anti-Kickback Statute, the government must prove the defendant acted "knowingly" to prove a violation occurred. The PPACA added a provision to clarify that with respect to violations of the Anti-Kickback Statute, "a person need not have actual knowledge" of the statute or specific intent to commit a violation of the statute. This change effectively overturns case law interpretations that set a higher standard under which prosecutors had to prove the specific intent to violate the law. In addition, the PPACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

We plan to provide the initial training to providers and patients necessary for appropriate use of our ASSURE WCD through training and educating patients, cardiologists, cardiac electrophysiologists, key opinion leaders from these disciplines and medical societies. We may hire or contract with a network of ASSURE patient specialists to assist with fitting and training patients and such specialists will be reimbursed for their services at fair market value.

Noncompliance with the federal Anti-Kickback Statute could result in our exclusion from Medicare, Medicaid or other governmental programs, restrictions on our ability to operate in certain jurisdictions, and civil and criminal penalties.

Federal law also includes a provision commonly known as the "Stark Law," which prohibits a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," including a company that furnishes durable medical equipment, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs. We believe that we have structured our provider arrangements to comply with current Stark Law requirements. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Federal False Claims Act

The Federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the Federal False Claims Act have made it easier for private parties to bring "qui tam" whistleblower lawsuits against companies under the Federal False Claims Act. Penalties include fines ranging from $5,500 to $11,000 for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

There are other federal anti-fraud laws that that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Additionally, HIPAA established two federal crimes in related to healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

Civil Monetary Penalties Law

In addition to the Anti-Kickback Statute and the civil and criminal False Claims Acts, the federal government has the authority to seek civil monetary penalties ("CMPs"), assessments, and exclusion against an individual or entity based on a wide variety of prohibited conduct. For example, the Civil Monetary Penalties Law authorizes the imposition of substantial CMPs against an entity that engages in activities including, but not limited to: (1) knowingly presenting or causing to be presented, a claim for services not provided as claimed or which is otherwise false or fraudulent in any way; (2) knowingly giving or causing to be given false or misleading information reasonably expected to influence the decision to discharge a patient; (3) offering or giving remuneration to any beneficiary of a federal healthcare program likely to influence the receipt of reimbursable items or services; (4) arranging for reimbursable services with an entity which is excluded from participation from a federal healthcare program; (5) knowingly or willfully soliciting or receiving remuneration for a referral of a federal healthcare program beneficiary; or (6) using a payment intended for a federal health care program beneficiary for another use. Noncompliance can result in civil money penalties of up to $10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

State Fraud and Abuse Provisions

Many states have also adopted some form of anti-kickback and anti-referral laws and a false claims act. We believe that we are in compliance with such laws. Violations of state fraud and abuse laws may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from state healthcare programs, disgorgement, and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Physician Payment Sunshine Act

Transparency laws regarding payments or other items of value provided to healthcare providers and teaching hospitals may also impact our business practices. The federal Physician Payment Sunshine Act requires most medical device manufacturers to report annually to the Secretary of Human Health Services financial arrangements, payments, or other transfers of value made by that entity to physicians and teaching hospitals. The payment information is made publicly available in a searchable format on a CMS website. We will need to dedicate significant resources to establish and maintain systems and processes in order to comply with these regulations. Failure to comply with the reporting requirements can result in significant civil monetary penalties.

Data Privacy and Security Laws

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information, applicable to health plans, healthcare clearinghouses and certain health care providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as service providers of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. In performing our activities as a DME supplier, we are a covered entity under HIPAA, and as a result, must implement a HIPAA privacy and security program in accordance with HIPAA requirements. In addition, we are a business associate with respect to our billing distribution partnership with a third-party DME provider, to which we will provide assistance with preparing and reviewing claims to be submitted to payors, and as a result, must comply with the HIPAA privacy and security requirements set forth in our business associate agreement. With regard to our other operations, we are not a covered entity or a business associate, though we may be subject to certain HIPAA requirements in our collection of individually identifiable health information from patients. HITECH also created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from HIPAA and each other in significant ways and may not have the same effect. At the state level, the California Consumer Privacy Act, as amended by the California Privacy Rights Act, for example, affords California residents expended privacy rights and provides for civil penalties for violations and a private right of action related to certain data security breaches; and Washington's My Health My Data Act extends privacy protections for Washington residents for health data beyond what HIPAA covers, granting Washington residents with more control over their health data by allowing them to access, delete, and restrict its use. Similar legislations have been advanced in other states as well as in Congress.

The Federal Trade Commission (the "FTC") also has authority to initiate enforcement actions against entities that mislead customers about HIPAA compliance, make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information, or engage in other unfair practices that harm customers or that may violate Section 5 of the FTC Act. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce under the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities.

Our business is also subject to the Bermuda Personal Information Protection 2016 Act ("PIPA"). The PIPA regulates how any organization in Bermuda may use personal information. PIPA will be brought fully into effect on January 1, 2025. After this date, organizations in Bermuda will be required to comply with a combination of principle based and prescriptive rules. Prescriptive rules for in scope organizations (i.e., those that use personal information, noting "use" is broadly defined) include a requirement to only use personal information where a legal condition applies, a requirement to appoint a data privacy officer, a requirement to provide all individuals with a privacy notice that must contain at a minimum certain required information and requirement to understand and comply with individual rights around access, rectification and erasure.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations, research protocols, and other obligations, any actual or perceived failure by us or our employees, representatives, contractors, consultants, or other third parties to comply with such requirements or adequately address data privacy and security concerns, even if unfounded, could result in, among other adverse impacts, damage to our reputation, loss of customer confidence in our security measures, withdrawal or withholding of customer consent for using patient data, government investigations, and enforcement actions and litigation and claims by third parties, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act (the "FCPA") prohibits U.S. corporations and their representatives from offering, promising, authorizing or making corrupt payments, gifts or transfers to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

U.S. Centers for Medicare and Medicaid Services; Coverage and Reimbursement

In the United States, our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our products and related services. Medicare is a federal program administered by CMS through fiscal intermediaries and carriers. Available to individuals aged 65 or over, and certain other individuals, the Medicare program provides, among other things, healthcare benefits that cover, within prescribed limits, the major costs of most medically necessary care for such individuals, subject to certain deductibles and copayments.

CMS has established guidelines for the coverage and reimbursement of certain products, supplies and services. In general, in order to be reimbursed by Medicare, a healthcare product or service furnished to a Medicare beneficiary must be reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. The methodology for determining coverage status and the amount of Medicare reimbursement varies based upon, among other factors, the setting in which a Medicare beneficiary received healthcare products and services. Any changes in federal legislation, regulations and policy affecting Medicare coverage and reimbursement relative to our products could have a material effect on our performance.

CMS also administers the Medicaid program, a cooperative federal/state program that provides medical assistance benefits to qualifying low income and medically needy persons. State participation in Medicaid is optional, and each state is given discretion in developing and administering its own Medicaid program, subject to certain federal requirements pertaining to payment levels, eligibility criteria and minimum categories of services. The coverage, method and level of reimbursement varies from state to state and is subject to each state's budget restraints. Changes to the coverage, method or level of reimbursement for our products may affect future revenue negatively if reimbursement amounts are decreased or discontinued.

All CMS programs are subject to statutory and regulatory changes, retroactive and prospective rate adjustments, administrative rulings, interpretations of policy, intermediary determinations, and government funding restrictions, all of which may materially increase or decrease the rate of program payments to healthcare facilities and other healthcare providers, including those paid for our products.

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may seek regulatory approval by the FDA or other government authorities. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. With respect to our ASSURE WCD, and any other product candidates we may develop, to the extent they are approved, the distribution of our ASSURE WCD and other future product candidates will depend, in part, on the extent to which third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers, and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the accuracy of claims and overall cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive clinical studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our revenues, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the U.S. healthcare system. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products.

For example, in March 2010, the Affordable Care Act (the "ACA") was enacted in the United States. The ACA contains a number of significant provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act includes a provision that decreased the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the "individual mandate," to $0, effective January 1, 2019. On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. On June 17, 2021, the United States Supreme Court dismissed this challenge to the ACA without specifically ruling on its constitutionality.

On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA -mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices; however, on December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted.

In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. In addition, CMS published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, particularly in light of the current presidential administration which has stated its intent to make some changes to the regulatory landscape overseen by, for example, the HHS, including the FDA, any of which could, among others, change product approval pathways, or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures.

Cost Containment Measures

Our products are directly distributed by our sales personnel to our healthcare provider customers. We may be directly reimbursed by third-party payors, including Medicare, Medicaid, private payors and other healthcare-related organizations, for the lease of our devices. There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the U.S. healthcare system. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products.

On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, and subsequent legislation, these Medicare sequester reductions are suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. On April 14, 2021, the Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes, extended the sequestration suspension from April 1, 2021 to December 31, 2021.

On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, recently, under the former Trump administration, 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 and state legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. At this time, it is unclear whether the current administration will continue to pursue legislative and/or administrative measures to control product costs.

Additionally, 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. CMS also continues to implement a competitive bidding program ("CBP") enacted under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 that applies to certain suppliers of durable medical equipment, prosthetics, orthotics and supplies. Under the CBP, suppliers that operate in a designated bidding area are required to submit electronic bids for certain products; CMS awards contracts to suppliers that offer the best price and meet applicable quality and financial standards. At this time, it is unclear whether the CBP will have an impact on the pricing or the commercialization of our current or future products.

Executive Officers of the Company

Set forth below is a list of names and ages of the executive officers of the Company indicating all positions and offices with the Company held by each such person and each person's principal occupations or employment during the past five years unless otherwise noted. Our executive officers do not have a specific term of office. No director or executive officer has a "family relationship" with any other director or executive officer of the company, as that term is defined for purposes of this disclosure requirement. There is no understanding between any executive officer or director and any other person pursuant to which the executive officer was selected.

Name	Age	Titles and Business Experience
Brian Webster	61	President, Chief Executive Officer (CEO) and Director. Mr. Webster has served in these roles at Kestra Medical Technologies, Ltd. since 2021 and at Kestra Medical Technologies, Inc. since 2016. Mr. Webster has over 32 years in the medical device industry, including 10 years as President and Chief Executive Officer of Physio-Control, Inc. Mr. Webster is a founder of our company and has been building the company as Chief Executive Officer since 2014, when the predecessor company Physio-Control Development Corporation became fully independent from Physio Control Inc., following its acquisition by Bain Capital, LLC in 2012. Mr. Webster previously held executive positions including vice president roles in operations, sales, and marketing at Physio-Control. Mr. Webster brings broad knowledge of emergency medicine, the cardiac field, and the external defibrillation industry. Mr. Webster received his Bachelor of Arts in Business from the University of Puget Sound and his M.B.A. from Seattle University. We believe Mr. Webster is qualified to serve on our Board due to his more than 32 years of leadership experience in the medical device industry, including his pivotal role as founder and Chief Executive Officer in building Kestra Medical Technologies, Ltd.
Vaseem Mahboob	55	Chief Financial Officer (since 2021). Mr. Mahboob has over 23 years of finance leadership experience. Prior to joining our company, Mr. Mahboob served as the Executive Vice President, Chief Financial Officer and Chief Operations Officer of DIH Technology Ltd. from 2020 to 2021. From 2015 to 2020, Mr. Mahboob served as the Chief Financial Officer of ENDOLOGIX Inc. ENDOLOGIX Inc. filed for Chapter 11 bankruptcy protection with the United States Bankruptcy Court for the Northern District of Texas in July 2020. Mr. Mahboob was also a member of the board of directors and the audit committee chair for INSYS Therapeutics from 2018 to 2019. Prior to ENDOLOGIX Inc., Mr. Mahboob held various positions at GE Healthcare, including as the Chief Financial Officer of the Global Magnetic Resonance Business from 2006 to 2010, as Chief Financial Officer of the Global Ultrasound Business from 2010 to 2012, as Chief Financial Officer of the Eastern and African Growth Markets from 2013 to 2015 and as Chief Financial Officer of GE Healthcare IT from June 2015 to September 2015. Mr. Mahboob received his M.B.A. in Financial Markets and Institutions and Information Systems from the Jacobs School of Management at the State University of New York.
Traci S. Umberger	62	General Counsel, Chief Administrative Officer and Director. Ms. Umberger has served in these roles at Kestra Medical Technologies, Ltd. since 2021 and at Kestra Medical Technologies, Inc. since 2016. Ms. Umberger has over 34 years of life sciences representation, including 10 years as General Counsel and Chief Administrative Officer at Physio-Control, Inc. Ms. Umberger is a co-founder of our company and has been building the company since 2014, when the predecessor company Physio-Control Development Corporation became fully independent from Physio Control Inc. following its acquisition by Bain Capital, LLC in 2012. Ms. Umberger currently has responsibility for the company's Legal, Compliance, and Human Resources functions. Previously, Ms. Umberger practiced in the areas of commercial and healthcare litigation, representing physicians and hospitals. Ms. Umberger received her Bachelor of Arts in Psychology/English from the University of British Columbia and her J.D. from the University of British Columbia. We believe Ms. Umberger is qualified to serve on our Board based on her extensive legal career to date and knowledge of our company through her role as our General Counsel and Chief Administrative Officer.

Al Ford	54	Chief Commercial Officer (since 2025). Mr. Ford has 20 years of experience driving global strategic sales, marketing, business development, product development, and commercial operations primarily within the medical device industry. Mr. Ford served as Chief Commercial Officer of Axonics, Inc. (Nasdaq: AXNX), a medical device company with implantable technologies to treat bladder and bowel disorders, from 2017 to 2025, Chief Commercial Officer, General Manager and Senior Vice President of Global Sales & Marketing at Cardiac Science Corporation from 2015 to 2017. Mr. Ford received his B.S. in Marketing and his M.S. in International Business from Saint Joseph's University.

Team Members and Human Capital Resources

As of April 30, 2025, we had over 330 team members, all of which were located in the United States. None of our team members is subject to a collective bargaining agreement or represented by a trade or labor union, and we have not experienced any material work stoppages to date. We consider our relationship with our team members to be good, and we are committed to inclusion and policies and procedures to maintain a safe work environment.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our team members. We believe our success depends on our ability to attract, retain, develop and motivate diverse highly skilled personnel. In particular, we depend upon the personal efforts and abilities of the principal members of our senior management to partner effectively as a team, and who provide strategic direction, develop our business, manage our operations and maintain a cohesive and stable work environment. We also rely on qualified sales managers and other skilled employees, who possess technical expertise in operations, scientific knowledge, engineering and quality management experience, in order to operate our business successfully.

Our compensation program is designed to retain, motivate and, as needed, attract highly qualified executives. Accordingly, we use a mix of competitive base salary, cash-based annual incentive compensation, performance-based equity compensation awards and other employee benefits.

Corporate Information

Our principal office is located at 3933 Lake Washington Blvd Northeast, Suite 200, Kirkland, Washington, 98033. We use our website at kestramedical.com to communicate important information about our company, including news releases and financial information. We also make available on our investor relations webpage, free of charge, copies of our Securities and Exchange Commission ("SEC") filings and submissions, which can be found at the SEC's website, www.sec.gov, as soon as reasonably practicable after electronically filing or furnishing such documents with the SEC. Shareholders may also request copies of these documents by writing to our Corporate Secretary at the address above. Website references are provided throughout this document for convenience only. The contents of these websites do not constitute a part of this Annual Report and shall not be deemed incorporated by reference into this Annual Report unless expressly noted.

Item 1A. Risk Factors.

Investing in our common shares involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes thereto, before deciding to invest in our common shares. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the market price of our common shares could decline, and you could lose all or part of your investment. Please also see "Special Note Regarding Forward-Looking Statements".

Risks Related to Our Business

We have a limited operating history, which may make it difficult for you to evaluate our current business and its likelihood of success and viability. If we are unable to manage our business and any fluctuations in our business effectively, our business and growth prospects could be materially and adversely affected.

We are a commercial-stage, wearable medical device and digital healthcare company focused on transforming patient outcomes in cardiovascular disease using monitoring and therapeutic intervention technologies that are intuitive, intelligent, and connected. We have developed and are commercializing our Cardiac Recovery System platform, a comprehensive and advanced system that integrates monitoring, therapeutic treatment, digital health, and patient support services into a single, unified solution. The cornerstone of our Cardiac Recovery System platform is the ASSURE WCD. We completed clinical trials for our ASSURE WCD in March 2020, received our PMA for our ASSURE WCD on July 27, 2021 and fully commercially launched our ASSURE WCD in August 2022. Until the ASSURE WCD was approved by the U.S. FDA, the WCD market was served by a single competitor, which was providing the only other commercially available WCD for over 20 years and as a result, has a significantly longer commercial track record than our company. We are continuing to develop the capabilities and infrastructure to increase our commercial organization, distribution, supply chain and revenue cycle management capabilities to further strengthen our market penetration. However, there is no assurance as to the extent to which we will be able to continue to scale our business and expand our market penetration. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. We may be unsuccessful for a number of reasons, including:

- responses of our primary competitor, and other start-up or large companies that are emerging or may emerge as competitors in the future, who have or may develop more technologically advanced products, stronger relationships with healthcare providers, and greater capital, marketing and other resources than our company;
- limitations on our ability to demonstrate the differentiation and advantages of our ASSURE WCD or other products we may develop in the future and their relative safety, efficacy and ease of use over other products in the market;
- the limited size and geographic scope of our sales and marketing capabilities as compared to our competitors and the learning curve required for our direct sales force personnel to become effective in processing prescriptions of our products and capturing market share;
- our inability to continue to provide products that are clinically effective, meet our desired product profile and are capable of being supplied at quantities and at a cost that addresses the clinical needs and commercial opportunities we target;
- our inability to obtain sufficient and timely supplies of components necessary to manufacture our products or secure second source suppliers if our primary suppliers are unable to fulfill our orders;
- our inability to timely make improvements to our products in response to feedback from patients or from the medical community;
- insufficient financial or other resources to support our commercialization efforts; and
- the introduction and market acceptance of new, more effective or less expensive competing products and technologies.

In addition, as a company with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. The challenges we face in managing our evolving business place significant demands on our management, financial, operational, manufacturing, technological and other resources. In particular, rapid and continued growth increases the challenges involved in a number of areas, including recruiting and retaining sufficient skilled personnel, maintaining consistent and high-quality products and customer service to meet increased demand for our products, developing revenue cycle management, inventory management, payor contracting, supply chain and information technology infrastructure that can support the growing scale of our business and ensuring our compliance with the laws and regulations of new markets we may enter into. We are continuing to transition from a company with a research and development focus to a company with increasingly significant commercial activities. As we continue to grow, we may also need to invest significant resources to improve and expand our portfolio of technologies and solutions, scale up our manufacturing capabilities through our third-party suppliers and expand our distribution resources, including our network of APSs, which we may not be able to do so in a cost-effective manner or at all. We cannot assure you that any changes in scale, related quality or compliance assurance will be successfully implemented or that appropriate personnel will be available to facilitate the management of and changes to our business. If we do not adequately address these risks and difficulties, our ability to support and further grow our current commercial activities may be negatively impacted.

In addition, our business is affected by general macroeconomic and business conditions worldwide, including the impacts of inflation, increased interest rates, market instability and evolving regulation. If we do not effectively manage our business through the various challenges we face, we may not be able to execute on our business plan, respond to competitive pressures, take advantage of market opportunities, satisfy patient requirements or maintain high-quality products, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We expect our financial condition and results of operations to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We have a history of net losses, and there is no assurance as to when we will achieve profitability, if at all, even as we continue to grow and scale our business. As part of such continued growth, we may need to raise equity or debt financing in the future. If we are unable to raise capital when needed, we may be forced to delay or scale back our growth plans, which could materially and adversely affect our results of operations and prospects.

The development, manufacturing and distribution of medical technologies is capital intensive. From our inception in 2014 through the full commercial launch of our ASSURE WCD in August 2022, we made significant investments in research and development efforts, developing and running clinical trials to obtain regulatory approval for our ASSURE WCD, and enabling manufacturing activities in support of our product development efforts to prepare for the commercialization of our ASSURE WCD. Since the commercial launch of our ASSURE WCD, we have incurred, and expect to continue to incur, significant expenses related to our sales, marketing, product manufacturing and distribution functions and processes and establishing the infrastructure, including revenue cycle management capabilities, necessary to continue to support its commercialization. We have incurred net losses since our inception in 2014 largely due to these expenses. We had net losses of $113.8 million and $94.1 million for the fiscal years ended April 30, 2025 and 2024, respectively, and as of April 30, 2025, we had an accumulated deficit of $520.2 million.

In order to achieve profitability, we will need to continue to make investments to successfully grow and scale our business while managing our expenses. We expect to continue to incur losses for the next several years and there is no assurance as to when we will achieve profitability, if at all, or whether we will be able to maintain profitability, if achieved, in the future. Factors that have impacted, and that we expect will continue to impact, our ability to achieve profitability and our capital requirements include:

- our continued investments in recruiting, training and retaining our direct sales force and supporting our commercial infrastructure as our operations continue to grow;
- our ability to manage the costs of manufacturing and distributing our ASSURE WCD and increase our gross profits through supply chain efficiencies and manufacturing process improvements;
- changes in reimbursement rates for WCDs, including as a result of improved market access and shifts in patient mix towards patients with longer wear duration;
- the availability of reimbursement from payors, including Medicare, Medicaid and private payors, to cover the cost of our products;
- the effectiveness of our revenue cycle management infrastructure and our ability to timely and accurately collect payments from payors, which may be impacted by seasonality due to the resetting of patient healthcare insurance plan deductibles at certain times of the year;

- our ability to establish and maintain collaborations with technology, commercial and clinical partners on favorable terms, if at all; and

- the scope, prioritization and number of our research and development initiatives.

We expect our expenses to continue to increase as our business grows, including as a result of our ongoing efforts to grow our sales and commercial organization, increase our brand awareness through programmatic and industry-specific advertising, conduct clinical studies to expand the clinical evidence supporting the efficacy of our ASSURE WCD and our broader Cardiac Recovery System platform and engage in research and development initiatives to enhance and broaden our suite of solutions. Our efforts to continue to grow and scale our business may not be successful or may prove more expensive than we currently anticipate, and we may not succeed in increasing our revenue sufficiently to offset these higher expenses or at all. In addition, as a public company, we will incur significant additional expenses that we did not incur as a private company, including expenses related to audit, legal, regulatory, compliance, director and officer insurance, investor and public relations, and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange.

While we believe that our existing cash and cash equivalents will be sufficient to fund our operating and capital needs for at least the next 12 months, we may need additional funding, which may include future equity and debt financing. We may experience lower than expected cash generated from operating activities or greater than expected capital expenditures, cost of revenue or operating expenses, and we may require additional funding in the future to further our growth plans. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to further commercialize our ASSURE WCD. Any disruptions in the financial markets or other adverse macroeconomic conditions may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms favorable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or current or future products or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, financial condition, results of operations and prospects. Additionally, if we are capital constrained and unable to raise capital when needed, we may not be able to meet our obligations, which may limit or halt our ability to continue operations, or we may be forced to delay or scale back our growth plans, including our initiatives to increase market adoption of our ASSURE WCD and further our market penetration, which could materially and adversely affect our results of operations and prospects.

We generate revenue primarily from the lease of our ASSURE WCD as part of our Cardiac Recovery System platform, and we are therefore highly dependent on our ASSURE WCD for our continued success.

We generate revenue primarily by leasing our ASSURE WCD to patients for a fixed amount on a month-to-month basis as part of our Cardiac Recovery System platform. We expect that revenues from our ASSURE WCD and associated products and services delivered as part of our Cardiac Recovery System platform will continue to account for nearly all of our revenue for the foreseeable future. Our ability to execute our growth strategy and become profitable will significantly depend upon educating healthcare providers on the clinical efficacy and diagnostic utility of WCD therapy, broadening healthcare providers' awareness of WCD-eligible populations, advancing the adoption of our ASSURE WCD and increasing our brand awareness, including through peer-to-peer education and effectively engaging with payors to educate them of the benefits of our Cardiac Recovery System platform and optimize reimbursement. We may incur significant expenses in our efforts to engage with healthcare providers to broaden awareness of the benefits of our ASSURE WCD, and there is no assurance that such efforts will lead to increased adoption of our ASSURE WCD or that we will generate sufficient revenue to offset the expenses incurred in connection with such efforts. In addition, some healthcare providers may have a preference for other treatment options or may be reluctant to alter their practice patterns and undergo the training and other transition processes, including updating billing procedures, required to enable them to prescribe our ASSURE WCD to their patients. Additionally, patients may decide to not utilize, and some payors may decide not to provide reimbursement for, our ASSURE WCD if, among other potential reasons, they believe our pricing is too high or that alternative devices are either more clinically efficacious, cost-effective or more comfortable to use than our product.

We derive nearly all our revenue from the direct billing of various third-party payors, including Medicare, Medicaid, private payors and other healthcare-related organizations, for the lease of our ASSURE WCD to patients as part of our Cardiac Recovery System platform. We also bill patients for co-insurance payments and deductibles. As such, our cash flows and our ability to generate revenue depend on our ability to obtain and maintain broad in-network payor coverage of and optimize reimbursement for our ASSURE WCD. Patients are unlikely to use our product unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. As a result, healthcare providers may be reluctant to adopt our product for patients covered by non-contracted insurance policies because of the uncertainty surrounding reimbursement. Our gross profit is also affected by payors' reimbursement rates for our ASSURE WCD, as well as our ability to increase our reimbursement realization. Although reimbursement rates for WCDs have generally increased in recent years, there is no assurance that they will remain at or increase from historical levels. A decrease in reimbursement rates for our ASSURE WCD, or the introduction of other limitations to payors' coverage for our ASSURE WCD, could adversely affect our results of operations and financial condition. For more information on factors that may affect our reimbursement rates, see also "—Our commercial success depends in part on the extent to which governmental authorities and health insurers provide coverage and adequate reimbursement levels. Failure to obtain and maintain coverage and adequate reimbursement for our products could limit our ability to market those products and make it difficult for us to operate profitably." Additionally, as we continue to scale our business, our ability to achieve profitability will depend on our efforts to increase our reimbursement realization for our ASSURE WCD, including through achieving manufacturing process improvements and supply chain efficiencies. If we are unable to achieve such efficiencies, including as a result of increased costs of manufacturing and distributing our products such as increased pricing of materials and electronics components, labor rates, shipping rates and inflation, our ability to grow our business could be adversely affected.

Our business is dependent upon healthcare providers, hospitals and patients adopting our solutions, and if we fail to obtain and maintain broad adoption, our business would be adversely affected.

Our ability to execute our growth strategy and become profitable will depend on our ability to educate healthcare providers, hospitals and patients on the benefits of our ASSURE WCD and associated products and services delivered as part of our Cardiac Recovery System platform over the existing product and services in the market. There is no assurance that the products and solutions we offer through our Cardiac Recovery System platform or other potential products we may develop in the future will achieve and maintain widespread market adoption over the long term or at all. Market acceptance of the solutions and services we provide through our Cardiac Recovery System platform or other potential products we may develop may be negatively impacted if healthcare providers, hospitals and patients do not perceive WCDs, including our ASSURE WCD, to be useful, safe, effective, reliable and trustworthy or do not perceive the advantages of ASSURE WCD over our main competitor, or if we are unable to provide adequate customer service and sufficient training to patients or effectively harmonize our products with healthcare providers and processes in which we operate. We are currently engaged in a post-approval study of our ASSURE WCD and may in the future engage in additional clinical trials and other clinical initiatives to support additional indications and stronger guideline recommendations for WCD therapy and to obtain regulatory approvals to market our products in new markets. Any studies we, or third parties that we sponsor, may conduct may be expensive, time consuming and may not yield positive results. Negative clinical research results from past, current or future clinical studies or negative publicity or an adverse change to published or unpublished guidelines or recommendations from third parties (including, without limitation, key opinion leaders, medical societies and clinical advisory boards) relating to the use, clinical benefit or risk profile of WCDs in general, including our ASSURE WCD, generally could result in negative perception of the efficiency and safety of our products and affect our brand and reputation. Healthcare providers play a significant role in determining the course of a patient's treatment and, as a result, the type of product that will be used to treat a patient. If we are not successful in convincing healthcare providers of the merits of our ASSURE WCD, they may not prescribe it or recommend it to other healthcare providers and we may be unable to increase revenue, sustain our growth or achieve profitability.

Furthermore, we believe healthcare providers may not adopt our ASSURE WCD unless they determine, based on their personal experience, recommendations from other healthcare providers, available clinical data and published peer-reviewed journal articles, that our ASSURE WCD is an attractive alternative to our competitors' products. Healthcare providers may be hesitant to adopt or switch to our ASSURE WCD for the following reasons, among others:

- long-standing relationships with competitors and distributors that sell other products and their competitive responses and negative selling efforts aimed at our product;
- lack of experience with our products and concerns that we are relatively new to the WCD industry, or concerns that our competitors have greater resources than our company;
- reluctance to change to or use new products;
- perceived liability risk generally associated with the use of new products;

- adverse clinical evidence regarding the clinical benefits of our ASSURE WCD and WCDs in general;

- perception that the clinical evidence for our products is not sufficient or that our products are unproven or experimental; and

- the time commitment that may be required to gain familiarity with and establish the infrastructure, including billing processes, required to adopt our products.

In addition, the medical device industry's relationship with healthcare providers is under increasing scrutiny by federal, state and other foreign and domestic government agencies. In recent years, Congress, the Department of Justice (the "DOJ"), the Office of the Inspector General (the "OIG") of the Department of Health and Human Services (the "HHS") and the state attorneys general have issued subpoenas and other requests for information to, as well as initiated enforcement actions against and entered into settlements with, medical device manufacturers, primarily related to financial arrangements with healthcare providers, regulatory compliance and marketing and product promotional practices. Furthermore, the federal government and certain state governments have enacted legislation to limit and/or increase the transparency of interactions between medical device manufacturers and healthcare providers, pursuant to which we are or may be required by law to disclose certain payments and other transfers of value to healthcare providers or marketing expenditures both nationally and those licensed by certain states. Our failure to comply with laws, rules and regulations governing our relationships with healthcare providers, or an investigation into our compliance by the DOJ, the HHS OIG, state attorneys general or other government agencies, could significantly harm our business.

Additionally, adoption of our products may be directly influenced by a number of financial factors, including the extent to which our products have broad coverage from third-party payors and have well-established reimbursement codes and adequate reimbursement rates. The efficacy, safety, performance, patient compliance benefits and cost-effectiveness of our solutions, on a stand-alone basis and relative to competing products and/or services will determine the availability and level of reimbursement received by us. There is no assurance that we will be able to obtain and maintain adequate levels of coverage and reimbursement for our products. In particular, as we seek to expand into new markets in the future, including select international markets, we may be subject to different, and potentially conflicting requirements, to obtain the necessary coverage and reimbursement for our products. Complying with various coverage and reimbursement requirements in each jurisdiction in which we distribute our products may be costly, and we may face difficulty in adequately adjusting our business to comply with any diverging requirements, which could hinder our ability to expand our market reach or launch new products. In order to generate revenue, we will need to target potential prescribers of our products, such as hospitalists, cardiologists and other healthcare providers, as well as potential end-users of our products with whom we have had little contact, which may require significant marketing and sales efforts. Even if we succeed in increasing adoption of our products by healthcare providers and hospitals, maintaining and creating new relationships with third-party payors and developing and commercializing new features or indications for our products we may be unable to generate sufficient revenue to achieve or sustain profitability.

The revenue we generate from distributing our ASSURE WCDs also varies, in part, based on the wear time of patients who are prescribed our ASSURE WCD. We bill third-party payors for patient use of our ASSURE WCDs based on their wear time. Although we have designed our ASSURE WCD to enhance the comfort of patients and allow for more extended wear times as part of their longer-term cardiac care, the actual wear time of our ASURE WCDs can vary due to a number of factors, many of which are beyond our control. The emergence of new medical technologies, therapies and other medical advances may reduce the need to wear a WCD for an extended period. Patients may shorten their wear time due to any inconvenience or discomfort from wearing a WCD or because they do not perceive the need to wear a WCD for an extended period of time and are willing to take on the heightened risk of experiencing a SCA from not wearing a WCD. Additionally, healthcare providers may elect to prescribe our ASSURE WCD for a more limited period of time because of concerns of reduced patient compliance with longer wear times, difficulties with obtaining reimbursement from third-party payors for extended wear times, changes in medical guidelines on recommended wear times or other clinical factors that result in the need to shorten or terminate the use of a WCD, such as a patient requiring an ICD sooner than anticipated. If the average wear time of our ASSURE WCD does not increase or is reduced over time, this may limit the revenue we generate, which may negatively impact our results of operations, cash flows and the growth of our business.

Our commercial success depends in part on the extent to which governmental authorities and health insurers provide coverage and adequate reimbursement levels. Failure to obtain and maintain coverage and adequate reimbursement for our products could limit our ability to market those products and make it difficult for us to operate profitably.

In the United States and in other countries, patients who are prescribed medical treatment generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. In the United States, third-party payors include government healthcare programs such as Medicare, Medicaid, TRICARE and the Veterans Administration and private payors. Coverage and adequate reimbursement from payors are critical to new product acceptance. As we expand our business and enter into new markets, we will need to enter into new payor contracts with national, state, regional and international payors. There is no assurance that we will be able to enter into new payor contracts, or renew our existing payor contracts upon their expiration, on terms acceptable to us, or at all.

Government healthcare programs and other third-party payors may change their coverage and reimbursement policies, as well as payment amounts, in a way that could prevent or limit reimbursement for our products, which would significantly harm our business. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including macro-economic developments, as well as the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- cost-effective;
- supported by peer-reviewed publications and key opinion leaders;
- appropriate for the specific patient; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that typically requires us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. There is no assurance that we will be able to maintain adequate coverage and reimbursement for our ASSURE WCD in each of the markets it is distributed.

Market adoption of our products also depends on whether we are able to obtain reimbursement codes so that our products are eligible for reimbursement by payors such as Medicare and Medicaid. Our ASSURE WCD is currently reimbursable under the Healthcare Common Procedure Coding System ("HCPCS") code K0606, which is well-established. HCPCS is a standardized system used by all U.S. insurance payors to provide descriptions of healthcare equipment, supplies and services. HCPCS codes are used by payors to identify what services are being billed and to assign payment rates to those specific services. HCPCS codes for durable medical equipment are assigned and managed by the CMS and a Medicare contractor responsible for Pricing, Data Analysis and Coding ("PDAC"). New products and product revisions must go through a coding verification process to confirm the products meet the requested HCPCS definitions. CMS or its contractor can also review and revise coding assignments if they believe a product no longer meets the assigned HCPCS definition. If the PDAC contractor determines one of our products does not meet the current HCPCS definition, it could remove all coding or assign a different HCPCS code with a lesser payment rate. This could have an adverse impact on our reimbursement rates, results of operations and cash flows.

We were issued a Medicare Provider Number by the CMS, which enables us to bill Medicare for reimbursement for our ASSURE WCD as an accredited DME supplier to the extent the claim meets medical necessity and coverage requirements set forth by Medicare. Determinations of which products or services will be reimbursed under Medicare can be developed at the national level through a national coverage determination ("NCD"), by CMS, or at the local level through a local coverage determination ("LCD"), by one or more of the regional Medicare Administrative Contractors ("MACs"), which are private contractors that process and pay claims on behalf of CMS for different regions. In the absence of an NCD, the MAC with jurisdiction over a specific geographic region will have the discretion to make an LCD and determine the fee schedule and reimbursement rate within the region, and regional LCDs may not always be consistent in their determinations. Currently, no NCD has been issued with respect to products reimbursed pursuant to HCPCS Code K0606, so reimbursement for our ASSURE WCD will depend on the medical necessity and coverage requirements set forth with respect to K0606 in the relevant LCD. Reductions in reimbursement rates, if enacted, could have a material adverse effect on our business. Further, a reduction in coverage by Medicare could cause some commercial third-party payors to implement similar reductions in their coverage or level of reimbursement of our products. Given the evolving nature of the healthcare industry and on-going healthcare cost reforms, we may be subject to changes in the level of coverage for our products by government healthcare programs, once approved for commercial sales, and unfavorable coverage determinations at the national or local level could adversely affect our business and results of operations.

Additionally, healthcare reform legislation or regulation may be proposed or enacted in the future that may adversely affect such policies and amounts. Changes in the healthcare industry directed at controlling healthcare costs or perceived over-utilization of cardiac monitoring products and services in ambulatory care environments could reduce the volume of demand for our products. If more healthcare cost controls are broadly instituted throughout the healthcare industry, the volume of cardiac monitoring solutions prescribed could decrease, resulting in pricing pressure and declining demand for our products.

Our operating results fluctuate significantly and may not fully reflect the underlying performance of our business.

Our results of operations, including our revenue, profitability and cash flow, may vary significantly in the future and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuation in quarterly and annual results may decrease the value of our common shares. Factors that may cause fluctuations in our quarterly and annual results include, without limitation:

- market acceptance of our ASSURE WCD and other products and solutions we may develop in the future;
- our ability to obtain marketing approval for our ASSURE WCD in international markets we enter in the future or for other products and solutions we may develop in the future, and the timing and scope of any such approvals we may receive;
- the availability of reimbursement for our ASSURE WCD or any future product candidates at acceptable reimbursement rates;
- the availability of reimbursement for our products and solutions through government healthcare programs at acceptable reimbursement rates;
- the cost of manufacturing our ASSURE WCD or any future product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers and other vendors;
- our ability to attract, hire, train and retain qualified personnel;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our future pricing policies or those of our competitors;
- the level of demand for our ASSURE WCD or any future product candidates that receive necessary marketing and other regulatory approvals, which may vary significantly;
- general economic, industry and market conditions or extraordinary external events, such as a recession;
- changes in our regulatory environment;

- expenses associated with unforeseen product quality issues;
- the timing and success or failure of clinical trials or post-approval studies for our ASSURE WCD or any future product candidates or competing product candidates;
- any other change in the competitive landscape of our industry, including consolidation amongst our competitors or partners;
- litigation or other claims against us for intellectual property infringement or otherwise;
- expenses associated with indemnification obligations to third parties that are subject to litigation or claims, including in relation to intellectual property infringement, or incur other losses as a result of their use of our products;
- our ability to obtain additional financing as necessary; and
- advances and trends in new technologies and industry standards.

In addition, our revenue is subject to seasonality as our billings and collections efforts during January and February tend to be lower because of resetting annual patient healthcare insurance plan deductibles. In addition, as our sales grow in the United States and any international markets we may enter into in the future, we may experience seasonality based on holidays, vacations and other factors. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common shares could decline substantially. Such a share price decline could occur even if we meet any previously publicly-stated guidance we may have provided.

If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

Any growth that we experience in the future could provide challenges to our organization, requiring us to expand our sales personnel and general and administrative infrastructure. In addition to the need to establish effective sales, marketing, patient support and clinical operations capabilities, our future growth will impose significant added responsibilities on our management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people market and offer our products, which could result in inefficiencies, unanticipated costs and cause disruptions to our operations. Additionally, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. The time and resources required to optimize these systems and procedures are uncertain, and failure to complete optimization in a timely and efficient manner could adversely affect our operations. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

Our clinical study initiatives may be complex, lengthy, expensive and carry uncertain outcomes. Future trials and studies by us or others may fail to replicate positive results observed to date.

In order to support the continued adoption of our products, we will need to continue to invest in clinical study initiatives to grow the body of clinical evidence supporting the safety, efficacy and benefits of our products and solutions. We conduct our own clinical studies and provide support for third party-initiated trials that evaluate different aspects of the ASSURE WCD. As of the date of this Annual Report, we have one ongoing active surveillance post-approval study, the ACE-PAS, which is continuing to enroll patients. There is no assurance of whether we will be able to complete patient enrollment for our ACE-PAS study or other clinical trials we may conduct in the future and delays in completing patient enrollment may result in increased costs or affect the timing or outcome of our ongoing and planned clinical trials. If we are unable to timely complete our clinical studies, our ability to continue to develop a sufficient body of clinical evidence to support the safety, efficacy and benefits of our products may be adversely affected, which may negatively impact adoption rates for our products. Clinical trials are difficult to design and implement, can take many years, can be expensive and carry uncertain outcomes. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned, or future products may not be predictive of the results of later clinical trials or real-world performance, and interim results of a clinical trial do not necessarily predict final results. Additionally, clinical trials may produce different results depending on the type of statistical analysis used to report data results, such as per protocol analyses and intent-to-treat analyses. Results produced under one type of statistical analysis may not be consistent with or may not be as favorable as results produced under alternative types of statistical analysis. For example, in the VEST study published in 2018, initial intention-to-treat analysis of WCD therapy did not indicate a statistically significantly lower rate in sudden arrhythmic death when compared to treatment through GDMT alone, whereas the as-treated analysis showed that a significantly lower percentage of patients died when they were wearing the WCD than when they were not. If any studies conducted by third parties on any of our products produce results that are not as favorable as the findings in the clinical trials we conduct, the adoption of our products could be impeded and our reputation in the medical community may be damaged, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Additionally, failure to establish the safety and efficacy of any additional products we may develop in the future would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that product or indication for use. Even after any products are cleared or approved in the United States, commercialization of our products in foreign countries would require clearance, certification or approval by regulatory authorities in those countries. Clearance, certification or approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional pre-clinical studies or clinical trials. Adjusting our clinical trial procedures to satisfy the clearance, certification or approval requirements of different foreign jurisdictions may be costly and may result in delays in our ability to complete our clinical trials and commence the commercialization of our products in such jurisdictions.

The initiation and completion of any of our clinical trials or investigations may be prevented, delayed or halted for numerous reasons. We may experience delays in future clinical trials or investigations for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical trials, including related to the following:

- we may be required to submit an IDE application to FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and FDA may reject our IDE application and notify us that we may not begin clinical trials;

- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials or investigations;

- regulators and/or institutional review boards (“IRB”) or other reviewing bodies may not authorize us or our investigators to commence a clinical trial or investigation, or to conduct or continue a clinical trial or investigation at a prospective or specific trial site;

- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- clinical trials or investigations may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or investigations or abandon product development programs;

- the number of subjects or patients required for clinical trials or investigations may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials or investigations being conducted at any given time may be high and result in fewer available patients for any given clinical trial or investigation, or patients may drop out of these clinical trials at a higher rate than we anticipate;

- our third-party contractors, including those manufacturing products or conducting clinical trials or investigations on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we might have to suspend or terminate clinical trials or investigations for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;

- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;

- regulators, IRBs, other reviewing bodies or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;

- the cost of clinical trials or investigations may be greater than we anticipate;

- clinical sites may not adhere to our clinical protocol or may drop out of a clinical trial;

- we may be unable to recruit a sufficient number of clinical trial sites;

- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and

- our current or future products may have undesirable side effects or other unexpected characteristics.

Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials or investigations may also ultimately lead to the denial of regulatory approval of any future product candidates. Clinical trials and investigations must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs or other regulatory bodies at the medical institutions where the clinical trials or investigations are conducted. In addition, clinical trials and investigations must be conducted with supplies of our devices produced under current good manufacturing practice, or cGMP, requirements and other regulations. Furthermore, we may rely on CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we may have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both.

We have limited experience supplying our ASSURE WCD in quantities and providing services on a broad scale that is both commercially successful and meets clinical needs, and production or service delays or shortfalls may occur, which could adversely affect our business.

As we fully commercially launched our ASSURE WCD in August 2022, we have limited experience in supplying our ASSURE WCD in commercial quantities and providing services on a broad scale that is both commercially successful and meets clinical needs. As a result, we may encounter production or service delays or shortfalls. Such production or service delays or shortfalls may be caused by many factors, including the following:

- our ability to develop and maintain the infrastructure necessary to drive our operational efficiency and support our growth;

- key components of our ASSURE WCD are provided by a limited number of suppliers, and we do not currently maintain large inventory levels of these components; if we experience a shortage of or quality issues in any of these components, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;

- our current suppliers and service providers may not be able to provide adequate coverage for new markets we intend to distribute our products to, and there is no assurance that we will be able to engage with new suppliers to cover such new markets on terms acceptable to us, or at all;

- we and our manufacturing partners are subject to state and federal regulations, including the FDA's Quality System Regulation (the "QSR"), for both the manufacture of our products and provision of our services, non-compliance with which could cause an interruption in our ability to manufacture and deliver our products and services; and

- to increase our revenue significantly and scale our services, we will be required to attract, hire, train and retain qualified personnel.

If we are unable to keep up with demand for our products, including our ASSURE WCD, our revenue could be negatively impacted, market adoption of our products could be harmed and we may not be able to compete against our current or future competitors. We utilize a lease business model, whereby when a patient's indicated wear time has concluded, our ASSURE WCDs are returned for reprocessing and reintroduction into the distribution network. Patients are typically prescribed our ASSURE WCDs for 40 to 90 days, during which time the patient wears the ASSURE WCD primarily at home. Upon conclusion of the prescription period, the patient must return our ASSURE WCD so that we can refurbish and recondition the equipment. We rely on a third-party manufacturer to recondition our used ASSURE WCDs. If our patients fail to return their equipment on time or at all or if the equipment is severely damaged requiring extensive repairs and we are unable to timely deploy the equipment for the next customer's use, then our business, financial condition, results of operations and prospects could be adversely affected. Although historically we have not experienced any material losses due to damaged or unreturned equipment, there is no assurance that we will not be adversely affected by such losses in the future.

The manufacturing facilities and processes of our third-party suppliers are subject to unannounced FDA and state regulatory inspections for compliance with the QSR. Developing and maintaining a compliant quality system is time consuming and expensive. Failure to maintain compliance with, or not fully complying with the requirements of the FDA and state regulators could result in enforcement actions against us or our third-party suppliers, which could include the issuance of warning letters, seizures, prohibitions on product sales, recalls and civil and criminal penalties. Additionally, our third-party suppliers have in the past and may in the future receive 483 letters or warning letters from the FDA for violations of the FDA's requirements. If our third-party suppliers fail to adequately rectify any such violations, they may be subject to fines or penalties, which could significantly impact our manufacturing supply and provision of services and impair our reputation and financial results.

We depend on a limited number of third-party suppliers and contract manufacturers to manufacture and recondition our ASSURE WCD and its components, which could make us vulnerable to supply shortages and price fluctuations that could harm our business.

We outsource the manufacturing of our ASSURE WCD and all of its components to third-party suppliers, including contract manufacturers that manufacture garments, chargers, monitors, batteries, cables and various accessories for our ASSURE WCD. We also rely on a third-party manufacturing partner to recondition our ASSURE WCDs for use by subsequent patients. As a result, we depend on our third-party suppliers and contract manufacturers to provide us with materials and services in a timely manner that meet our quality, quantity and cost requirements. These suppliers and contract manufacturers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet demand for our products. Our reliance on third-party suppliers subjects us to a number of risks, including, but not limited to:

- inability to obtain sufficient quantities of components used in our products in a timely manner or on commercially acceptable terms, including shortages of off-the shelf commercial components;
- delays in the reconditioning of our ASSURE WCDs, which impacts the fleet of devices available to be deployed to new patients;
- supply interruptions resulting from disruptions or changes to, or discontinuations of, a supplier's operations;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications;
- the inability of the manufacturer or supplier to comply with the QSR and other relevant state or federal regulations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to consistently produce quality components;
- third party litigation or other claims for intellectual property infringement based on key components provided by suppliers;
- delays or increased costs due to the inability of a manufacturer or supplier to provide or import components due to injunctions or import bans;
- delays or increased costs due to the need to secure components from alternative manufacturers or suppliers in order to secure appropriate intellectual property licenses or equivalent rights;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to control the quality of components manufactured by our third-party suppliers;
- trade protection measures, laws and business practices that favor local companies, tariffs, and other duties, especially in light of trade disputes between the United States and several foreign countries, that may impact the supply and costs of certain components that our third-party suppliers source from foreign countries;
- exchange controls, currency restrictions, and fluctuations in currency values;
- political, social, and economic instability;
- difficulties in the protection of intellectual property;
- the outbreak of contagious diseases;
- inflation and/or deflation;
- potential adverse tax consequences;

- labor disputes, terrorism, vandalism, cyberattacks, infrastructure failures, natural disasters, severe weather or work stoppages; and

- delays in delivery by our suppliers due to changes in demand from us or their other customers and consequently, our inability to fulfill our contractual obligations to deliver our products to our end-users.

In addition, our suppliers and contract manufacturers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. If we inaccurately forecast demand for finished products, we may be unable to meet customer demand, which could harm our competitive position and reputation.

In addition, if we fail to effectively manage our relationships with our suppliers and contract manufacturers, we may be required to change suppliers or contract manufacturers. While we believe replacement suppliers exist for all materials, components and services necessary to manufacture our ASSURE WCD, establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time-consuming and expensive, and may result in interruptions in our operations and product delivery. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain regulatory authority approval before we implement the change, which could result in further delay and which may not be obtained at all. If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our ASSURE WCD, the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition, results of operations and prospects. Pandemics, such as the COVID-19 pandemic, other health crises, adverse weather conditions, natural disasters and accidents have in the past and may in the future result in supply chain disruptions that adversely affect our contract manufacturing partners' ability to provide the supplies we require on a timely basis. Any significant delays or interruption in the supply of components and materials necessary for our products, or our inability to obtain substitute components or materials from alternate sources at acceptable terms and in a timely manner could impair our ability to meet demand for our products, fulfill our contractual obligations to deliver our products and harm our business.

If our suppliers' manufacturing facilities become damaged or inoperable, or if they are required to vacate a facility, they may be unable to manufacture our products or we may experience delays in production or an increase in costs, which could adversely affect our results of operations.

Facilities and equipment of our suppliers could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, terrorism, flooding, cyberattacks, power outages and other infrastructure failures. Any of these may render it difficult or impossible for our suppliers to manufacture products for some period of time. If our suppliers' manufacturing facilities are inoperable for even a short period of time, the inability to manufacture our ASSURE WCD may result in harm to our reputation and our ability to achieve profitability. Our research and development facilities are subject to similar risks, and inability to access such facilities may result in interruptions to our research and development efforts for other products we are developing. Additionally, it may be costly and time-consuming to repair or replace our facilities and the equipment we use to conduct our research and development activities and manufacture our products.

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our ASSURE WCD to our customers and for tracking of these shipments. In particular, this is because we employ a lease model whereby at the end of a prescription, each patient ships our ASSURE WCD back to our third-party manufacturing partner, who then reconditions the ASSURE WCD before it is redistributed to the next patient. Delays in the transport of our ASSURE WCDs to and from our suppliers could cause shortages in our inventory of ASSURE WCDs and adversely affect our ability to respond to customer demands. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any ASSURE WCDs or components thereof, it would be costly to replace such systems or components in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis.

If we are unable to support demand for our current or future products or services, our business could suffer.

As we continue to commercialize our products and demand for our ASSURE WCD and associated products and services delivered as part of our Cardiac Recovery System platform or any future products or services increases, we will need to continue to expand our customer service, billing and systems processes and enhance our internal quality assurance program. Additionally, we will need to ensure that our third-party suppliers and service providers, including the third-party suppliers we rely on to manufacture and recondition our ASSURE WCDs, are able to provide adequate supplies and services to support increasing demand for our products. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing data or inability to meet increased demand. There can be no assurance that we will be able to analyze data regarding patients' clinically relevant health events on a timely basis at a level consistent with demand, quality standards and healthcare provider expectations. If we encounter difficulty meeting market demand, quality standards or healthcare provider expectations, our reputation could be harmed and our prospects and business could suffer.

If we are unable to successfully expand our sales and customer service resources, including hiring and retaining relevant personnel, and adequately address our customers' needs, it could negatively impact our profitability and market acceptance of our ASSURE WCD and other products we may develop in the future.

Our commercial team is comprised of approximately 80 direct sales representatives as well as more than 40 sales and clinical support professionals as of April 30, 2025. Once a healthcare provider prescribes our ASSURE WCD to a patient, our direct sales team is supported by a contracted team of over 300 APSs as of April 30, 2025 who assist patients with fitting and training. As we continue to commercialize our products, we will need to grow and optimize the size and geographic scope of our sales and marketing capabilities, as well as our network of APSs, in order to develop broad brand awareness and increase market penetration. There is significant competition for qualified and experienced sales force personnel, as well as healthcare personnel who are able to assist with WCD-related training and patient fittings. Identifying and recruiting qualified personnel and training them in the application of our solutions, on relevant federal and state laws and regulations and on our internal policies and procedures require significant time, expense and attention. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force or network of APSs in the future, new hires may not become as productive as may be necessary to maintain or increase our sales. Upon completion of the training, our direct sales force personnel will require lead time in the markets in which they operate to grow their network of accounts and achieve the productivity levels we expect them to attain. Newly-contracted APSs may also require lead time before they are able to complete patient fittings at the levels of quality and efficiency we expect them to attain. In addition, in order to attract and maintain qualified personnel, we will need to offer competitive compensation and benefits packages to current and prospective employees. Our business may be harmed if our efforts to expand and train our sales force and grow our network of APSs do not generate a corresponding increase in revenue. In particular, we have in the past and expect in the future to enter into compensation arrangements with our commercial team that may include minimum guaranteed commissions, which may increase our compensation costs without a commensurate increase in revenue if our sales personnel do not operate as efficiently as expected. In particular, if we are unable to attract, hire, develop and retain talented sales personnel and APSs or if new sales personnel or APSs are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue. Moreover, to the extent we would consider hiring sales or marketing personnel from our competitors, we may be required to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories. We also may partner with technology, commercial and clinical partners to market and distribute our products and grow our brand. We have executed one distribution agreement with a DME supplier in order to facilitate billing and collections related to the distribution of our ASSURE WCD. We may also consider entering into other arrangements with third parties to perform certain sales, marketing, patient support and distribution services. There is no assurance of whether we will be successful in entering into arrangements with third parties to sell and market our ASSURE WCD or any future product candidates on terms that are favorable to us, if at all. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our ASSURE WCD or any future product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, in a cost-effective manner, we may not be able to maintain or grow sales of our ASSURE WCD or commercialize any future product candidates and our revenue may be materially adversely affected. In addition, since we have a limited history as a direct sales organization, we may not be as effective or efficient in utilizing our sales personnel as other companies with longer histories utilizing a direct sales organization. As a result, we may be required to restructure our sales organization to utilize our sales personnel more effectively and efficiently, which would be costly, may divert attention from management, and lead to both planned and unplanned turnover. If we are unable to expand our sales and marketing capabilities and our product-related educational initiatives domestically and internationally, we may be unable to effectively commercialize our products.

In addition, our future revenues will also be impacted by our ability to provide high-quality customer service to address our customers' needs. We may be unable to attract and retain sufficient personnel to maintain an effective customer service force and adequately train our personnel to ensure consistently high-quality customer service. If we are unable to adequately address our customers' needs, it could negatively impact revenues generated by and market acceptance of our ASSURE WCD and other products we may develop in the future, and we may not generate sufficient revenue to achieve or sustain profitability.

If the ASSURE WCD is not effective or if we or our competitors receive negative publicity about the effectiveness of WCDs, then our brand and reputation could suffer and our business could be adversely impacted.

In the course of conducting our business, we must adequately address quality issues that may arise with our products, as well as defects in third-party components included in our products. We employ a rigorous manufacturing and supplier partner assessment, qualification, and selection process to target partners that meet the requirements of the FDA and the International Organization for Standardization, as well as quality standards supported by internal policies and procedures. While our quality assurance program monitors and maintains manufacturing and supplier partner performance through qualification and periodic reviews and audits, we may be unable to eliminate or mitigate quality control issues and associated liabilities. Lasting harm to our brand may be caused by actual or perceived quality issues even if we are able to subsequently address such issues.

Additionally, if our products or similar products offered by our competitors are involved in an instance of patient harm, even if it is through misuse of such products, it could result in decreased demand for our products and damage to our reputation. For example, our competitor has been subject to negative publicity from the media and medical journals relating to false alarms and inappropriate shocks delivered by their WCDs. Reports of device failures or other instances of patient harm relating to our products or similar products offered by our competitor could negatively impact demand and adoption rates for our ASSURE WCD or WCDs more generally, which could adversely affect our results of operations. This adverse impact may occur whether or not we are directly related to, or otherwise control, such events and even the mere perception of our involvement could dilute, tarnish or otherwise adversely affect our reputation and brand.

The rising popularity of social media and other consumer-oriented technologies has increased the speed and accessibility of information dissemination and given users the ability to organize collective actions more effectively, such as boycotts and other brand-damaging events. Many, if not all, social media platforms immediately publish their participants' posts, often without filters or checks on the accuracy of the content posted. Any failure to respond quickly and effectively to negative or potentially damaging social media content about our products or our affiliates, regardless of the content's accuracy, could damage our reputation, which in turn could harm our business, prospects, financial condition and results of operations. The harm may be immediate without affording us an opportunity for redress or correction.

Billing for our products is complex, and we must dedicate substantial time and resources to the billing process.

Billing for medical devices and durable medical equipment is complex, time consuming and expensive. In connection with the distribution of our ASSURE WCD, we currently bill, and expect to continue to bill, several types of payors, including Medicare, Medicaid, private payors and other healthcare-related organizations, each of whom have different billing requirements, procedures and expectations. We are also required to bill patients for co-insurance payments and deductibles. As our business expands and we distribute our products into new markets, we may need to obtain new reimbursement codes, adapt our billing processes to more payors and invest additional resources into our billing infrastructure to ensure that claims are timely and accurately prepared and submitted according to the individual requirements of each payor.

Healthcare providers in the U.S. generally rely on third-party payors, principally Medicare, Medicaid and private payors, to cover and reimburse all or part of the cost of our ASSURE WCD. The revenue we can generate from the lease of our ASSURE WCD depends in large part on the availability of reimbursement from such payors. These payors may deny reimbursement if they determine that our ASSURE WCD was not medically necessary for the patient or was not used in accordance with the payor's coverage policy. A significant component of our operational efforts includes working with private payors to ensure positive coverage decisions for our product and investing in our revenue cycle management infrastructure to collect cash from payors. Additionally, we are reimbursed for the use of our ASSURE WCD based on patient wear time and are therefore dependent, to an extent, on patients complying with their prescriptions and wearing our ASSURE WCD for the time periods prescribed by their healthcare providers. Lack of patient compliance with prescribed wear times may also result in healthcare providers becoming less likely to prescribe our ASSURE WCDs at the same volumes we have experienced in the past, or at all, which would adversely impact our revenues and the growth of our business.

Additionally, as part of our collection efforts, we may face potential contractual adjustments and write-offs of doubtful accounts and long collection cycles, which could in turn adversely affect our profitability and financial condition. Factors that may render our billing and collection processes more uncertain or costly include:

- differences between the submitted price for our products and the reimbursement rates of payors;
- differences between our expected or contract price for our products and the reimbursement by the payers and/or our patients;
- compliance with applicable federal and state regulations related to billing government healthcare programs;
- differences in coverage among payors and the effect of patient co-payments, co-insurance and deductibles; and
- incorrect or missing patient history, indications or billing information.

Further, our billing activities require us to implement compliance procedures and oversee, train and monitor our employees and undertake internal review procedures to evaluate compliance with applicable laws, regulations and internal policies. We have made significant investments in our revenue cycle management processes and have partnered with a third-party DME supplier to perform certain billing and collection services. However, as our business continues to grow, we may face increasing billing complexities, and the potential uncertainties in obtaining payments for our products, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

Federal and state governments have contracted with private entities to audit and recover revenue resulting from payments made in excess of those permitted by government healthcare program rules. These entities include, but are not limited to, Recovery Audit Contractors that are responsible for auditing Medicare claims, Unified Program Integrity Contractors that are responsible for the identification of suspected fraud through medical record review and Medicaid Integrity Contractors, that are responsible for auditing Medicaid claims. We believe audits, inquiries, and investigations from these contractors and others will occur from time to time in the ordinary course of our business. We also may be subject to increased audits from commercial payors. Our efforts to be responsive to these audits, inquiries, and investigations may result in substantial costs and divert management's time and attention away from the operation of our business. Moreover, an adverse outcome with respect to any audit, inquiry or investigation may result in damage to our reputation, or in fines, penalties or other sanctions imposed on us. Such pending or future audits, inquiries, or investigations, or the public disclosure of such matters, could have a material adverse effect on our business, financial condition, results of operations and prospects.

In many instances, there are only limited publicly-available guidelines and methodologies for determining errors with certain payor audits. As a result, there can be a significant lack of clarity regarding required documentation and audit methodology. The clarity and completeness of each patient medical file, some of which is the work product of healthcare providers not employed by us, is essential to successfully challenging any payment denials. For example, certain provisions under CMS guidance manuals, local coverage determinations, and the Durable Medical Equipment Medicare Administrative Contractor ("DME MAC") Supplier Manuals provide that clinical information from the "patient's medical record" is required to justify the initial and ongoing medical necessity for the provision of DMEPOS. Some DME MACs, CMS staff and other government contractors have taken the position, that the "patient's medical record" refers not to documentation maintained by the DMEPOS supplier but instead to documentation maintained by the patient's healthcare providers and hospitals, and that clinical information created by the DMEPOS supplier's personnel and confirmed by the patient's healthcare provider is not sufficient to establish medical necessity. If treating healthcare providers do not adequately document, among other things, their diagnoses and plans of care, the risks that the Company will be subject to audits and payment denials are likely to increase. Moreover, auditors' interpretations of these policies are inconsistent and subject to individual interpretation, leading to significant increases in individual supplier and industry-wide perceived error rates. High error rates could lead to further audit activity and regulatory burdens, and could result in our making significant refunds and other payments to Medicare and other government programs. Accordingly, our future revenue and cash flows from government healthcare programs may be reduced.

Commercial payors also may conduct audits and may take legal action to recover alleged overpayments. We could be adversely affected in some of the markets in which we operate if the auditing payor alleges substantial overpayments were made to us due to coding errors or lack of documentation to support medical necessity determinations. We cannot currently predict the adverse impact these measures might have on our financial condition and results of operations, but such impact could be material.

If our competitors are able to develop or market products and services that are more effective, or gain greater acceptance in the marketplace, than any products and services we develop, our commercial opportunities will be reduced or eliminated.

We operate in a competitive business environment that is evolving. Historically, the WCD market has been served by a single incumbent commercial product, the LifeVest WCD, marketed by ZOLL, our primary competitor. Recently, a new market entrant also obtained FDA approval for an adhesive-based external defibrillator. As we continue to scale our business, our competitor may take competitive actions against us, including competitive pricing actions and litigation challenges, such as intellectual property challenges. In the future, we may also face competition from new market entrants. The development of new or more effective drug candidates could also negatively impact the adoption and average wear time of our WCD system. Healthcare providers who are accustomed to using the products of our primary competitor may be reluctant to try new products from a source with which they are less familiar. Larger medical device companies may also acquire, invest in or form alliances with smaller companies to diversify their product offerings and enhance their competitive position in the competitive business environment, including the WCD industry and industries for other related products and services. Other potential competitors are publicly traded, or are divisions of publicly traded, major medical device or technology companies that enjoy significant competitive advantages and may be able to deploy larger or more effective sales and marketing resources than we currently have. We may also face challenges in overcoming the long-standing preferences of healthcare providers for using the products of larger, more established companies. Competition with these companies could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition, results of operations and prospects. Our competitors may also enjoy other competitive advantages such as:

- greater financial and other resources than us which enable them to market and discount their products more effectively than us;
- large and established sales, marketing and worldwide distribution channels that have greater reach in both domestic and international markets;
- greater brand recognition in the medical community;
- established business and financial relationships with a more expansive network of healthcare providers, hospitals and medical schools;
- greater collaborations with key opinion leaders, medical societies and clinical advisory boards;
- greater market share in the cardiac monitoring products market;
- greater resources devoted to research and development of competing products and greater capacity to allocate additional resources;
- greater experience in obtaining and maintaining regulatory clearances and approvals for new products and product enhancements and commercializing new products; and
- larger patent portfolios and other intellectual property rights.

Medical innovation is accelerating and the market for WCD products and services is becoming increasingly competitive. Our planned innovation pipeline includes apparel, hardware, software and service solutions to remotely and securely monitor and manage patients in an ambulatory care environment. We compete with a variety of companies offering alternative products and services for ambulatory cardiac solutions. Our ability to compete effectively depends on our ability to distinguish our company and our products from our competitors and their products, and includes such factors as:

- product safety and effectiveness;
- detection algorithm sensitivity, specificity and false alarm rate;
- patient physical and psychological comfort and ease of use;
- patient compliance;
- ability to integrate within the patient monitoring ecosystem;

- quality, breadth and ongoing generation of clinical evidence;
- technological innovation, product enhancements and speed of innovation;
- capital required to achieve PMA approval as well as to facilitate post-commercial initial inventory; and
- regulatory status and speed to market.

Additionally, our ability to commercially compete in the WCD market will be impacted by factors such as:

- patient and healthcare provider connectivity and engagement;
- post-event monitoring and emergency support;
- effective marketing to and education of patients, physicians, other healthcare providers and hospitals;
- company, product and brand recognition;
- device reusability and durability;
- reimbursement and payor coverage;
- complexity in building up the remote cardiac monitoring ("RCM") capabilities and logistics to support broad-based commercialization and service levels; and
- recruitment and retention of a qualified and experienced sales force.

If our competitors and potential competitors are better able to develop WCDs and related products than us or introduce more effective, more comfortable or less expensive WCDs and related products before we are able to introduce and commercialize our products, the products and services we offer may be rendered obsolete or non-competitive.

Our marketing and sales practices, as well as our interactions with healthcare providers, may entail risks that could result in significant liability, require us to change our business practices and restrict our operations in the future.

We are subject to numerous domestic (federal, state and local) and foreign laws addressing fraud and abuse in the healthcare industry, including the federal False Claims Act, the Federal Anti-Kickback Statute, self-referral laws, the Foreign Corrupt Practices Act, the U.K. Bribery Act, FDA promotional restrictions, the federal Physician Payment Sunshine Act and state marketing and disclosure laws. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment of responsible corporate officers, and exclusion from participation in government healthcare programs such as Medicare and Medicaid as well as health programs outside the U.S., and even alleged violations can result in the imposition of corporate integrity agreements or deferred prosecution agreements that could severely restrict or limit our business practices. These laws and regulations are complex and subject to changing interpretation and application, which could restrict our sales or marketing practices. Even minor and inadvertent irregularities could potentially give rise to a charge that the law has been violated. Although we believe we have implemented and will maintain an appropriate healthcare compliance program we cannot be certain that the program will adequately detect or prevent violations and/or the relevant regulatory authorities may disagree with our interpretation. Additionally, if there is a change in law, regulation or administrative or judicial interpretations, we may have to change one or more of our business practices to be in compliance with these laws. Required changes could be costly and time consuming.

If our business practices or operations are found to be in violation of these laws or any other government regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, imprisonment of responsible corporate officers, the curtailment or restructuring of our operations, or exclusion from government healthcare programs including Medicare and Medicaid, any of which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Our ability to compete depends on our ability to innovate successfully.

The market for medical devices, including the WCD market, is marked by technological development and product innovation. Demand for our ASSURE WCD and associated products and services delivered as part of our Cardiac Recovery System platform, or other products and services that we are developing or may develop in the future could be diminished by equivalent or superior products and technologies offered by our competitors. If we are unable to innovate successfully, our products and services could become obsolete, and as a result, we may not be able to achieve profitability as customers purchase our competitors' products and services.

In order to remain competitive, we must continue to enhance our existing products and services and develop new product offerings. We will need to ensure that our Cardiac Recovery System platform and other products we develop in the future can support extensions and enhancements in response to evolving patient needs. We can provide no assurance that we will be successful in monetizing our medical technologies, including our ASSURE WCD, developing new products or commercializing them in ways that achieve broad market acceptance. In addition, if we develop new products, the distribution of those products may reduce revenue generated from our existing products. Maintaining adequate research and development personnel and resources to meet the demands of the market is essential. If we are unable to develop new products, applications or features or improve our algorithms due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, our competitors may devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

Due to the significant resources required for the development of our products, we may expend our limited resources to pursue the development and commercialization of select products and fail to capitalize on other products that may be more profitable or for which there is a greater likelihood of success.

The initial focus of our Cardiac Recovery System platform is to serve high-acuity patients who require both continuous monitoring and therapy. We fully commercially launched our ASSURE WCD, the cornerstone of our Cardiac Recovery System platform, in August 2022 and have introduced various updates and complementary technologies and services related to our Cardiac Recovery System platform since then. We also recently launched our ASSURE wearable ECG as part of our efforts to expand into providing monitoring and connectivity solutions to patients who longer indicated for a WCD but who still require ongoing support. As of the date of this Annual Report, we are also in various stages of research and development for other potential solutions and new indications for our technology. We seek to maintain a process of prioritization and resource allocation among our various research and development efforts to maintain a balance between advancing our ASSURE WCD and developing other current and any future cardiovascular solutions. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular products or therapeutic areas may not maximize our ability to generate potential profits, may not lead to the development of any viable commercial product and may divert resources away from other products and solutions tailored to other therapeutic areas that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product, we may relinquish valuable rights to that product through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. In addition, if we make incorrect determinations regarding the viability or market potential of any of our products and solutions or misread trends in cardiovascular care and the wearable healthcare technology industry, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Our outstanding debt may affect our ability to operate our business and secure additional financing in the future.

As of April 30, 2025, we had an aggregate principal amount of $45.0 million outstanding under the Credit Agreement and Guaranty, dated as of September 29, 2023, as amended by the Second Amendment to Credit Agreement and Guaranty, dated February 25, 2025 (as may be further amended from time to time, the "Term Loan"), among Perceptive Credit Holdings IV, LP, as administrative agent and as a lender, the other lenders party thereto, West Affum Holdings and Kestra Medical Technologies, Inc., as borrowers, and the guarantors party thereto. We must make significant quarterly interest payments under the loan agreement, which will divert resources from other activities. Our outstanding debt under the Term Loan is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to, among other things, dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. The covenants in the Term Loan, as well as in any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. The Term Loan also contains a minimum liquidity covenant, and a minimum revenue covenant which increases on a quarterly basis through maturity of the Term Loan. Additionally, there are certain non-financial covenants. See Note 7, "*Long-Term Debt*" to the consolidated financial statements included elsewhere in this Annual Report. Our ability to comply with these covenants may be affected by a number of events, some of which may be beyond our control and future breaches of any of these covenants could result in a default under the loan agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the loan agreement to become immediately due and payable and terminate commitments to extend further credit. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business. See the section titled "Description of Certain Indebtedness" for more information on the Term Loan.

We may be able to incur significant additional indebtedness in the future. Although the Term Loan limits our ability and the ability of our present and future subsidiaries to incur additional indebtedness, the terms of the Term Loan permit us to incur significant additional indebtedness. In addition, the Term Loan does not prohibit us from incurring obligations that do not constitute indebtedness as defined therein. To the extent that we incur additional indebtedness or such other obligations, the risk associated with our substantial indebtedness described above, including our potential inability to service our debt, will increase.

If there were an event of default under the Term Loan relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately. We cannot guarantee that our assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments if accelerated upon an event of default.

Further, if we are unable to repay, refinance or restructure our indebtedness under our secured debt, the holders of such debt could proceed against the collateral securing that indebtedness. In addition, any event of default or declaration of acceleration under one debt instrument could also result in an event of default under one or more of our other debt instruments.

As a result, any default by us on our indebtedness could have a material adverse effect on our business, results of operations and financial condition.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.

Our success depends largely on the continued services of key members of our executive management team and others in key management positions, as well as our ability to attract, motivate, develop and retain a sufficient number of other highly skilled personnel. Our senior management team has extensive experience in the medical device industry, and we believe that the depth of their experience is instrumental to our continued success. For example, the services and expertise provided by Brian Webster, our President and Chief Executive Officer, are critical to our overall management, as well as the continued development of our solutions, our culture, our strategic direction, our innovation and our operations. Our employees may terminate their employment with us at any time. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. We do not currently maintain key person life insurance policies on these or any of our employees.

In addition, our research and development programs depend on our ability to attract and retain highly skilled engineers. We may not be able to attract or retain qualified engineers in the future due to the competition for qualified personnel. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than us. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the share awards they receive in connection with their employment. If the perceived value of our share awards declines, either because we are a public company or otherwise, it may harm our ability to recruit and retain highly skilled employees. Additionally, maintaining a positive company culture is necessary to enable us to retain and hire key talent and have a cohesive, aligned employee base. Our ability to maintain this culture will directly affect the continued growth and success of our company. Our culture could face sustainability challenges as we continue to grow and scale our business. Potential obstacles include reduced adoption of our culture by new employees, limited ability to maintain consistency of culture within business teams, and failure to attract and retain leaders who support our culture and business plans. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business, financial condition, results of operations and prospects could be materially adversely affected.

Security breaches, loss of data, unauthorized uses or disclosures, and other disruptions involving our systems, products or data could compromise sensitive information related to our business or patients, result in operational disruption, or prevent us from accessing critical information, exposing us to liability, and adversely affecting our business, financial condition, results of operation and prospects.

In the ordinary course of our business, we, and certain of our vendors on our behalf, collect, transfer, process and store sensitive data, including legally-protected personally identifiable health information about patients. We also collect, transfer, process and store, and use additional third parties to collect, transfer, process and store on our behalf, sensitive confidential information, including intellectual property, other proprietary business information, and preclinical and clinical trial data, including that of our customers, payors and collaborative partners. We employ administrative, technical and physical controls to secure personally identifiable health information, and we maintain our applications and data utilizing a combination of public cloud platforms and software-as-a-service providers. These applications and data encompass a wide variety of critical information, including patient data collected and processed through the digital solutions and services offered as part of our Cardiac Recovery System platform, clinical evidence collected through our ASSURE Patient Registry, other research and development information, commercial information and business and financial information.

We are highly dependent on information technology networks and systems, including the internet, to securely process, transmit and store this critical information to ensure the effective operation of our business and the timely delivery of our solutions and services. For example, we rely on information technology networks to ensure that our digital solutions, such as our Heart Alert Services and ASSURE Assist services, are able to deliver timely critical alerts to healthcare providers and notify emergency services when therapy is administered to patients. Our third-party information technology systems may not remain available on terms acceptable to us and may require replacement, which could result in substantial operational expense, diversion of our resources, and reduced efficiency, any of which could result in any a material adverse effect on our business, financial condition, results of operations and prospects. Security breaches of our information technology infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure, access, use or modifications of confidential information, including patient information and trade secrets. The secure collection, use, processing, storage, maintenance, protection and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Data security-related incidents and fraudulent activity are increasing in frequency, sophistication, and variety, and can originate from many sources, including third-party suppliers and nation-state actors. Our information technology and infrastructure, and those of our vendors, has been and will continue to be vulnerable to attacks by hackers or viruses or breaches due to employee error, malfeasance or other disruptions. While we have taken steps to identify critical and high-risk vulnerabilities to and protect our infrastructure and sensitive information from unauthorized access, disclosure, or other activity, and while we have implemented compliance measures along those lines, we continue to develop our policies and procedures for protecting such information, and there can be no assurance that these will prevent, detect, or mitigate such issues given the unpredictability of the timing, nature, and scope of data security-related incidents and fraudulent activity. Furthermore, some confidential and protected health information is transmitted to us by third parties, who may not implement adequate security and privacy measures. Our third-party vendors and other business partners may also experience breaches to their information technology systems that could lead to disruptions to our business and ability to deliver our solutions and services.

As part of the delivery of our digital solutions and services through our Cardiac Recovery System platform, we collect, process and analyze a substantial amount of patient data, including through our ASSURE Patient Registry. A security breach or privacy violation that results in a business interruption or leads to disclosure or modification of, or prevents or interferes with access to, patient information, including protected health information, could harm our reputation, compel us to comply with disparate U.S. state and other international breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. The loss of patient data and other information critical to our solutions and services as a result of data breaches could also impair our ability to grow our clinical evidence to support the continued development of our products. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm. We do not currently maintain cyber insurance, which could help to mitigate certain losses related to security events that may occur, and we have no assurance that we will be able to obtain such coverage in the future. Therefore, any breach or cyber incident may expose us to certain potential losses, damages or penalization with fines in an amount exceeding our resources.

Any such breach or interruption of our systems, or those of any of our third-party information technology partners, could compromise our networks or data security processes and sensitive information could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings (such as class actions), liability under laws that protect the privacy of patient information, such as the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and regulatory penalties (such as state data breach laws). Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform our services, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our current and future solutions and engage in other patient and healthcare provider education and outreach efforts. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our business and competitive position.

In addition, the individually identifiable health information we collect, receive, store, access, transfer, process and use from patients and covered entity healthcare providers may be subject to limitations on use and disclosure, and may require us to obtain HIPAA-compliant authorizations or other consents from patients for such uses and disclosures, including use of patient information in connection with the ASSURE Patient Registry. To the extent we fail to collect necessary authorizations or consents to use or disclose such information, or to the extent our uses or disclosures of such information violate applicable laws that protect the privacy of patient information, including HIPAA, we may be subject to liability, legal claims or proceedings (such as class actions), fines, or penalties pursuant to such laws.

Our existing general liability and cybersecurity liability insurance policies may not cover, or may cover only a portion of, any potential claims related to security breaches to which we are exposed or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim. Accordingly, if our cybersecurity measures, and those of our customers and service providers, fail to protect against unauthorized access, attacks (which may include sophisticated cyberattacks), and the mishandling of data, then our reputation, business, financial condition, results of operations and prospects could be materially and adversely affected.

We are subject to complex and rapidly evolving laws, regulations, rules, and standards relating to data privacy and security, and our failure to comply with such laws, regulations, rules and standards could adversely affect our business, financial condition, results of operations and prospects.

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, as well as HIPAA, govern the collection, use and disclosure of personal information. For example, the California Consumer Privacy Act of 2018, as amended ("CCPA"), went into operation on January 1, 2020 and broadly defines personal information, affords California residents expanded privacy rights and protections and provides for civil penalties for violations and a private right of action related to certain data security breaches. These protections were expanded by the California Privacy Rights Act ("CPRA"), which was approved by California voters in November 2020 and became operational in most key respects on January 1, 2023. In addition, the My Health My Data Act of 2023 went into effect in Washington state on April 27, 2023 and protects personal health data that falls outside the ambit of HIPAA. Several states have enacted similar types of privacy laws and there are similar legislative proposals being advanced in other states, as well as in Congress. Our business is also subject to the PIPA, and other international laws, such as the General Data Protection Regulation, which could also apply to our operations as we expand internationally. Failure to provide adequate privacy protections and maintain compliance with applicable privacy laws could result in significant penalties.

The interpretation and application of data protection laws, rules and regulations in the United States and elsewhere are often uncertain, contradictory and in flux, with new laws passing or entering into force on a regular basis. It is possible that these laws, rules and regulations may be interpreted and applied in a manner that is inconsistent with our practices or those of our distributors and partners. If we or these third parties are found to have violated such laws, rules or regulations, it could result in government-imposed fines, orders requiring that we or these third parties change our or their practices, or criminal charges, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business. In addition, certain of these laws, such as the CCPA, may provide for a private right of action with respect to certain data breaches. This private right of action may increase the likelihood of, or the risks arising from, data breach litigation.

We may be subject to fines, penalties, or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, resulting in damage to our reputation and our business. Further, the use, misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Our business exposes us to potential product liability claims that are inherent in the provision of medical devices for cardiovascular support. Furthermore, if our customers are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. Similarly, if we are unable to sufficiently train APSs who assist with customer fittings, our ASSURE WCD may be ineffective, or may result in patient discomfort, injury or unsatisfactory patient outcomes. Our ASSURE WCD has been approved by FDA for use in adult patients who are at risk for SCA and are not candidates for, or refuse, an ICD. However, we cannot prevent a healthcare provider from prescribing our devices off-label when they deem it appropriate. The use, misuse or off-label use of our products, including our ASSURE WCD, may in the future result in outcomes and complications potentially leading to product liability claims and harm to our reputation. If our products are defectively designed, manufactured or labeled, contains defective components or is misused, we may become subject to costly litigation initiated by healthcare providers, the hospitals and clinics where healthcare providers prescribing our products work or their patients and reputational harm.

If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizeable damage awards against us that may not be covered by insurance, all of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Product liability claims are especially prevalent in the medical device industry, and regardless of the merit or eventual outcome, may result in:

- decreased demand for our products;
- injury to our reputation;
- significant litigation costs;

- substantial monetary awards to or costly settlements with patients;
- product recalls;
- material defense costs;
- loss of revenue;
- the inability to commercialize new products; and
- diversion of management attention from pursuing our business strategy.

Although we maintain product liability insurance, we may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses and reduce our revenues. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results.

If the FDA determines that our promotional materials, sales practices or training constitute improper promotion of an off-label use, they could request that we modify our training, sales practices or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, warning letter, injunction, seizure, civil fine or criminal penalties. These types of enforcement actions could have a material adverse impact on our business, revenues and financial results. It is also possible that other federal or state enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

We bear the risk of warranty claims on our products.

We bear the risk of warranty claims on our products. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or any recovery from such vendor or supplier may not be sufficient to cover our losses. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in our inability to recover any costs incurred by us.

We may acquire other companies or technologies, which could divert our management's attention, result in additional dilution to our shareholders and otherwise disrupt our operations and harm our operating results. The failure to effectively manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, increase our debt or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or in-license other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- unanticipated problems or liabilities with the businesses or products acquired;
- diversion of management's attention from our core business and disruption of ongoing operations;

- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment. To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer.

Consolidation among commercial payors could result in payors eliminating coverage or demanding price concessions, which may affect our ability to offer our products at prices necessary to support our current business strategies.

The commercial payor industry is undergoing significant consolidation. In recent years, a number of health insurers have merged or increased efforts to consolidate with other commercial payors. Insurers are also increasingly pursuing alignment initiatives with healthcare providers. Consolidation within the health insurance industry may result in insurers having increased negotiating leverage and competitive advantages, such as greater access to performance and pricing data. Our ability to negotiate prices and favorable terms with health insurers in certain markets could be affected negatively as a result of this consolidation. When payors combine their operations, the combined company may elect to reimburse our products at the lowest rate paid by any of the participants in the consolidation or use its increased size to negotiate reduced rates. If one of the payors participating in the consolidation does not provide reimbursement for our products, or provides reimbursement at reduced rates, the combined company may elect not to provide reimbursement for our products, or provide such reimbursement at reduced rates, which would adversely affect our operating results. In addition, the shift toward value-based payment models could be accelerated if larger insurers, including those engaging in consolidation activities, find these models to be financially beneficial. There can be no assurance that we will be able to negotiate favorable terms with payors and otherwise respond effectively to the impact of increased consolidation in the payor industry or vertical integration efforts.

Our management team has limited experience managing a public company.

Most members of our management team have limited experience managing a publicly traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. Our management team may not successfully or efficiently manage us as a public company that is subject to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, results of operations, financial condition and prospects.

We have identified material weaknesses in our internal control over financial reporting, and may identify additional material weaknesses. If our remediation of the material weaknesses is not effective, or we fail to develop and maintain effective internal control over financial reporting, our ability to produce timely and accurate financial statements could be impaired, which could harm our business and negatively impact the value of our common shares.

Prior to completion of the IPO, we were a private company with limited accounting personnel to address our internal control over financial reporting. This lack of adequate accounting resources contributed to audit adjustments to our financial statements in the past, including in connection with our financial statements for the fiscal year ended April 30, 2025. In connection with the preparation of our consolidated financial statements, we identified material weaknesses in our internal control over financial reporting. 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 consolidated financial statements will not be prevented or detected on a timely basis.

- We did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of resources in the accounting, finance and IT functions to appropriately analyze, record and disclose accounting matters timely and accurately. This material weakness contributed to the following additional material weaknesses.

- We did not design and maintain effective controls to ensure the financial statements were properly presented and classified for certain non-routine or complex transactions. Specifically, we did not design and maintain controls to appropriately account for the classification of selling, general and administrative expenses, paid-in-kind interest, restricted cash, right of use lease assets, and the cash flow presentation of leases. This material weakness resulted in immaterial audit adjustments to the aforementioned accounts, which were recorded in previous years, prior to the issuance of the consolidated financial statements.

- We did not design and maintain effective controls to verify personnel would not have the ability to prepare and post manual journal entries or review account reconciliations without an independent review by someone without the ability to prepare and post manual journal entries. This material weakness did not result in adjustments to the consolidated financial statements.

Additionally, these material weaknesses could result in a misstatement of substantially all of the financial statement accounts and disclosures that would result in a material misstatement to our annual or interim consolidated financial statements that would not be prevented or detected.

- We did not design and maintain effective controls over IT general controls for information systems that are relevant to the preparation of our consolidated financial statements. Specifically, we did not design and maintain: (i) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately; (ii) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate Company personnel; (iii) computer operations controls to ensure that data backups are authorized and monitored; and (iv) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

These IT deficiencies did not result in adjustments to our consolidated financial statements; however, the deficiencies, when aggregated, could impact maintaining effective segregation of duties, as well as the effectiveness of IT-dependent controls (such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports) that could result in misstatements potentially impacting all financial statement accounts and disclosures that would not be prevented or detected. Accordingly, we have determined these deficiencies in the aggregate constitute a material weakness.

We continue to make progress towards remediating these material weaknesses. These remediation measures are ongoing as of the date of this Annual Report and include: hiring additional personnel, such as financial planning and accounting, compliance, information technology, and other professionals with appropriate levels of knowledge and experience; engaging a third parties to assist with technical accounting and in designing and implementing controls related to period-end financial reporting, segregation of duties and IT general controls; designing and implementing controls to properly present and classify non-routine or complex transactions; and enhancing IT governance processes.

We intend to evaluate current and projected resource needs on a regular basis and hire additional qualified resources as needed. Our ability to maintain qualified and adequate resources to support the Company and our projected growth will be a critical component of our internal control environment.

We are working to remediate the material weaknesses as efficiently and effectively as possible and expect full remediation will go beyond the fiscal year ended April 30, 2025. At this time, we cannot provide an estimate of costs expected to be incurred in connection with implementing this remediation plan; however, these remediation measures will be time consuming, incur significant costs, and place significant demands on our financial and operational resources.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be negatively impacted, we may be unable to maintain compliance with securities law requirements in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our common share price may decline as a result.

We are subject to risks from legal and arbitration proceedings that may prevent us from pursuing our business activities or require us to incur additional costs in defending against claims or paying damages.

We may become subject to legal disputes and regulatory proceedings in connection with our business activities involving, among other things, product liability, product defects, intellectual property infringement, employment matters, and/or alleged violations of other applicable laws in various jurisdictions. We may not be insured against all potential damages that may arise out of any claims to which we may be party in the ordinary course of our business. A negative outcome of these proceedings may prevent us from pursuing certain activities and/or require us to incur additional costs in order to do so and pay damages. In addition, 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 would harm our business, financial condition, results of operations and prospects. Additionally, the significant increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

The outcome of pending or potential future legal and arbitration proceedings is difficult to predict with certainty. In the event of a negative outcome of any material legal or arbitration proceeding, whether based on a judgment or a settlement agreement, we could be obligated to make substantial payments, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, the costs related to litigation and arbitration proceedings may be significant, and any legal or arbitration proceedings could have a material adverse effect on our business, financial condition, results of operations and prospects, even if ultimately resolved in our favor.

Our estimates relating to our market and forecasts of market growth are based on a number of complex assumptions and estimates that may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not increase at similar rates, if at all.

Our estimates and forecasts in this Annual Report relating to, among other things, our total addressable market and the expected growth in the WCD market are subject to significant uncertainty and may prove to be inaccurate. In particular, our estimates of our total addressable markets in the U.S. and outside the U.S. are based on a number of internal and third-party estimates and assumptions relating to, amongst other things, the number of patients who are at risk of suffering a SCA, are not immediately eligible for an ICD and are either currently using or may in the future use WCDs; the reimbursement rates for WCDs by Medicare and private payors in the U.S. and payors outside the U.S.; the average WCD patient wear time; and the use of WCDs over alternative treatments such as ICDs. In addition, our estimates of our total addressable markets in the U.S. and outside the U.S. both reflect the opportunities available to all current and potential participants in the market, and we cannot predict with precision our ability to address the potential demand for WCDs or the extent of market adoption of our ASSURE WCD over solutions offered by our current or future competitors. While we believe that our assumptions and the data underlying our estimates for our total addressable markets in the U.S. and outside the U.S. are reasonable, they may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of such underlying factors. Our estimated addressable markets in the U.S. and outside the U.S. may not materialize for many years, if ever. Accordingly, our forecasts of market growth should not be taken as indicative of our future growth.

Macroeconomic conditions could materially adversely affect our business, financial condition, results of operations and prospects.

Macroeconomic conditions, such as high inflationary pressure, changes to monetary policy, high interest rates, volatile currency exchange rates, credit and debt concerns, decreasing consumer confidence and spending, including capital spending, concerns about the stability and liquidity of certain financial institutions, the introduction of or changes in tariffs or trade barriers, and global recessions can adversely impact demand for our products, which could negatively impact our business, financial condition, results of operations and prospects. Recent macroeconomic conditions have been adversely impacted by geopolitical instability and military hostilities in multiple geographies and monetary and financial uncertainties.

The impacts of these macroeconomic conditions, and the actions taken by governments, central banks, companies, and consumers in response, have resulted in, and may continue to result in, higher inflation in the United States and globally, which is likely, in turn, to lead to an increase in costs and may cause changes in fiscal and monetary policy, including additional increases in interest rates. Although reimbursement rates for WCDs, including our ASSURE WCD, have increased in recent years, adverse macroeconomic conditions could result in payors reducing reimbursement rates, which could negatively impact our profitability and cash flows. Such conditions could also reduce demand for our ASSURE WCD if they adversely affect insured customers' ability to pay insurance deductibles and uninsured customers' ability to lease our device. Other adverse impacts of recent macroeconomic conditions have been, and may continue to be, supply chain constraints, logistics challenges, liquidity concerns in the broader financial services industry, and fluctuations in labor availability.

In a higher inflationary environment, we may be unable to raise the prices of our products sufficiently to keep up with the rate of inflation. A higher inflationary environment can also negatively impact raw material, component, and logistics costs that, in turn, may increase the costs of producing and distributing our products.

We may in the future experience supply chain constraints, including difficulties obtaining a sufficient supply or increased prices of component materials used in our products. Increased interest rates may make access to credit more difficult, which may result in the insolvency of key suppliers, which would exacerbate supply chain challenges. Such supply chain constraints could cause us to fail to meet product demand or maintain our margins.

Our annual effective income tax rate can change materially as a result of changes in our mix of U.S. and non-U.S. earnings and other factors, including changes in tax laws and changes made by regulatory authorities.

Our overall effective income tax rate is equal to our total tax expense as a percentage of total earnings before tax. However, income tax expense and benefits are not recognized on a global basis but rather on a jurisdictional or legal entity basis. Losses in one jurisdiction may not be used to offset profits in other jurisdictions and may cause an increase in our tax rate. Changes in the mix of earnings (or losses) between jurisdictions and assumptions used in the calculation of income taxes, among other factors, could have a significant effect on our overall effective income tax rate.

We may be subject to additional taxes if our transfer pricing arrangements are challenged or we fail to establish tax residency in Ireland.

We have entered into transfer pricing arrangements that establish prices for our intercompany operations. However, our transfer pricing procedures are not binding on the applicable taxing authorities. No official authority in any jurisdiction has made a determination as to whether or not we are operating in compliance with such authority's transfer pricing laws. Accordingly, a taxing authority could challenge our transfer prices and require us to adjust them to reallocate our income. Any change to the allocation of our income as a result of review by a taxing authority could have a negative effect on our results of operations and financial condition.

Taxing authorities may disagree with and may challenge our tax positions. If our tax positions are not sustained in the event of such challenge, we could be required to pay additional taxes, interest, penalties or other costs which could impact our results of operations and financial condition.

We are subject to taxation in Ireland and multiple other jurisdictions. As a result, any adverse development in the tax laws of Ireland or any of these jurisdictions or any disagreement with our tax positions could have a material adverse effect on our business, consolidated financial condition or results of operations.

Our Company and certain of our subsidiaries are resident in Ireland for Irish corporation tax purposes. We believe that, as Irish tax resident entities, our status should improve our ability to maintain a competitive worldwide effective corporate tax rate; however, we cannot give any assurance as to what our effective tax rate will be because of, among other things, uncertainty regarding the tax policies of the jurisdictions where we operate. In general, under current Irish legislation, a company is regarded as resident for tax purposes in Ireland if it is incorporated in Ireland (unless broadly this is displaced by the terms of a double taxation treaty that Ireland has entered into) or it is centrally managed and controlled in Ireland. Trading income (active business income) of an Irish resident company is generally taxable at the Irish corporation tax rate of 12.5% (provided that the company is not part of a consolidated multinational group with more than EUR750 million of annual consolidated revenue in which case the company may be subject to Irish corporation tax at 15%). Non-trading income of an Irish resident company is taxable at a rate of 25% and capital gains at a rate of 33%. It is possible that in the future, whether as a result of a change in law or the practice of any relevant tax authority or as a result of any change in the conduct of our affairs, those companies could become, or be regarded as having become, tax resident in a jurisdiction other than Ireland. Should any of those companies cease to be Irish tax resident, they may be subject to a charge to Irish capital gains tax as a result of a deemed disposal of their assets. Our actual effective tax rate may vary from our expectation and that variance may be material. Additionally, the tax laws of Ireland, the United States and other jurisdictions could change in the future, and such changes could cause a material change in our effective tax rate.

A number of factors may increase our future effective tax rates, including:

- the jurisdictions in which profits are determined to be earned and taxed;
- the resolution of issues arising from tax audits with various tax authorities;
- loss of tax treaty benefits in one or more jurisdictions;
- changes in the valuation of our deferred tax assets and liabilities;
- increases in expense not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions;
- changes in available tax credits;
- changes in share-based compensation;
- changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles; and
- challenges to the transfer pricing policies related to our structure.

Ireland is a Member State of the European Union (the "EU"). The EU has become increasingly active in the area of direct taxation in recent years, in some cases on foot of wider international tax initiatives such as the OECD BEPS (Base Erosion and Profit Shifting) initiative and in other cases unilaterally. A number of EU legislative tax measures have been implemented in recent years such as the Anti-tax Avoidance Directive, the EU Mandatory Disclosure Regime DAC6 requiring the reporting of certain cross-border arrangements, and the EU Global Minimum Tax Directive. There are also a number of proposed EU legislative tax measures such as the Business in Europe: Framework for Income Taxation which proposes a new legislative framework for corporate taxation in the EU. Additionally, the EU Commission has carried out a number of investigations concerning unlawful EU State Aid involving tax measures in Member States, most notably in the European Court case of *European Commission v Ireland and Apple Sales International* (Case C-465/20 P) which was held in favor of the European Commission. State Aid is any aid granted by an EU Member State or through EU Member State resources in any form whatsoever which distorts or threatens to distort competition by favoring certain undertakings or the production of certain goods. Any of these proposed or actual legislative measures or EU law related actions could impact our tax treatment.

Our tax position could be adversely impacted by changes in tax rates generally, tax laws, tax treaties or tax regulations or changes in the interpretation of such laws, treaties or regulations by the tax authorities in Ireland, the United States and other jurisdictions. In addition, the tax authorities in any applicable jurisdiction may disagree with the positions we have taken or intend to take regarding the tax treatment or characterization of any of our transactions.

Failure to manage the risks associated with such changes, or misinterpretation of the laws relating to taxation, could result in increased charges, financial loss, including penalties, and reputational damage and materially and adversely affect our results, financial condition and prospects.

If we are required to reclassify independent contractors as employees, we may incur additional costs and taxes which could adversely affect our business, financial condition, results of operations and prospects.

We engage independent contractors in our operations for whom we do not pay or withhold any federal, state or other employment tax. There are a number of different tests used in determining whether an individual is an employee, or an independent contractor and such tests generally take into account multiple factors. There can be no assurance that legislative, judicial, or regulatory (including tax) authorities will not introduce proposals or assert interpretations of existing rules and regulations that would change, or at least challenge, the classification of our independent contractors. Although we believe we have properly classified our independent contractors, the U.S. Internal Revenue Service or other U.S. federal or state authorities or similar authorities of a foreign government may determine that we have misclassified our independent contractors for employment tax or other purposes and, as a result, seek additional taxes from us or attempt to impose fines and penalties. If we are required to pay employer or withholding taxes with respect to prior periods with respect to or on behalf of our independent contractors, our operating costs will increase, which could adversely impact our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

Third parties may assert that we are employing their intellectual property and other proprietary technology without authorization, and we may become a party to litigation or administrative proceedings related to intellectual property that could be costly, time-consuming, or unsuccessful and could hinder our ability to commercialize our existing or future products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, copyrights and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications, trademarks, copyright registrations or other intellectual property controlled by third parties may be alleged to cover our products or services, or components of our products or services, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include hardware and software components and other elements that we purchase or license from vendors and other third parties, and may include design components (including open-source components) or other elements that are outside of our direct control and could become unavailable on terms acceptable to us or be found or alleged to infringe, misappropriate or otherwise violate the intellectual property rights of third parties. Our direct or indirect competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, copyright registrations, and other intellectual property rights and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, have made, use, sell, offer to sell, and/or import our products and services (or components thereof) or to use product names. Moreover, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and publications in the scientific literature often lag behind actual discoveries. Thus, we cannot be certain that others have not filed patent applications directed to our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights, if available, to any resulting third-party patents directed to such technologies. Given the number of patents directed toward the medical device industry or otherwise applicable to technologies utilized in the medical device industry, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. If a patent holder believes our Cardiac Recovery System platform, any components thereof including the ASSURE WCD, any other products or any future product candidates infringe its patent, the patent holder may sue us even if we have received patent protection. Our Cardiac Recovery System platform, including existing products and any future products that we commercialize, could be alleged to infringe patent rights and other proprietary rights of third parties. Any lawsuits resulting from such allegations, if we are not successful, could subject us to significant liability for damages. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, having made, selling, offering to sell, importing or using products or technologies that allegedly infringe or violate the asserted intellectual property;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing or violating, including enhanced damages if we are found to be willfully infringing or violating such intellectual property rights;

- pay the attorneys' fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing or violating;

- redesign those products that contain the allegedly infringing or violating intellectual property or replace components thereof that contain the allegedly infringing or violating intellectual property, which could be costly, disruptive, infeasible, or require further FDA approval; and

- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

Any litigation or claim against us, even those without merit or that we are able to successfully defend, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. The defense and prosecution of these matters are both costly and time-consuming. Vendors and other parties from which we purchase or license hardware, software or other intellectual property may not indemnify us in the event that such hardware or software is accused of infringing a third party's patent or trademark or of misappropriating a third party's trade secret or otherwise violating a third party's intellectual property rights. There can be no assurance with respect to the outcome of any litigation brought against us, and even if any litigation is resolved in our favor, the outcome of any such litigation could have a material adverse impact on our business, operating results and financial condition. Litigation is inherently unpredictable and outcomes are uncertain. Further, as the costs and outcome of these types of claims and proceedings can vary significantly, it is difficult to estimate potential losses that may occur. Accordingly, we are unable at this time to estimate the effects of these potential future lawsuits on our financial condition, operations or cash flows.

In the event of a successful claim against us for infringement, misappropriation or other violation of third-party intellectual property rights, we may have to pay substantial damages.

If patents, trademarks, trade secrets, or other intellectual property rights are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. A finding of infringement could prevent us from continuing to sell our Cardiac Recovery System platform or any components thereof including the ASSURE WCD, or prevent us from commercializing any future product candidates or force us to cease some or all of our business operations, which could materially harm our business. In addition, if we are found to have willfully infringed third party patents or trademarks, or to have willfully misappropriated trade secrets or otherwise violated other intellectual property rights of others, we could be required to pay enhanced damages in addition to other penalties, including attorneys' fees.

In addition, we may have to obtain one or more licenses from third parties to continue developing and marketing our products and technology, pay royalties and/or redesign our products or technologies, which may be impossible or require substantial time and monetary expenditure. Although patent, trademark, trade secret and other intellectual property disputes in the medical device area sometimes may be settled through licensing or similar arrangements, we may not be able to obtain such arrangements at all and if we do, costs associated with such arrangements may be substantial and could include ongoing royalties that materially adversely impact our revenue. We may be unable to obtain necessary licenses on satisfactory terms and one or more third parties may refuse to grant necessary licenses. Some licenses from third parties may include access to technologies for use by us on defined terms. Other licenses from third parties may not provide access to any additional technologies and may be limited to granting permission for us to utilize existing or future technology in exchange for additional fees. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement, which could result in a material adverse effect on our business. Even if we were able to obtain such licenses, then it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to any technologies licensed to us.

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

We may be subject to claims that current or former employees, partners or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our pipeline assets or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office ("USPTO") or other jurisdictional bodies may be necessary to determine priority or originality with respect to our patents or patent applications. We may also become involved in other proceedings, such as reexamination, *inter partes* review, post-grant reviews, cancellations, derivation or opposition proceedings before the USPTO or other jurisdictional bodies relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products or using product names, which would have a significant adverse impact on our business.

We may become involved in litigation or administrative proceedings related to intellectual property, including litigation to protect, enforce or defend the validity of our intellectual property.

We may need to commence proceedings or assert counterclaims against others to enforce our patents, trademarks or other intellectual property, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others when we determine that a successful outcome may lead to an increase in the value of the intellectual property. If we choose to enforce our patent rights against a party, then that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced. Additionally, the validity of our patents and the patents we have licensed may be challenged if a petition for post-grant proceedings, such as *inter partes* review and post-grant review, is filed within the statutorily applicable time with the USPTO. Proceedings to challenge patents are also available internationally, including for example, opposition proceedings and nullity actions. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability and U.S. Patent Trial and Appeal Board ("PTAB") challenges are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before the PTAB, even outside the context of litigation. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. There is also the risk that, even if the validity or enforceability of such patents is upheld, a court or jury may find that the other party's products or services do not infringe our patents. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may not be able to stop a competitor from marketing and selling products that are the same or similar to our products and services or from using product or service names that are the same or similar to ours, and our business may be materially harmed as a result.

Our ability to enforce our patent rights depends on our ability to detect infringement by third parties. It may be difficult to detect infringers that do not advertise the components or methodologies that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Adverse proceedings can be expensive, time-consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, a court or other judicial body may decide that the patent we seek to enforce is not patentable, invalid or unenforceable. Additionally, a court or other judicial body may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the allegedly infringing technology in question or otherwise refuse to enjoin a party found to have infringed a patent. An adverse result in any proceeding could put one or more of our patents at risk of being found not patentable, invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property proceedings, and may have significantly larger intellectual property portfolios to assert against us if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property or issues, which proceedings and claims may also include claims related indirectly to our intellectual property such as breach of contract, antitrust, or unfair competition. In addition, we generally indemnify our customers and distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers, distributors or suppliers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, distributors or suppliers, regardless of the merits of these claims. If any of these claims succeeds or settles, we may be forced to pay damages or settlement payments on behalf of our customers, distributors or suppliers or may be required to obtain licenses for the products they use or produce for us. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop purchasing and using our products, which could expose us to substantial losses or liability and otherwise have an adverse effect on our business.

Our efforts to obtain intellectual property protection and the intellectual property rights we obtain may be inadequate, and our business may be adversely affected as a result.

As part of our competitive strategy, we have and will continue to develop, maintain, enforce and protect the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements with employees and third parties to protect our intellectual property rights. These legal measures afford only limited protection. As of April 30, 2025, we have rights to 237 issued U.S. and foreign patents, consisting of 205 issued patents in the U.S., 16 issued patents in the European Union, 7 issued patents in Japan, 4 issued patents in Australia and 5 issued patents in China. Additionally, as of April 30, 2025, we had 130 pending published and unpublished U.S. and foreign patent applications, consisting of 117 pending published and unpublished patent applications in the U.S., 5 pending published patent applications in the European Union, 3 pending published patent applications in Japan, 2 pending published patent applications in Australia and 3 pending published patent applications in China. Assuming all required fees and other charges are paid, the earliest expiry date for issued patents owned or used and maintained by us is in July 2025. We rely, in part, on our ability to obtain and maintain patent protection for our proprietary products and processes. The process of applying for and obtaining a patent 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, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. We cannot be certain that our or our licensors' claims in U.S. pending and corresponding international or foreign patent applications will be considered patentable. In addition, the issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties.

Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our products or technology. Furthermore, the issuance of a patent does not give us the right to make, have made, use, offer to sell, sell or import the patented invention. Other parties may have developed technologies that may be related or competitive to our products, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patents or patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we or others have or may obtain cannot be predicted with certainty. Third parties may have blocking patents that could prevent us from manufacturing, marketing or distributing our own products and making, using, offering to sell, selling, or importing the Cardiac Recovery System platform, one or more products or components thereof, or existing or future products or components. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents and other intellectual property rights, including by filing lawsuits or asserting counterclaims alleging patent infringement, misappropriation and other violations of intellectual property. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid or unenforceable; competitors may then be able to market and sell products and use manufacturing and analytical processes that are substantially similar to ours. In addition, such proceedings may be costly. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. The legal systems of certain countries may not favor the enforcement of patents and other intellectual property protection, particularly those relating to medical devices, and some jurisdictions, such as Europe, Japan, and China, may have a higher standard for patentability than in the United States. Consequently, we may not be able to prevent third parties from making, having made, using, selling, offering to sell, or importing in all countries outside of the United States, or from making, having made, using, selling offering to sell, or importing products incorporating our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. 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.

We may not be able to correctly estimate or control our future operating expenses in relation to obtaining intellectual property, enforcing intellectual property and/or defending intellectual property, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of preparing, filing, prosecuting, defending, and enforcing patent and trademark claims and other intellectual property-related costs, including adverse proceedings (such as litigation) costs.

To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect, maintain and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position may be harmed.

We rely heavily on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, proprietary information, including parts of our Cardiac Recovery System platform, including the ASSURE WCD, and to maintain our competitive position. However, trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to our technologies, these trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and movement of personnel, including from academic to industry scientific positions. In addition to pursuing patents on our products and technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with parties who have access to them, such as our employees, consultants and other third parties. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of these confidentiality agreements and other restrictions. These agreements may not provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use, misappropriation or disclosure of such trade secrets, know-how or other proprietary information. We may not be able to execute assignment agreements with each relevant party and such agreements may be unenforceable or not self-executing. There can be no assurance that employees, consultants, vendors, clients and others with access to the confidential and proprietary information have executed such agreements or have not breached or will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate.

While we use commonly accepted security measures, trade secret violations are often a combination of federal and state law in the United States, and the criteria for protection of trade secrets can vary among different jurisdictions. If the steps we have taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States and there can be no assurance that we have sufficiently protected our intellectual property in every foreign country in which our products may be sold. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. We may be subject to claims challenging the inventorship or ownership of our intellectual property. We also may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Further, it is possible that others independently will develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially adversely affected. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors or their former employers.

We also may employ or otherwise engage personnel who were previously or are concurrently employed or engaged at research institutions or other medical device companies, including our competitors or potential competitors. We may be subject to claims that these personnel, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former or concurrent employers, or that patents and applications we have filed to protect inventions of these personnel, even those related to one or more of our products, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

We rely on trademarks, service marks, trade names and brand names, such as our registered trademarks ASSURE, ASSURE ASSIST, KESTRA and KESTRA CARESTATION, to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that we have applied for all the marks in the jurisdictions and classes of goods and services that are or will be material to our business or, where we have applied, that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO or equivalent institutions in other jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings have and may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands. Moreover, any name we propose to use with our ASSURE WCD or any future medical device product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed medical device names, including an evaluation of potential for confusion with other medical device names. If the FDA objects to any of our proposed proprietary medical device names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Further, we cannot assure you that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. We also face risks in connection with our international expansion, including in countries that may have less protection for our trademarks than the United States. There is a risk that our trademarks may not be adequate to protect our brand or may conflict with the trademarks of other companies, both domestically and abroad, which may require us to rebrand our products, obtain costly licenses, defend against third-party claims, or substantially change our product or service offerings. Should such risks manifest, we may be required to expend considerable resources and divert the attention of our management, which could have an adverse effect on our business and results of operations.

If we do not adequately protect our trademarks and trade names, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks may be challenged, infringed, circumvented, declared to be descriptive, declared generic or conflict with third-party rights. We may not be able to protect our rights to these trademarks, which we need to build name recognition by potential partners or customers in our markets of interest. In addition, third parties may file first for our trademarks in certain countries. If they succeed in registering such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In such cases, over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then our marketing abilities may be impacted.

Changes in U.S. or foreign patent law or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

As is the case with other medical device and medical technology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the medical device and medical technology industries involve both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain, due in part to ongoing changes in patent laws. Depending on decisions by Congress, the federal courts and the USPTO and equivalent institutions in other jurisdictions, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce existing or future patents. For example, in recent years the U.S. Supreme Court has ruled on several patent cases that have been interpreted to have either narrowed the scope of patent protection or weakened the rights of patent owners in certain situations. In addition, patent reform legislation or regulation, such as the Patent Eligibility Restoration Act of 2023 which was introduced to the U.S. Senate on June 22, 2023, may be proposed or enacted in the future that may impact our ability to obtain patents in the future. Therefore, there is increased uncertainty with regard to our ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Patent reform legislation or changes to USPTO regulations or fees could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act enacted in September 2011 (the "Leahy-Smith Act"), the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations and prospects. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Additionally, as of June 2023, the Company's EPO-registered patents are subject to the jurisdiction of the European Unitary Patent system and the European Unified Patent Court ("UPC"). It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC.

Even if our patents are determined by a court to be valid and enforceable, courts may not interpret them sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents. For example, third parties may be able to make product that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that were not the first to make the inventions covered by our issued patents. The claims of our issued patents or patent applications when issued may not cover our proposed commercial technologies or the future products that we develop. We may not have freedom to commercialize our products unimpeded by the patent rights of others. Third parties may have dominating, blocking, or other patents relevant to our technology of which we are not aware. There may be prior public disclosures or art that could be deemed to invalidate one or more of our patent claims. Further, we may not develop additional proprietary technologies in the future, and, if we do, they may not be patentable.

Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many international jurisdictions, policy regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how they interpret the patent laws of the United States. Similarly, international courts have made, and will likely continue to make, changes in how they interpret the patent laws in their respective jurisdictions. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and international legislative bodies. Those changes may materially affect our patent rights and our ability to obtain issued patents.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file, prosecute, maintain, protect, defend, enforce or license all necessary or desirable patents or patent applications, as applicable, at a reasonable cost, in a timely manner, in all potentially relevant jurisdictions, or at all. It is possible that defects as to 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, claim scope, or requests for patent term adjustments. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. If we delay filing a patent application, and a competitor files a patent application on the same or similar invention before we do, our ability to secure patent rights may be limited and we may not be able to patent the invention at all. Even if we can patent the invention, we may be able to patent only a limited scope of the invention, and the limited scope may be inadequate to protect our assets and technologies, or to block competitor's products and technologies that are similar or adjacent to ours. There are also uncertainties or limitations in our ability to properly protect and defend patents covering our products, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Our earliest patents and patent filings are public. A competitor may review our published patent filings and arrive at the same or similar technology advances for our assets as we developed. If the competitor files a patent application on such an advance before we do, then we may no longer be able to protect that aspect of our assets and technologies and we may require a license from the competitor, which may not be available on commercially viable terms or at all. Moreover, we may not develop additional proprietary products, methods and technologies that are patentable. We also rely to a certain extent on trade secrets, know-how, and technology, that are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially and adversely affected.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and certain pending patent applications are required to be paid to the USPTO or foreign patent agencies in several stages over the lifetime of a patent. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. While an inadvertent lapse in many cases can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications directed to our Cardiac Recovery System platform, any components thereof including the ASSURE WCD, other products or any future product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business, financial condition, results of operations and prospects.

In addition, patent expiration dates may be affected by a number of factors. For example, patent terms may be shortened or lengthened by terminal disclaimers, patent term adjustments, supplemental protection certificates, and patent term extensions. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Non-payment or delay in payment of patent fees or annuities, delay in patent filings or delay in extension filing (including any patent term extension or adjustment filing), whether intentional or unintentional, may also result in the loss of patent rights important to our business.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any existing products or product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own or license now or in the future;

- we might not have been the first to make the inventions covered by the issued patent or pending patent application that we own now or in the future;

- we might not have been the first to file patent applications directed to certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;

- it is possible that our pending held or licensed patent applications or those that we may file or license in the future will not lead to issued patents;

- issued patents to which we hold rights may be held invalid or unenforceable, including as a result of legal challenges by other persons;

- our competitors might conduct research and development activities in the United States under FDA-related safe harbor patent infringement exemptions and/or in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for distribution in our major commercial markets;

- we may not develop additional proprietary technologies or products that are patentable;

- the patents or pending patent applications of others may harm our business;

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;

- we cannot assure that any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;

- we may not be able to successfully commercialize our products on a substantial scale, if approved, before our relevant patents expire;

- we cannot assure that our commercial activities or products will not infringe the intellectual property rights of others; and

- we cannot assure any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties.

Should any of these events occur, they could harm our business, financial condition, results of operations and prospects.

We include technology in our products that is licensed to us by third parties. Any loss of our rights to this technology could prevent us from selling our products.

We hold certain intellectual property and technology licenses under which we license intellectual property and technology from third parties that we use in our products or other parts of our business. We do not own the intellectual property that underlies these licenses. Our rights to use the licensed intellectual property is subject to the continuation of and compliance with the terms of the licenses, including terms that may restrict our ability to expand our use of such intellectual property into other fields. We expect that we may need to enter into additional license agreements in the future. Our business could suffer, for example, if any current or future licenses terminates, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

As we have done previously, we may need or may choose to obtain patent or other licenses from third parties to advance our research or allow commercialization of our current or future products. We cannot provide any assurances that third-party patents do not exist that might be enforced against our current or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may not be exclusive. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting the commercialization of our products or an obligation on our part to pay royalties and/or other forms of compensation.

Disputes may arise in the future between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- whether and the extent to which our technology and processes infringe or violate intellectual property rights of the licensor that is not subject to the licensing agreement;

- our right to enlist third party vendors or contractors to manufacture or assemble components under the scope of the license agreement;

- our right to sublicense patent and other rights to third parties under collaborative development relationships;

- royalty calculations, including our obligation to disclose proprietary manufacturing information, determining products included or excluded from royalty obligations, and compliance with audit rights;

- disclosure of terms of existing license agreements to third parties based on confidentiality obligations included in the license agreements;

- mergers, acquisition, dissolutions, or other business entity transactions that can affect the ownership of intellectual property rights subject to the license agreement or obligations under the license agreement;

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations; and

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

Disputes regarding our current licensing arrangements may have an adverse effect on our business.

In addition to agreements pursuant to which we in-license intellectual property, we have granted in the past, and will continue to grant in the future licenses under our intellectual property. Like our in-bound licenses, our out-bound licenses are complex and disputes may arise between us and our licensees, such as the types of disputes described above. Moreover, our licensees may breach their obligations, or we may be exposed to liability due to our failure or alleged failure to satisfy our obligations. Any such an occurrence could have an adverse effect on our business.

Risks Related to Government Regulation

Changes in the regulatory environment may make it more difficult and costly for us to manufacture, market or distribute our products, or to obtain approval for any future products.

Healthcare laws and regulations change frequently and may change significantly in the future. We may not be able to adapt our operations to address every new regulation, and new regulations may adversely affect our business. We cannot assure you that a review of our business by courts or regulatory authorities would not result in a determination that adversely affects our revenue and operating results, or that the healthcare regulatory environment will not change in a way that restricts our operations. In addition, there is risk that the U.S. Congress may implement changes in laws and regulations governing providers of healthcare services and products, including measures to control costs, or reductions in reimbursement levels, which may adversely affect our business and results of operations.

Government payors, such as Medicare, as well as private payors, have increased their efforts to control the cost, utilization and delivery of healthcare services and products. From time to time, the U.S. Congress has considered and implemented changes in the Medicare fee schedules in conjunction with budgetary legislation. For example, The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2030. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Further reductions of reimbursement by Medicare for services or changes in policy regarding coverage of tests or other requirements for payment, such as prior authorization or a healthcare provider or qualified practitioner’s signature on test requisitions, may be implemented from time to time. Reductions in the reimbursement rates and changes in payment policies of other third-party payors may occur as well. Similar changes in the past have resulted in reduced payments as well as added costs and have added more complex regulatory and administrative requirements.

The FDA and other regulatory agencies that impact our operations may also change their policies or take other actions, including as a result of legal challenges against such agencies, which may increase the cost of compliance and prevent or delay marketing authorization of our future products under development or impact our ability to enhance products for which we have already obtained marketing authorizations on a timely basis or at all. The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* (the "Loper decision") overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and guidance issued by federal agencies applicable to our business, including those of the FDA, the USPTO, the FTC and the International Trade Commission. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations.

If we fail to comply with healthcare and other governmental regulations, we could face substantial penalties and our business, results of operations and financial condition could be adversely affected.

The products and services we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our business practices, distribution and billing arrangements with third-party DME providers, and other arrangements with healthcare providers, hospitals, and patients may expose us to scrutiny under broadly applicable fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell and distribute our products and services. U.S. federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- federal and state laws and regulations regarding billing and claims payment applicable to our products and regulatory agencies enforcing those laws and regulations;

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the furnishing, purchase, order or recommendation of, any good or service for which payment may be made under government healthcare programs, such as the Medicare and Medicaid programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the government, healthcare programs. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act; the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the federal Physician Payment Sunshine Act, created under the Affordable Care Act (as defined below), and its implementing regulations, which requires manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS information related to payments or other transfers of value made to licensed physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Additionally, beginning in 2022, applicable manufacturers are also required to report certain payments and other transfers of value made during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information upon "covered entities" (health plans, healthcare clearinghouses and certain healthcare providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the HHS Office of Civil Rights, affected individuals, and, if the breach is large enough, the media. Entities that are covered by HIPAA (e.g., covered entities and business associates) found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by the HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with the HHS to settle allegations of HIPAA non-compliance. HIPAA also created criminal liability for executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Additionally, the FTC also has authority to initiate enforcement actions against entities for, amongst other things, misleading customers about HIPAA compliance, making deceptive statements about privacy and data sharing in privacy policies, failing to limit third-party use of personal health information, failing to implement policies to protect personal health information, or engaging in other unfair practices that harm customers or that may violate Section 5 of the FTC Act;

- the Federal Food, Drug and Cosmetic Act, which regulates the manufacturing, labeling, marketing and sale of medical devices and prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers;

- the federal physician self-referral prohibition, commonly known as the Stark Law; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers, state-mandated disclosures of payments or other transfers of value to healthcare providers or marketing expenditures, state laws related to insurance fraud in the case of claims involving private insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

These laws and regulations, among other things, constrain our business, marketing, sales, distribution and other promotional and research activities by limiting the kinds of financial arrangements that we may have with hospitals, healthcare providers or other potential referral sources for our products, as well as our arrangements with other third parties for the purchase, sale, billing, and distribution of our products. In particular, these laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements, as well as interactions with healthcare providers through consultant arrangements, product training, sponsorships, or other activities. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare and other laws and regulations will involve substantial costs.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, governmental authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations. To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act including mandatory treble damages and significant per-claim penalties. Additionally, as a result of these investigations and qui tam actions, we may have to agree to additional compliance and reporting requirements as part of a consent decree, deferred prosecution or corporate integrity agreement.

We have implemented a corporate compliance program designed to actively identify, prevent and mitigate risk through the implementation of compliance policies, training, auditing and monitoring. We expect to devote substantial resources to implement, maintain, administer and expand the compliance program as necessary. Our company is a member of AdvaMed and complies with the AdvaMed Code. We cannot be certain, however, that our compliance program will ensure compliance with the various complex laws and regulations to which we are subject now or in the future. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal and state laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment, for individuals, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, or oversight if we become subject to a consent decree, deferred prosecution or corporate integrity agreement, and we could be required to curtail or cease our operations. Any of the foregoing consequences could materially adversely affect our business, financial condition, results of operations and prospects.

Our team members, consultants and commercial partners may engage without our awareness in misconduct or other improper activities, including non-compliance with regulatory standards and requirements despite any policies we may have in place to prevent such misconduct, and we may be found liable for their actions.

Our products and operations are subject to extensive government regulation and oversight. If we fail to obtain and maintain necessary regulatory clearances or approvals for our products, or if clearances or approvals for future products and indications are delayed or not issued, or if we fail to comply with post-marketing regulatory requirements, our commercial operations would be harmed.

Our products are subject to extensive regulation by the FDA. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development and manufacture;
- laboratory, pre-clinical and clinical testing, labeling, packaging, storage and distribution;
- premarketing clearance and approval;
- record keeping;
- establishment registration and device listing;
- product marketing, promotion, advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths or serious injuries, recalls, corrections and removals.

Before a new medical device or service, or a new intended use for an existing product or service, can be marketed in the United States, a company must first submit and receive either 510(k) clearance or premarketing approval from the FDA, unless an exemption applies. Either process can be expensive, lengthy and unpredictable. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;

- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of clinical trials or the interpretation of data from pre-clinical studies or clinical trials of our products;

- serious and unexpected adverse device effects experienced by participants in clinical trials of our products;

- the data from pre-clinical studies and clinical trials of our products may be insufficient to support clearance or approval, where required;

- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;

- the manufacturing process or facilities we use may not meet applicable requirements; and

- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly, including as a result of changes in administration, in a manner resulting in delays in the approval process or rendering our performance testing and clinical data or regulatory filings insufficient for clearance or approval.

Although we have obtained FDA approval to market our ASSURE WCD, we are subject to ongoing and pervasive post-marketing regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, registration, and listing of devices. For example, we are required to file various reports with the FDA, including reports required by the medical device reporting regulations that require that we report to the regulatory authorities if our products 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 the malfunction were to recur. If these reports are not filed in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. In addition, our PMA for our ASSURE WCD was subject to several conditions of approval, including labeling, useful life restrictions, the commencement of a post-approval registry and post-market study requirements. Though we believe we have complied with these conditions to date, any failure to comply with the conditions of approval could result in the withdrawal of our PMA and the inability to continue to market our ASSURE WCD.

If we initiate a correction or removal for any of our products to reduce a risk to health posed by any such products, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause healthcare providers to delay or cancel prescriptions, which could harm our reputation.

The FDA and the FTC also regulate the advertising and promotion of our products and services to ensure that the claims we make are consistent with our regulatory approvals and clearances, that there is adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

- repair, replacement, refunds, recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;

- delays or denial of our requests for 510(k) clearance or premarket approval of new products or services, new intended uses or modifications to existing products or services;

- withdrawal of 510(k) clearance or premarket approvals that have already been granted; and

- criminal prosecution.

If any of these events were to occur, our business, financial condition, results of operations and prospects could be materially adverse affected.

Material modifications to our ASSURE WCD or any future products may require new PMAs, 510(k) clearances, CE Marks or other premarket approvals or may require us to recall or cease marketing our products and services until clearances are obtained.

Material modifications to the intended use or technological characteristics of our products will require new PMA or 510(k) clearances or CE Mark grants or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA cleared device or service that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new PMA or 510(k) clearance. We may not be able to obtain additional PMA or 510(k) clearances for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would have an adverse effect on our business, financial condition, results of operations and prospects. For device modifications that we conclude do not require a new regulatory clearance or approval, we may be required to recall and to stop marketing the modified devices if the government agency disagrees with our conclusion and requires new clearances or approvals for the modifications. This could have an adverse effect on our business, financial condition, results of operations and prospects.

If we or our suppliers fail to comply with the federal, state and international regulations, our operations could be delayed or shut down and our revenue could suffer.

The manufacturing processes of our third-party suppliers are required to comply with the FDA's QSR, which covers procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 and ISO 14971 compliance in all operations, including design and service. In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic unannounced inspections by governmental agencies, including the FDA and state authorities. If we or our third-party suppliers fail a regulatory inspection, our operations could be disrupted and manufacturing interrupted. Failure to take adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our third-party suppliers' manufacturing operations, our product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

The FDA has broad post-market and regulatory enforcement powers. We and our third-party suppliers are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations at both our design and third-party manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers. We can provide no assurance that we will continue to remain in compliance with the QSR. If the FDA inspect any of our facilities or our third-party suppliers' facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management, which may have an adverse impact on our ability to continue with our research and development projects and implement our business growth plans.

If our products cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury, we will be subject to medical device reporting regulations and other applicable laws, and may need to initiate voluntary or mandatory corrective actions, such as the recall of our healthcare products.

Under the FDA's medical device reporting regulations, we are required to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or in which a product of ours malfunctioned and, if the malfunction were to recur, would be likely to cause or contribute to death or serious injury. Other countries we may market our products to in the future will similarly have regulatory agencies requiring us to report any incident in which our products cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, including when the FDA may disagree with our determination that an event was not reportable, the FDA or other governmental authorities could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and similar foreign regulatory authorities have the authority to require the recall of our products in the event of material deficiencies or defects in, for example, design, labeling or manufacture. The FDA must find that there is a reasonable probability that the device would cause serious adverse health consequences or death in order to require a recall. The standard for recalling deficient products may be different in foreign jurisdictions. Manufacturers may, under their own initiative, recall a product if any material deficiency is found in a device or they become aware of a safety issue involving a marketed product. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Any correction or removal initiated by us to reduce a health risk posed by our device, or to remedy a violation of the Federal Food, Drug, and Cosmetic Act or other regulations caused by our product that may present a risk to health, must be reported to the FDA. If the FDA subsequently determines that a report was required for a correction or removal of our products that we did not believe required a report, we could be subject to enforcement actions.

Any recalls or corrections of our products or enforcement actions would divert managerial and financial resources and could have an adverse effect on our financial condition and results of operations. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals 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 FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines. In addition, given our dependence upon healthcare provider and consumer perceptions, any negative publicity associated with any recalls could materially and adversely affect our business, financial condition, results of operations and prospects.

We may also be required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us, and negatively affect our revenues, in addition to the FDA enforcement actions. Any corrective action, voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, attention of our management, and may harm our reputation, business, financial condition, results of operations and prospects.

If we do not obtain international regulatory registrations, clearances, certifications or approvals for our products, we will be unable to market and offer our products outside of the United States.

Any future distribution of our products outside of the United States is subject to foreign regulatory requirements that we have limited experience with and that may vary widely from country to country. As of the date of this Annual Report, we have not received any regulatory approvals to commercialize our products outside of the U.S. and have not submitted any applications to obtain such regulatory approvals. However, we are currently planning to pursue CE Mark approval in Europe and, in the future, intend to strategically commercialize in selected international markets. We anticipate Western Europe to be our initial focus due to favorable market dynamics and our goal is to obtain regulatory approvals to begin distributing our ASSURE WCD in certain markets in Western Europe within the next three years. There is no assurance of when we will successfully obtain the CE Mark, if at all. In addition, as a result of the United Kingdom leaving the European Union, since January 1, 2021, the regulatory framework and regimes for medical devices in the United Kingdom and the European Union have diverged. As such, we may need to invest additional time and resources to obtain the relevant approvals if we intend to distribute our products in both the European Union and in the United Kingdom. We may incur significant costs in our efforts to obtain foreign regulatory approvals and there is no assurance that we will generate sufficient revenues to offset such costs. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the clearance, certification or approval of a specified regulatory body. Moreover, clinical studies or manufacturing processes conducted in one country may not be accepted by regulatory authorities in other countries. Complying with foreign regulatory requirements, including obtaining registrations, clearances, certifications or approvals, can be expensive and time-consuming, and we may not receive regulatory clearances, certifications or approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations, clearances, certifications or approvals, if required by other countries, may be longer than that required for FDA clearance or approval, and requirements for such registrations, clearances, certifications or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for regulatory clearances or approvals before we are permitted to sell the modified product.

Regulatory clearance or approval by the FDA does not ensure registration, clearance, certification or approval by regulatory authorities in other countries, and registration, clearance, certification or approval by one or more foreign regulatory authorities does not ensure registration, clearance, certification or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or regulatory clearance, certification or approval in one country may have a negative effect on the regulatory process in others.

Healthcare reform measures could hinder or prevent the commercialization of our products and our ability to achieve profitability.

There have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could harm our future revenue and profitability. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, the Affordable Care Act contains a number of provisions, including those governing enrollment in government healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs.

Under the prior Trump administration, there were ongoing efforts to modify or repeal all or certain provisions of the Affordable Care Act. For example, tax reform legislation was enacted at the end of 2017 that eliminated the tax penalty established under Affordable Care Act for individuals who do not maintain mandated health insurance coverage beginning in 2019. The Affordable Care Act has also been subject to judicial challenge. The case *Texas v. Azar*, which challenges the constitutionality of the Affordable Care Act, including provisions that are unrelated to healthcare reform but were enacted as part of the Affordable Care Act, was argued before the Supreme Court in November 2020. The Supreme Court determined the Affordable Care Act would remain in place. The nature and scope of healthcare reform under the current presidential administration remains uncertain.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare, particularly in light of the current presidential administration which has stated its intent to make some changes to the regulatory landscape overseen by the HHS, including the FDA. Under the current presidential administration, Congress is also considering significant cuts to federal spending under the Medicaid program. Reductions in funding may lead to decreased membership in government health plans, or cause membership to grow at lower levels than we currently expect. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may make it more difficult and costly to manufacture, market, or distribute our commercialized products, or may impose additional costs, lengthen regulatory application and approval review times, or make it more difficult to obtain marketing authorizations for any future products we develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

If we fail to maintain required licenses, certifications, or accreditation, or if we do not fully comply with requirements to provide notice to or obtain approval from regulatory authorities due to changes in our ownership structure or operation, it could adversely impact our operations.

We are required to maintain state and/or federal licenses and certifications for our operations and facilities. From time to time, we may become subject to new or different licensing requirements due to legislative or regulatory requirements or the development of or changes to our business. We are subject to periodic inspection by governmental and other authorities to assure continued compliance with the various standards necessary for licensing and certifications, some of which are complex and may be unclear or subject to varying interpretation.

Accurate licensure is also a critical threshold issue for Medicare enrollment as a DMEPOS Supplier, which is required in order to bill Medicare for products provided to Medicare beneficiaries. In addition, many private payors and Medicaid agencies require DMEPOS suppliers to maintain Medicare enrollment, and we are required to comply with the Medicare DMEPOS Supplier Standard in order to maintain such Medicare enrollment. Although we believe we have the right systems in place to monitor licensure and certification, our failure to obtain and maintain appropriate licensure or certification for our operations, facilities, and healthcare providers could result in interruptions in our operations and our ability to service patients, refunds to state and/or federal payors, and the imposition of sanctions or fines, which could have an adverse and material impact on our business, financial condition, results of operations and prospects.

Accreditation is required by most commercial payors and is a mandatory requirement for all Medicare DMEPOS suppliers. Our company has received DME accreditation via a virtual inspection and a confirmatory onsite visit. CMS has also issued a Medicare P-TAN number to our company as a Medicare DMEPOS supplier. If we fail to maintain our accreditation or Medicare P-TAN number, or lose our accreditation or Medicare P-TAN number, it could have a material adverse effect on our business, financial condition, results of operations and prospects.

The requirements for licensure and certification may include notification or approval in the event of a transfer or change of ownership or certain other changes. Government healthcare programs or commercial payors with which we intend to enter into contracts may have similar requirements and some of those processes may be complex. Failure to provide required notifications or obtain the requisite approvals could result in the delay or inability to complete an acquisition or transfer, loss of licensure, lapses in reimbursement or other penalties. While we make reasonable efforts to substantially comply with these requirements, if we are found to have failed to comply in some material respect, it could have an adverse or material impact on our business and our financial conditions.

Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability.

Our research and development operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could materially adversely affect our business, financial condition, results of operations and prospects.

Our products contain third-party open source software components and failure to comply with the terms of the underlying open source software licenses could restrict our ability to sell our products, affect our ability to protect our proprietary information and subject us to possible litigation.

Our products contain software tools licensed by third parties under open source software licenses. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source software licenses generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code and have not been interpreted by United States courts. We may be subject to suits by third parties claiming ownership of what we believe to be open source software, or claiming non-compliance with the applicable open source licensing terms. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our solutions on terms that are not economically feasible, to re-engineer our products, services or technology, to discontinue the sale of our products, services or technology if re-engineering could not be accomplished on a timely basis, to pay statutory or other damages to the license holder or to make generally available, in source code form, our proprietary code, any of which could materially adversely affect our business, financial condition, results of operations and prospects. Use of open source software may also present additional security risks because the public availability of such software may make it easier for hackers and other third parties to compromise or attempt to compromise our technology platform and systems.

Risks Related to Ownership of Our Common Shares

Bain Capital has significant influence over us, and its interests may conflict with ours or yours.

Bain Capital beneficially owns approximately 52.6% of our common shares and controls approximately 48.6% of the voting power represented by our outstanding common shares, which means that, based on its percentage voting power, Bain Capital is currently our largest shareholder and has significant influence over the vote of all matters submitted to a vote of our shareholders, including the election of the members of our Board of Directors and other corporate decisions. For so long as Bain Capital continues to own a significant percentage of our shares, Bain Capital will be able to significantly influence actions relating to the composition of our Board of Directors, new issuances of equity, including to our employees under equity incentive plans, amendments of our organizational documents and approval of any merger, amalgamation, sale of assets or other major corporate transaction. Accordingly, for such period of time, Bain Capital will have substantial influence with respect to our management, business plans and policies. In particular, for so long as Bain Capital continues to own a significant percentage of our shares, Bain Capital will be able to cause or prevent a change of control of us or a change in the composition of our Board of Directors and could preclude any unsolicited acquisition of us. The concentration of ownership could deprive you of an opportunity to receive a premium for your common shares as part of a sale of us and ultimately might affect the market price of our common shares.

Bain Capital and its affiliates engage in a broad spectrum of activities, including investments in the healthcare industry generally. In the ordinary course of its business activities Bain Capital and its affiliates may engage in activities where their respective interests conflict with our interests or those of our other shareholders, such as investing in or advising businesses that directly or indirectly compete with certain portions of our business or are suppliers or customers of ours. Bain Capital also may pursue acquisition opportunities that may be complementary to our business, and, as a result, those acquisition opportunities may not be available to us. In addition, Bain Capital may have an interest in pursuing acquisitions, divestitures and other transactions that, in its judgment, could enhance its investment, even though such transactions might involve risks to you.

Our amended and restated bye-laws provide that the Company will renounce to the fullest extent permitted by applicable law any interest or expectancy in, or in being offered an opportunity to participate in, any business opportunity that may from time to time be presented to Holdings, L.P. ("Bain Charger") and its affiliates, and that may be a business opportunity for such parties, even if the opportunity is one that the Company might reasonably have pursued or had the ability or desire to pursue if granted the opportunity to do so. In addition, to the fullest extent permitted by applicable law, Bain Charger and its affiliates will not be liable to the Company for breach of any fiduciary or other duty by reason of the fact that Bain Charger pursues or acquires any such business opportunity, directs any such business opportunity to another person or fails to present any such business opportunity, or information regarding any such business opportunity, to us. Bain Charger and its affiliates do not have any duty to refrain from engaging directly or indirectly in the same or similar business activities or lines of business as the Company or any of its subsidiaries.

We are an emerging growth company and a smaller reporting company, and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years from the date of our initial public offering ("IPO"). For as long as we are an emerging growth company, we will not be required to comply with certain requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, and may also take advantage of the reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements and the exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and obtaining shareholder approval of any golden parachute payments not previously approved. As a result, we take, and intend to continue to take, advantage of exemptions from various reporting requirements that would otherwise be applicable to public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to avail ourselves of the provision of the JOBS Act that permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. As a result, we will not be subject to new or revised accounting standards at the same time as other public companies that are not emerging growth companies. As a result of these elections, our financial statements may not be comparable to those of public companies that comply with such new or revised accounting standards.

We are also a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act. We may continue to be a smaller reporting company for so long as either (1) the market value of our common shares held by non-affiliates is less than $250.0 million as of the last business day of our most recently completed second fiscal quarter or (2) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our common shares held by non-affiliates is less than $700.0 million as of the last business day of our most recently completed second quarter. Any loss of our status as a smaller reporting company takes effect in the first quarter after the fiscal year in which we cease to qualify as a smaller reporting company. To the extent that we continue to qualify as a smaller reporting company at the time we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC.

Investors may find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the market price of our common shares may be adversely affected and more volatile.

Our share price may be volatile, and its market price may decline disproportionately in response to developments that are unrelated to our operating performance.

The market price of our common shares may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors. In addition, securities markets worldwide have experienced, and are likely to continue to experience, significant price and volume fluctuations. This market volatility, as well as general economic, market or political conditions, could subject the market price of our shares to wide price fluctuations regardless of our operating performance. The public trading price for our common shares may be affected by a number of factors, including:

- changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- quarterly variations in our or our competitors' results of operations;
- periodic fluctuations in our revenue;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- changes in reimbursement by potential payors;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- actual or anticipated changes in regulatory oversight of our products;
- the results of our clinical trials;
- the loss of key personnel, including changes in our Board of Directors and management;
- legislation or regulation of our market;
- lawsuits threatened or filed against us;
- the announcement of new products or product enhancements by us or our competitors;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- announcements related to patents issued to us or our competitors and related litigation;
- general economic conditions and trends;

- effects of public health crises; and

- developments in our industry.

These and other factors, many of which are beyond our control, may cause our results of operations and the market price and demand for our shares to fluctuate substantially. In addition, the share prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of those companies. While we believe that results of operations for any particular quarter are not necessarily a meaningful indication of future results, fluctuations in our quarterly results of operations could limit or prevent investors from readily selling their shares and may otherwise negatively affect the market price and liquidity of our shares. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. If any of our shareholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management from our business, which could significantly harm our profitability and reputation.

We may be a passive foreign investment company, which could result in adverse U.S. federal income tax consequences to United States Holders.

Under the United States Internal Revenue Code of 1986, as amended (the "Code"), a non-U.S. corporation (such as ourselves) will be classified as a passive foreign investment company (a "PFIC") for any taxable year if, for such year after the application of certain look-through rules with respect to subsidiaries, either (1) at least 75% of our gross income for the year is "passive income" (as described below), or (2) the average percentage of our assets (determined at the end of each quarter) during the taxable year which produce "passive income" or which are held for the production of "passive income" is at least 50%. "Passive income" generally includes dividends, interest, rents, royalties (other than rents or royalties derived from the active conduct of a trade or business) and gains from the disposition of passive assets.

If it is determined that we are a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. Holder (as defined below), such U.S. Holder may be subject to increased U.S. federal income tax liability and may be subject to additional reporting requirements.

For purposes of the discussion herein, a "U.S. Holder" is a beneficial owner of our common shares that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;

- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbian estate, the income of which is subject to U.S. federal income taxation regardless of its source; or

- a trust, if either (i) a court within the United States is able to exercise primary jurisdiction over its administration and one or more U.S. persons have the authority to control all of its substantial decisions or (ii) the trust has a valid election in effect under applicable Treasury regulations to treat such trust as a domestic trust.

Based on the nature of our business, our financial statements, our expectations about the nature and amount of our income, assets and activities and our share price, we do not expect to be a PFIC for U.S. federal income tax purposes for the current taxable year or in the foreseeable future. However, whether we will be a PFIC in the current year or any future year is a factual determination that must be made annually at the close of each taxable year, and, thus, is subject to significant uncertainty. Among other things, a determination of whether we are a PFIC will depend on the composition of our income and assets and the market value of our assets from time to time. Accordingly, there can be no assurance that we will not be a PFIC in the current year or any future taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder holds our common shares, we generally would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds our common shares even if we ceased to meet the threshold requirements for PFIC status, unless certain exceptions apply. Such a U.S. Holder may be subject to adverse U.S. federal income tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) compliance with certain reporting requirements. We do not currently expect to provide information that would allow a U.S. Holder to make a "qualifying electing fund" election in the event that we are classified as a PFIC and, therefore, U.S. Holders should assume such election would not be available.

A sale of a substantial number of shares of our common shares may cause the price of our common shares to decline.

As of April 30, 2025, approximately 27.6 million of our common shares are held by our directors, executive officers and other affiliates, 27.0 million shares of which an affiliate of Bain Capital has shared dispositive power over. These common shares will remain subject to restrictions on sales agreed at the time of our IPO until September 1, 2025. Thereafter, if Bain or our other affiliates sell, or indicate an intention to sell, a substantial number of our common shares in the public market, the trading price of our common shares could decline. The holders of a substantial number of shares of our outstanding common shares, have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our shareholders. We also have registered the sale of common shares that we may issue under our equity incentive plans. These shares are eligible to be freely tradeable in the public market to the extent permitted by the provisions of various vesting agreements, any lock-up agreements then in effect and Rules 144 and 701 under the Securities Act. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common shares could decline.

We are a Bermuda company, and it may be difficult for you to enforce judgments against us or our directors and executive officers.

We are a Bermuda exempted company limited by shares. As a result, the rights of our shareholders are governed by Bermuda law, our memorandum of association and the amended and restated bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in another jurisdiction. It may be difficult for investors to effect service of process on concerned persons not resident in the United States or to enforce in the U.S. judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. It is doubtful whether courts in Bermuda will enforce judgments obtained in other jurisdictions, including the United States, against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions.

Bermuda law differs from the laws in effect in the United States and may afford less protection to our shareholders.

We are incorporated under the laws of Bermuda. As a result, our corporate affairs are governed by the Bermuda Companies Act 1981, as amended (the "Companies Act"), which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to take action against directors or officers of the company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law in the same way they are under the laws of the United States. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be ultra vires or illegal, or would result in the violation of the company's memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company's shareholders than those who actually approved it.

When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company's affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our amended and restated bye-laws and as permitted by Bermuda law, each shareholder will waive any claim or right of action against our directors or officers for any action taken by directors or officers in the performance of their duties, except for actions involving fraud or dishonesty or any claims of violations of the Securities Act or the Exchange Act. In addition, the rights of our shareholders and the fiduciary responsibilities of our directors under Bermuda law are not as clearly established as under statutes or judicial precedent in existence in jurisdictions in the United States, particularly the State of Delaware. Therefore, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the United States.

There are regulatory limitations on the ownership and transfer of our common shares.

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003 as amended, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its notice to the public of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes the Nasdaq Global Select Market. The general permission would cease to apply if we were to cease to be listed on the Nasdaq Global Select Market or another appointed stock exchange.

We have anti-takeover provisions in our amended and restated bye-laws that may discourage a change of control, even if an acquisition would be beneficial to our shareholders, and may prevent attempts by our shareholders to replace or remove our current management.

Our amended and restated bye-laws contain provisions that could make it more difficult for a third party to acquire us without the consent of our Board of Directors. These provisions provide for:

- a classified Board of Directors with staggered three-year terms until the seventh annual general meeting of shareholders;
- directors only to be removed for cause and only with a resolution passed by holders of at least 66 2/3% of all issued shares entitled to vote, from and after the date that Bain Charger and its affiliates cease to beneficially own at least 50% of the issued common shares of our company (the "Trigger Event");
- from and after the Trigger Event, our amended and restated bye-laws and memorandum of association require the approval of our Board of Directors and a resolution passed by holders of at least 66 2/3% of all issued shares entitled to vote;
- from and after the Trigger Event, only permit shareholder action by written consent when it is unanimously approved by our shareholders;
- restrictions on the time period in which directors may be nominated;
- limitations on our shareholders' ability to call special general meetings; and
- the ability of our Board of Directors to determine the powers, preferences and rights of preference shares and to cause us to issue the preference shares without shareholder approval.

In addition, although the Companies Act does not contain specific provisions regarding "business combinations" between companies organized under the laws of Bermuda and "interested shareholders," these provisions are included in our amended and restated bye-laws. Specifically, our amended and restated bye-laws contain provisions which prohibit us, subject to certain exceptions, from engaging in business combinations and other specified transactions with persons (excluding Bain Charger and its affiliates) for a period of three years after the time of the transaction in which the person acquired 15% or more of our issued voting shares.

These anti-takeover defenses could discourage, delay or prevent a transaction involving a change of control of our company and may prevent our shareholders from receiving the benefit from any premium to the market price of our common shares offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our common shares if the provisions are viewed as discouraging takeover attempts in the future. These provisions could also discourage proxy contests, make it more difficult for our shareholders to elect directors of their choosing and cause us to take corporate actions other than those our shareholders desire.

Our amended and restated bye-laws provide that the Supreme Court of Bermuda or the federal district courts of the United States are the exclusive forum for certain types of lawsuits and this may have the effect of discouraging lawsuits against our directors and officers.

Our amended and restated bye-laws provide that, unless we, in writing, select or consent to the selection of an alternate forum, the Supreme Court of Bermuda shall be the exclusive forum for any dispute that arises under the Companies Act or out of or in connection with our amended and restated bye-laws, including any question regarding the existence, validity, application, enforceability or scope of any bye-law and/or whether there has been any breach of the Companies Act or our amended and restated bye-laws or any breach of a duty (including any fiduciary duty) by, or other wrongdoing by, a current or former officer, director, employee, agent or shareholder of the Company to the Company or its shareholders (whether or not such a claim is brought in the name of a shareholder or in the name of the Company). Further, unless we select or consent to the selection of an alternative forum, to the fullest extent permitted by applicable law, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act against the Company or any director, officer, employee or agent of the Company. Notwithstanding the foregoing, these provisions in our amended and restated bye-laws do not apply to suits brought to enforce any liability or duty created by the Exchange Act.

Any person or entity purchasing or otherwise acquiring or holding any interest in our common shares shall be deemed to have notice of and to have consented to the forum selection provisions described in our amended and restated bye-laws. These exclusive forum provisions may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or shareholders, which may discourage lawsuits with respect to such claims. Our shareholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions. Further, in the event a court finds the exclusive forum provisions contained in our amended and restated bye-laws to be unenforceable or inapplicable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

We have historically not paid cash dividends and do not expect to pay cash dividends in the foreseeable future, and, as a result, any return on investment may be limited to the value of our shares.

We have historically not paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of cash dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our Board of Directors may deem relevant. Our Term Loan limits our ability to, among other things, pay dividends or make other distributions or payments on account of our common shares, in each case, subject to certain exceptions. In addition, pursuant to Bermuda law, we cannot declare or pay dividends, or make distributions out of our contributed surplus, if there are reasonable grounds for believing that (1) our Company is, or would after the payment be, unable to pay our liabilities as they become due or (2) the realizable value of our assets would thereby be less than our liabilities. Our ability to pay dividends is also restricted by covenants in our Term Loan. Additionally, because we are a holding company with no material direct operations, we are financially dependent on loans, dividends and other payments from our operating subsidiaries. To the extent that we decide to pay dividends on our common shares in the future, we will be dependent on our operating subsidiaries to make funds available to us for the payment of any such dividends. If we do not pay dividends, our shares may be less valuable because a return on your investment will only occur if you sell our common shares after our share price appreciates.

Future securities issuances could result in significant dilution to our shareholders and impair the market price of our common shares.

Future issuances of shares of our common shares, or the perception that these sales may occur, could depress the market price of our common shares and result in dilution to existing holders of our common shares. Also, to the extent outstanding options to purchase shares of our common shares are exercised or options, restricted share units or other share-based awards are issued or become vested, there will be further dilution. The amount of dilution could be substantial depending upon the size of the issuances or exercises. Furthermore, we may issue additional equity securities that could have rights senior to those of our common shares. As a result, holders of our common shares bear the risk that future issuances of debt or equity securities may reduce the value of our common shares and further dilute their ownership interest.

General Risk Factors

We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company" or "smaller reporting company," we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the continued listing requirements of the Nasdaq Global Select Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have hired and expect that we may need to continue to hire additional accounting, finance and other personnel in connection with our efforts to comply with the requirements of being a public company. Our management and other personnel devote a substantial amount of time toward maintaining compliance with these requirements and the additional reporting requirements of the Exchange Act. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, on our board committees or as our executive officers. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common shares, fines, sanctions, other regulatory action, and potentially civil litigation action.

If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information, and the market price of our common shares may be negatively affected.

We are not currently required to comply with the SEC's rules implementing Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. We will be required to evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report after the completion of our IPO, provide a management report on the effectiveness of our internal control over financial reporting. In connection with the preparation of our consolidated financial statements for the fiscal year ended April 30, 2025, we identified material weaknesses in our internal control over financial reporting as of April 30, 2025. For more information, see "—Risks Related to Our Business—We have identified material weaknesses in our internal control over financial reporting, and may identify additional material weaknesses. If our remediation of the material weaknesses is not effective, or we fail to develop and maintain effective internal control over financial reporting, our ability to produce timely and accurate financial statements could be impaired, which could harm our business and negatively impact the value of our common shares." Future evaluations by us of our internal control over financial reporting in the future may identify additional material weaknesses. The identification of a material weakness in our internal control over financial reporting or the failure to remediate existing material weaknesses in our internal control over financial reporting may cause us to be unable to report our financial information on a timely basis and thereby subject us to adverse regulatory consequences, including sanctions by the SEC or violations of Nasdaq Global Select Market rules. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis may be a costly and time-consuming effort that will need to be evaluated frequently.

Moreover, when we are no longer an emerging growth company, our independent registered public accounting firm will be required to issue an audit report on the effectiveness of our internal control over financial reporting. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. If we are unable to conclude that our internal control over financial reporting is effective, or when we are no longer an emerging growth company, if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common shares to decline.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.

The trading market for our shares is influenced, in part, by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over these analysts. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price of our shares would likely be negatively impacted. In the event securities or industry analysts initiated coverage, and one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our shares, or if our results of operations do not meet their expectations, our share price could decline.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

The Company is committed to maintaining a robust cybersecurity risk management program designed to identify, assess, and mitigate cybersecurity risks, including those related to data breaches, phishing, ransomware, insider threats, third-party relationships, software vulnerabilities, regulatory compliance, cloud security, artificial intelligence, and end-user computing. We are constantly evolving our cyber defenses to prevent and minimize impacts from cyber threats by using a multi-pronged approach that helps safeguard our assets and data.

We maintain and process a range of sensitive information, including Personally Identifiable Information (PII), Protected Health Information (PHI), financial data, intellectual property, and other regulated or proprietary information. Our cybersecurity management program is designed to protect confidentiality, integrity, and availability of information systems and sensitive data. The program is aligned with cybersecurity frameworks and governance standards such as the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF) and NIST SP 800-53, and the International Organization of Standardization (ISO) 27001 information security management system framework as a structured approach to identifying, assessing, and mitigating cyber risk. Our cybersecurity management program includes the following elements:

Policies and Procedures: Processes are documented to formalize the implementation of the cybersecurity program.

Continuous Monitoring: Use of automated tools and third-party services for real-time threat detection, vulnerability scanning, penetration testing, and incident alerting.

Security Incident Response Plan: A formal plan that includes containment, eradication, recovery, and communication protocols.

Third-Party Risk Management: We assess the cybersecurity posture of third-party suppliers, vendors, and other partners through due diligence, including assessments at the initiation of the relationship and on an ongoing basis appropriate to the cyber risk.

Training and Awareness: All Kestra team members, including senior management, receive mandatory cybersecurity training and periodic phishing simulations.

Periodic risk assessment: We periodically re-assess the cybersecurity program for continuous improvement and to account for emerging risks.

In the event of a cybersecurity incident, our incident response team refers to the Company's Security Incident Response Plan. Pursuant to this process, designated personnel are responsible for assessing the severity of the incident and any associated threats, containing and resolving the incident as quickly as possible, managing any damage to the Company's systems and networks, minimizing the impact on the Company's stakeholders, analyzing and executing upon internal reporting obligations, escalating information about the incident to senior management, as appropriate, and performing post-incident analysis and program enhancements, as needed.

All Kestra team members participate in quarterly security awareness training, such as phishing tests as well as mandatory annual Security Awareness and HIPAA Covered Entity training to keep pace with industry standards, evolving challenges, and innovative solutions with respect to information security, data privacy, and cybersecurity risks to the Company. With respect to artificial intelligence, the Company has identified the potential exposure of trade secrets and protected health information to open large language models as a risk, accordingly an Artificial Intelligence Acceptable Use Policy has been implemented, and all Kestra team members have been trained on its requirements.

As of the date of this Annual Report, the Company has not experienced any material cybersecurity incidents. Cybersecurity risks that are not currently known to the Company, or that are currently deemed immaterial, could materially affect the Company's business, operations, or financial condition in the future.

We describe risks faced by us from identified cybersecurity threats in Item 1A, "Risk Factors—Risks Related to Our Business—*Security breaches, loss of data, unauthorized uses or disclosures, and other disruptions involving our systems, products or data could compromise sensitive information related to our business or patients, result in operational disruption, or prevent us from accessing critical information, exposing us to liability, and adversely affecting our business, financial condition, results of operation and prospects."*

Governance

The Company's Chief Information Officer (CIO) has primary responsibility for the Company's cybersecurity program and manages the implementation of the cybersecurity risk management strategy, coordinating efforts across technical and operational functions. Our CIO has over 12 years of experience leading information security functions, including over seven years with the Company in roles of increasing seniority. Cybersecurity oversight is coordinated through the Security Council, which meets regularly and consists of cross-functional leaders. The Security Council is advised by the CIO and the Director of Information Security and Compliance on strategic cybersecurity initiatives, emerging threats, and risk posture. The Security Council formulates our cybersecurity policies and determines the priorities of our risk management plan. The information security team, led by the CIO, executes the plan, uses automated tools, follows procedures to monitor and respond to cyber threats, and subscribes to reports and services to stay current on the threat landscape.

In addition to full time staff with cybersecurity responsibilities, we engage qualified third-party partners, including assessors, auditors, consultants and other entities to support our cybersecurity processes for security engineering, security monitoring, incident response, security assessments, and independent audits of cybersecurity controls. Third-party partners work under the direction of the CIO or their designee.

The Audit Committee of our Board of Directors is responsible for oversight of the Company's programs, policies, procedures, and risk management activities related to information security and data protection. The Audit Committee receives regular briefings on cybersecurity matters from the CIO, including updates on material risks, cyber incidents, cyber program maturity, and ongoing improvements. The CIO prepares regular updates on Cybersecurity, which are integrated into the Board of Directors' broader oversight of enterprise risk management, and any material cyber risk is treated as part of overall business and risk management strategy.

Item 2. Properties.

All of our operations are currently conducted at leased facilities to support research and development, finance, marketing, supply chain operations and administrative functions. As of April 30, 2025, we leased:

- 3933 Lake Washington Blvd., Kirkland, WA: 16,700 square feet of research and development and general administrative office space which also serves as our corporate headquarters. The lease term will expire on April 30, 2029, and we may extend the term of the lease for up to an additional period of five years; and

- 10210 Points Dr NE, Kirkland, WA: 18,500 square feet of general and administrative office space. The lease term will expire on April 30, 2029, and we may extend the term of the lease for up to an additional period of five years.

- 28 Fitzwilliam Place, Dublin 2, Ireland: 300 square feet of general and administrative office space. The lease will expire on July 31, 2025, and we may extend the term of the lease or move to a different leased premise.

We intend to add new facilities as we expand, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 3. Legal Proceedings.

The Company is from time to time a party to various lawsuits, claims and other legal proceedings that arise in the ordinary course of business. The Company does not expect any of its pending legal proceedings to have a material adverse effect on its results of operations, financial position or cash flows.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

On March 6, 2025, our common shares began trading on the Nasdaq Global Select Market under the symbol "KMTS." Prior to that time, there was no public market for our common shares.

Holders of Record

As of July 16, 2025, there were 361 registered holders of record of our common shares. The actual number of holders is greater than this number and includes shareholders who are beneficial owners but whose shares are held in "street name" by banks, brokers, and other financial institutions. This number of record holders also does not include shareholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We do not expect to pay dividends on our common share for the foreseeable future. Instead, we anticipate that all of our earnings, if any, will be used for the operation and growth of our business. Any future determination to declare cash dividends would be subject to the discretion of our Board of Directors and would depend upon various factors, including our results of operations, financial condition and capital requirements, restrictions that may be imposed by applicable law and our contracts and other factors deemed relevant by our Board of Directors. In addition, pursuant to Bermuda law, a company may not declare or pay dividends, or make distributions out of contributed surplus, if there are reasonable grounds for believing that (1) the company is, or would after the payment be, unable to pay its liabilities as they become due or (2) the realizable value of its assets would thereby be less than its liabilities. "Contributed surplus" is defined for purposes of Section 54 of the Bermuda Companies Act 1981, as amended, to include the proceeds arising from donated shares, credits resulting from the redemption or conversion of shares at less than the amount set up as nominal capital and donations of cash and other assets to the company. Additionally, as a holding company with no material direct operations, our ability to pay dividends on our common shares is dependent on the earnings and distributions of funds from our operating subsidiaries. We are not obligated to pay dividends on our common shares.

Use of Proceeds from our Initial Public Offering

On March 7, 2025, we completed the IPO, pursuant to which we issued and sold 11,882,352 shares of our common shares at a public offering price of $17.00 per share. We received net proceeds of $187.6 million, after deducting the underwriting discounts and commissions of $14.4 million. On March 14, 2025, the underwriters purchased an additional 1,782,352 Common Shares at an offering price of $17.00 per share and received additional net proceeds of $28.2 million after deducting underwriting discounts and commissions of $2.1 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities. There has been no material change in the planned use of proceeds from the IPO from that described in our final prospectus dated March 5, 2025 and filed with the SEC pursuant to Rule 424(b)(4) on March 6, 2025.

Recent Sales of Unregistered Securities

None.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved]

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

This Management's Discussion and Analysis of Financial Condition and Results of Operation should be read in conjunction with our audited consolidated financial statements and the related notes to those statements included in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under the sections entitled "Special Note Regarding Forward-Looking Statements" and "Risk Factors" included in this Annual Report on Form 10-K.

Overview

We are a commercial-stage, wearable medical device and digital healthcare company focused on transforming patient outcomes in cardiovascular disease using monitoring and therapeutic intervention technologies that are intuitive, intelligent, and connected. We have developed and are commercializing our Cardiac Recovery System platform, a comprehensive and advanced system that integrates monitoring, therapeutic treatment, digital health, and patient support services into a single, unified solution. The cornerstone of our Cardiac Recovery System platform is the ASSURE WCD, a next generation WCD used to protect patients at an elevated risk of SCA. The ASSURE WCD automatically monitors elevated risk patients and, if needed, delivers a defibrillation shock to return the patient's heart to normal rhythm. We believe the ASSURE WCD offers significant clinical and functional advantages, including greater patient compliance as a result of a major reduction in false alarms, enhanced comfort and improved wearability. In addition to the ASSURE WCD, our Cardiac Recovery System platform includes a comprehensive suite of fully integrated digital solutions and services that enable enhanced patient and provider engagement and oversight, with the objective of improving patient outcomes. We believe our Cardiac Recovery System platform has the potential to disrupt the large existing market and grow the underpenetrated addressable market.

We have been issued a Medicare Provider Number by the CMS, which enables us to bill Medicare for reimbursement for our ASSURE WCD as an accredited supplier to the extent the claim meets Medicare medical necessity and coverage requirements. We derive nearly all our revenue from the direct billing of various third-party payors, including Medicare, Medicaid, private payors and other healthcare-related organizations, for the lease of our ASSURE WCD to patients. We also bill patients for co-insurance payments and deductibles. As WCD therapy has existed for over 20 years in the United States, reimbursement codes are well-established, and WCDs are covered by Medicare, Medicaid and many private payors.

We outsource the manufacturing of our ASSURE WCD and all of its components to third-party suppliers, including contract manufacturers that manufacture garments, chargers, monitors, batteries, cables and various accessories for our ASSURE WCD. We believe that our contract manufacturing partners are recognized in their field for their competency to manufacture the respective components of our ASSURE WCD and have established quality systems that meet FDA requirements. We believe the manufacturers we currently utilize have sufficient capacity to meet our expansion requirements and can scale up their capacity to meet anticipated demand for our product for the foreseeable future.

Since our inception, we have devoted substantially all of our efforts to research and development, undertaking clinical trials, enabling manufacturing activities in support of our product development efforts, hiring personnel, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio, building and expanding a commercial team to market our Cardiac Recovery System platform in the United States, and raising capital to support and expand such activities.

Our fiscal year ends on April 30 of each year. We incurred net losses of $113.8 million and $94.1 million for the fiscal years ended April 30, 2025 and 2024, respectively. For the fiscal year ended April 30, 2025, we generated revenue of $59.8 million, with a gross profit of $24.2 million, compared to revenue of $27.8 million, with a gross profit of $0.4 million, for the fiscal year ended April 30, 2024. As of April 30, 2025 and 2024, we had cash and cash equivalents balances of $237.6 million and $8.2 million, respectively, and an accumulated deficit of $520.2 million and $406.4 million, respectively.

From our inception to the consummation of the IPO, our operations were primarily funded by proceeds from capital contributions made by West Affum Holdings, L.P., our direct parent prior to the Organizational Transactions (as defined in Note 1, "*The Company*," to our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K), in the form of common stock and redeemable preferred stock, and borrowings under our Term Loan 2024 (as defined below), as well as borrowings under our Term Loan (as defined below) prior to its repayment in September of 2023. For more information, see "—Liquidity and Capital Resources—Sources of Liquidity".

In the IPO, we issued and sold an aggregate of 13,664,704 common shares at an offering price to the public of $17.00 per share for net proceeds of $215.8 million, after deducting underwriting discounts and commissions, which includes the net proceeds from the underwriters' exercise in full of the over-allotment option. The Organizational Transactions and IPO were completed on March 7, 2025 and the proceeds from the shares sold pursuant to the underwriters' over-allotment option were received on March 14, 2025.

We have invested heavily in developing and commercializing our Cardiac Recovery System platform. We have also made significant investments in clinical studies to demonstrate the safety and effectiveness of our ASSURE WCD and to support applications for regulatory approvals. We have made and will continue to make significant investments to build our sales and marketing organization, and we intend to continue to increase the size of our commercial team to market our product in the United States. Based on our current operating plan, we believe that our existing cash and cash equivalents and cash generated from revenue transactions with customers will be sufficient to fund our operating and capital needs for at least the next 12 months. We may experience lower than expected cash generated from operating activities or greater than expected capital expenditures, cost of revenue or operating expenses and may require additional funding to execute on our growth plans, which may include future equity and debt financings. Adequate funding may not be available to us on acceptable terms or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Key Factors Affecting Our Results of Operations and Performance

Factors that have impacted, and that we expect will continue to impact, our operating performance and results of operations include:

- ***Commercial Organization***. We have made and continue to make significant investments in recruiting, training and retaining our direct sales force and supporting commercial infrastructure. Successfully recruiting and training additional commercial team members is required to achieve growth. As of April 2025, we had approximately 80 territories in the United States. We have in the past and expect in the future to enter into compensation arrangements with our commercial team that may include minimum guaranteed commissions.

- ***Gross Profit***. Our results of operations will depend, in part, on our ability to increase our gross profit by more effectively managing our costs to build and deliver our ASSURE WCD and obtaining higher reimbursement realization due to improved market access and shifts in patient mix towards patients with longer wear duration. We expect supply chain efficiencies to result from higher volume purchases of components, and continued manufacturing process improvements.

- ***Payor Coverage and Revenue Cycle Management***. Healthcare providers in the United States generally rely on third-party payors, principally Medicare, Medicaid and private payors, to cover and reimburse all or part of the cost of our product. The revenue we can generate from the lease of our ASSURE WCD depends in large part on the availability of reimbursement from such payors. A significant component of our operational efforts includes working with private payors to ensure positive coverage decisions for our product and investing in our revenue cycle management infrastructure to collect cash from payors.

- ***Seasonality***. Our billings and collections efforts during January and February tend to be lower because of resetting annual patient healthcare insurance plan deductibles. In addition, as our business grows in the United States and any international markets we may enter into in the future, we may experience seasonality based on holidays, vacations and other factors.

Key Components of Our Results of Operations

The following discussion describes certain key components of our consolidated statement of operations.

Revenue

We received FDA approval for the commercialization of our ASSURE WCD on July 27, 2021 and fully commercially launched our ASSURE WCD in August 2022. We generate revenue by leasing our ASSURE WCD to patients for a fixed amount on a month-to-month basis. The lease payments generally consist of the contracted amounts based on reimbursement arrangements with third-party payors, comprising Medicare, Medicaid, private payors and other healthcare-related organizations, and patient payments. The patient has the right to cancel the lease at any time during the lease period. We recognize lease revenue over the term of the lease when collectability is probable. If collectability of the lease payments is not deemed to be probable, the lease revenue is limited to the lesser of the income that would have been recognized if collectability was probable or the lease payments collected. If the lease payments are not deemed to be probable at inception, lease revenue is recognized when cash payments are received. We expect that our revenue will continue to increase as the number of patients that use our product increases.

Cost of Revenue

Cost of revenue consist of direct material, labor and indirect costs related to the lease performance of our ASSURE WCD such as the cost of disposable WCD device components, depreciation expense of reusable medical rental equipment components, shipping and order fulfillment costs, as well as other indirect costs incurred to support the manufacture and medical rental equipment delivery to and ongoing support for the patient incurred in connection with providing our ASSURE WCD to patients. Overall expenditures for disposable components and reprocessing costs will increase as the number of patients receiving our ASSURE WCD increases and to a lesser extent, depreciation expense will increase as additional reusable ASSURE WCD components are purchased. However, depreciation expense as a percentage of cost of revenue is expected to decrease in the long run through economies of scale as we continue to grow our business. For additional information on how depreciation impacts our financial results, see Note 2, "*Significant Accounting Policies*" to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Gross Profit

We calculate gross profit as revenue less cost of revenue. We expect our gross profit to increase as reimbursement realization increases due to improved market access and shifts in patient mix towards patients with longer wear duration, as well as supply chain efficiencies from higher volume purchases of components and manufacturing process improvements. In addition, as the number of patients we serve continues to increase, we expect the cost of fitting per patient to continue to decrease. However, gross profit may be negatively impacted by a number of factors, including increases in prices of materials and electronics components, labor rates, shipping rates, and inflation.

Research and Development Expenses

Research and development expenses consist of personnel expenses, including salaries, benefits and share-based compensation expense for product development personnel, prototype materials and other expenses related to the development of new products. We expense research and development expenses as they are incurred, although advanced payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

We expect our research and development expenses to decrease as a percentage of revenue for the foreseeable future as our revenue increases. We will continue to invest in research and development activities related to developing new products and services, further enhancing our products and services through introducing new extensions and enhancements, conducting clinical trials as necessary and preparing any new products and services for commercialization.

Selling, General and Administrative Expenses

Selling expenses consist primarily of personnel expenses, including salaries, commissions, bonuses, benefits, travel, and share-based compensation expense for sales, marketing and field clinical personnel, as well as investments in marketing initiatives to increase market awareness of our technology, including expenses related to travel, conferences, trade shows and consulting services.

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits and share-based compensation expense for personnel in executive, finance, accounting, commercial operations, distribution costs, revenue cycle management, legal, human resources, IT and administrative functions. General and administrative expenses also include direct or allocated expenses for rent and maintenance of facilities and insurance, not otherwise included in research and development expenses, selling expenses, or cost of revenue, as well as professional fees for legal, patent and consulting services. We expect expenses related to revenue cycle management to increase at higher rates than other types of general and administrative expenses as this function will continue to grow as the volume increases.

We expect that our overall selling, general and administrative expenses will increase in the foreseeable future as we increase our headcount to support the continued growth of our business. We also anticipate incurring additional expenses associated with operating as a public company, including increased expenses related to audit, legal, regulatory, compliance, director and officer insurance, investor and public relations, and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange. These expenses may further increase when we no longer qualify as an "emerging growth company" under the JOBS Act, which will require us to comply with certain reporting requirements from which we are currently exempt. However, we expect overall general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Interest and Other Expense (Income)

Interest and other expense (income) consists of cash and non-cash components. The cash component of interest expense (income) is attributable to borrowings under our term loans and a portion of loss on extinguishment of debt as well as interest received from various interest-bearing bank accounts. The non-cash component consists of interest expense recognized from the amortization of debt discounts and debt issuance costs. Loss on extinguishment of debt is included in other expense.

Provision for Income Taxes

To date, we have recorded a limited amount of United States federal and state income state expense. As of April 30, 2025, significant deferred tax assets include net operating loss carryforwards of $52.2 million, intangible assets of $35.4 million, interest carryforwards of $7.2 million, United States research and development credits of $5.5 million, and shared-based compensation of $5.0 million. In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income, carryback opportunities and tax planning strategies in making the assessment. We believe it is more likely than not that we will not realize the benefits of these deductible differences and have applied a full valuation allowance against them.

Results of Operations

The following tables set forth our results of operations for the fiscal years ended April 30, 2025 and 2024. We have derived the data for the fiscal years ended April 30, 2025 and 2024 from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. This information should be read in conjunction with our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The results for historical periods are not necessarily indicative of the results of operations for any future period.

	Fiscal Year Ended April 30,			
(in thousands)	**2025**	**2024**	**$ Change**	**% Change**
Revenue	$ 59,815	$ 27,814	$ 32,001	115%
Cost of revenue	35,605	27,452	8,153	30%
Gross profit	24,210	362	23,848	NM
Operating expenses:				
Research and development	15,652	15,490	162	1%
Selling, general and administrative	114,936	69,935	45,001	64%
Total operating expenses	130,588	85,425	45,163	53%
Loss from operations	(106,378)	(85,063)	(21,315)	25%
Other expense (income):				
Interest expense	7,734	6,230	1,504	24%
Interest income	(3,199)	—	(3,199)	100%
Other expense	2,766	2,803	(37)	(1%)
Net loss before provision for income taxes	(113,679)	(94,096)	(19,583)	21%
Provision for income taxes	135	24	111	463%
Net loss and comprehensive loss	(113,814)	(94,120)	(19,694)	21%
Less: Undeclared preferred stock dividends	12,321	6,721	5,600	83%
Net loss attributable to common shareholders, basic and diluted	$ (126,135)	$ (100,841)	$ (25,294)	25%

NM = Percentage not meaningful

Comparison of the Fiscal Years Ended April 30, 2025 and 2024

Revenue

Revenue increased by $32.0 million, or 115%, to $59.8 million for the fiscal year ended April 30, 2025, from $27.8 million for the fiscal year ended April 30, 2024, primarily driven by an increase in the number of patients using our product and an increase in reimbursement realization while reimbursement rates remained largely flat. There was an 88% increase in the number of patients using our product, along with a 15% increase in reimbursement realization due to additional payor contracts and a 75% increase in the size of our revenue cycle management team to improve collection efforts.

Cost of Revenue

Cost of revenue increased by $8.1 million, or 30%, to $35.6 million for the fiscal year ended April 30, 2025, from $27.5 million for the fiscal year ended April 30, 2024. The increase in cost of revenue was primarily driven by an increase of $10.5 million in the cost of disposable medical equipment supplies, equipment reconditioning and other supplier costs, which were directly attributable to an increase in the number of patients using our product, and an increase of $1.0 million in our reserve for lost or damaged equipment, partially offset by a $3.4 million decrease in depreciation expense due to the changes in useful life of therapy cables and batteries.

Gross Profit

Gross profit increased by $23.8 million to $24.2 million for the fiscal year ended April 30, 2025, from $0.4 for the fiscal year ended April 30, 2024. The increase in gross profit was primarily due to growth in both our total revenue, which was driven by an increased number of patients using our product, as well as an increase in revenue per patient as a result of an increase in reimbursement realization due to an increased number of payor contracts resulting in a higher percentage of patients having greater in-network coverage through their insurance providers and improved collection efforts driven by further increases in the size of our revenue cycle management team. The increase in gross profit was also driven by a decrease in cost of revenues per patient by 47% for the fiscal year ended April 30, 2025 compared to the fiscal year ended April 30, 2024, due to further improvements in the utilization of our rental pool of medical equipment and lower disposable costs driven by volume and manufacturing cost improvement programs we implemented during the fiscal year ended April 30, 2025, including a therapy cable repair program approved by the FDA in May 2024.

Research and Development Expenses

Research and development expenses were largely flat in the fiscal year ended April 30, 2025 compared to the prior year.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $45.0 million, or 64%, to $114.9 million for the fiscal year ended April 30, 2025, from $69.9 million for the fiscal year ended April 30, 2024. The increase was primarily driven by a $34.1 million increase in personnel expenses such as salaries, benefits and share-based compensation, resulting from an increase in headcount, a $5.7 million increase in professional services expense related to the IPO, a $1.8 million increase in travel expenses driven by increased headcount, and a net $3.4 million increase in other selling, general and administrative expenses.

Interest and Other Expense (Income)

Interest expense increased by $1.5 million, or 24%, to $7.7 million for the fiscal year ended April 30, 2025, from $6.2 million for the fiscal year ended April 30, 2024. The increase was primarily due to a $1.2 million increase in interest expense and amortization of debt discounts and debt issuance costs related to borrowings under our Term Loan 2024 and $0.3 million interest charged by a major vendor.

Interest income increased by $3.2 million, or 100%, to $3.2 million for the fiscal year ended April 30, 2025, from none for the fiscal year ended April 30, 2024. The increase was due to $3.2 million interest income received from various interest-bearing bank accounts driven by higher cash balances in depository accounts resulting from fundings in July of 2024 and IPO proceeds in March of 2025.

Other expense was largely flat at $2.8 million for the fiscal years ended April 30, 2025 and 2024. For the fiscal year ended April 30, 2025, other expense of $2.8 million was primarily consisted of a $2.6 million increase in the fair value of a warrant related to the Term Loan 2024 and $0.2 million related to other expenses. For the fiscal year ended April 30, 2024, other expense of $2.8 million was primarily consisted of an early loan termination fee and a loss on debt extinguishment totaling $2.7 million related to our Term Loan 2020 (as defined below), along with $0.1 million related to other expenses.

Provision for Income Taxes

For each of the fiscal years ended April 30, 2025 and 2024, the tax provision was less than $0.1 million, which was primarily related to state tax liabilities in the United States.

Liquidity and Capital Resources

Since inception, we have devoted substantially all our efforts to research and development, undertaking clinical trials, enabling manufacturing activities in support of our product development efforts, hiring personnel, organizing and staffing our company, performing business planning, establishing our intellectual property portfolio, building and expanding a commercial team to market our Cardiac Recovery System platform in the United States, and raising capital to support and expand such activities. We have incurred net losses in each year since inception and expect to continue to incur net losses in the foreseeable future. Our net loss and comprehensive loss were $113.8 million and $94.1 million for the fiscal years ended April 30, 2025, and 2024, respectively. As of April 30, 2025, we had an accumulated deficit of $520.2 million. For the fiscal years ended April 30, 2025, and 2024, we generated negative operating cash flows of $77.6 million and $72.2 million, respectively.

As of April 30, 2025 and 2024, our principal sources of liquidity consisted of $237.6 million and $8.2 million of cash and cash equivalents, respectively. Based on our current operating plan, we believe that our existing cash and cash equivalents, which includes the net proceeds from our IPO, as well as cash generated from revenue transactions with customers, will be sufficient to fund our operating and capital needs for at least the next 12 months.

Funding Requirements and Contractual Obligations

We have incurred significant operating losses and negative cash flows driven by substantial research and development expenses as well as our large investment in our fleet of ASSURE WCDs and building our commercial organization. Our operations have focused on developing products, establishing our intellectual property portfolio, marketing our product and staffing the Company to support continued growth. Our primary use of cash has been to fund operating expenses, which comprise research and development expenses, and costs of building the commercial team and necessary infrastructure to support our growth. Cash used to fund our operating expenses is impacted by the timing of when we pay for such expenses.

We obtained the PMA for our ASSURE WCD from the FDA on July 27, 2021 and fully commercially launched our ASSURE WCD in August 2022. We will continue to scale the business and therefore expect operating losses to continue. Based on our current operating plan, we believe that our existing cash and cash equivalents, which includes the net proceeds from our IPO, as well as cash generated from revenue transactions with customers, will be sufficient to fund our operating and capital needs for at least the next 12 months. We may experience lower than expected cash generated from operating activities or greater than expected capital expenditures, cost of revenue or operating expenses and may require additional funding to execute on our growth plans, which may include future equity and debt financings. Our assessment of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties.

Our future obligations primarily consist of our debt obligations. From our inception to the consummation of the IPO, our operations were primarily funded by proceeds from our capital contributions made by West Affum Holdings, L.P., our direct parent prior to the Organizational Transactions, borrowings under our Term Loan 2024 and, prior to its repayment in September of 2023, our Term Loan, and our revenues. We expect our cash generation from operations and future ability to refinance or secure additional equity or financing to be sufficient to repay our outstanding debt obligations. As of April 30, 2025, the outstanding principal amount under the Term Loan 2024 was approximately $45.0 million. The Term Loan was repaid in full in September 2023. For further information, see Note 7, "*Long-Term Debt,*" to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Sources of Liquidity

As of April 30, 2025, we had cash and cash equivalents and restricted cash balances of $237.9 million and an accumulated deficit of $520.2 million.

In the fiscal years ended April 30, 2025 and 2024, we received $103.4 million and $75.0 million, respectively, in cash from West Affum Holdings, L.P. in return for the issuance of redeemable preferred stock as described in Note 10, "*Redeemable Preferred Stock,*" to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Additionally, in July 2024, one of our subsidiaries received $17.1 million from a third-party investor in return for redeemable shares of the subsidiary.

On September 24, 2020, we entered into the Loan and Security Agreement with a lender providing for aggregate borrowings of up to $50.0 million (as amended, the "Term Loan"). Available commitments under our Term Loan were able to be drawn in up to three tranches, which were subject to the Company achieving certain funding, regulatory or revenue milestones, with $20.0 million available in the first tranche and $15.0 million available in each of the second and third tranches.

On December 28, 2020, we drew the first tranche of the Term Loan in the amount of $20.0 million. In conjunction with the draw on the first tranche, West Affum Holdings, L.P. issued a warrant to the lender to purchase up to 49,044 shares of West Affum Holdings, L.P.'s common units at an exercise price of $22.63 per unit. The fair value of the warrant is $0.3 million and is recognized as a debt discount and as a capital contribution, and the debt discount is amortized over the term of the loan to interest expense. On January 21, 2022, we drew on the second tranche of the Term Loan in the amount of $15.0 million. In conjunction with the draw of the second tranche, West Affum Holdings, L.P. issued a warrant to the lender to purchase up to 36,783 shares of West Affum Holdings, L.P.'s common units at an exercise price of $26.24 per unit. The fair value of the warrant was $0.4 million and was recognized as a debt discount and as a capital contribution, and the debt discount is amortized over the term of the loan to interest expense.

On September 29, 2023, we entered into a Credit Agreement with Perceptive Credit Holdings IV, LP, as administrative agent, which provides for a senior secured delayed draw term loan facility in an aggregate principal amount of up to $60.0 million ("Term Loan 2024") and used a portion of our borrowings to repay the Term Loan. The Term Loan 2024 matures on September 29, 2028. Borrowings under the Term Loan 2024 are made available in up to three tranches, the first of which is available upon closing of the Term Loan 2024 and two follow-on tranches of $7.5 million which become available before November 1, 2024 and February 1, 2025 and are dependent upon achievement of revenue milestones of trailing twelve month revenues of $50.0 million and $70.0 million, respectively. We did not meet the revenue milestone required to draw on the November 1, 2024 follow-on tranche of the Term Loan 2024. As of October 31, 2024, we determined it was not likely that we would meet the revenue milestone required to draw on the February 1, 2025 follow-on tranche of the Term Loan 2024. As a result, we expensed the asset related to debt issuance costs and facility fees in the amount of $0.5 million. The Term Loan 2024 bears interest on outstanding balances of Term SOFR plus a margin of 7.25% per annum. All interest is due and payable quarterly in arrears.

On September 29, 2023, we drew the initial $45.0 million under the Term Loan 2024. In conjunction with the draw of the first tranche, West Affum Holdings, L.P. issued a warrant to the lender to purchase up to 256,410 shares of West Affum Holdings, L.P.'s common units at an exercise price of $17.55 per share. The fair value of the warrant was $1.6 million and recognized as a debt discount and as a capital contribution, and the debt discount was amortized over the term of the loan to interest expense.

On February 25, 2025, we amended the Term Loan 2024 pursuant to the Second Amendment to Credit Agreement to adjust the revenue milestones set forth in the Term Loan 2024 and to amend our ability to draw on additional funds. Under the Second Amendment to Credit Agreement, an additional $15.0 million term loan draw is available to us through July 31, 2026 upon achievement of a twelve-month trailing revenue run rate of $60.0 million. In connection with the Second Amendment to Credit Agreement and the IPO, the warrant issued to Perceptive Credit Holdings IV, LP on September 29, 2023 was cancelled and replaced with a new warrant to purchase up to 325,847 of our common shares with an exercise price of $11.54 per share.

For further information, see Note 7, "*Long-Term Debt,*" to our consolidated financial statements for the fiscal years ended April 30, 2025 and 2024 included elsewhere in this Annual Report on Form 10-K.

Cash Flows

The following table presents a summary of our cash flows from operating activities, investing activities and financing activities for the periods indicated:

	Fiscal Year Ended April 30,	
(in thousands)	**2025**	**2024**
Net cash used in operating activities	$ (77,608)	$ (72,235)
Net cash used in investing activities	(23,308)	(12,229)
Net cash provided by financing activities	330,262	77,725
Increase (decrease) in cash, cash equivalents and restricted cash	$ 229,346	$ (6,739)

Cash Flows from Operating Activities

For the fiscal year ended April 30, 2025, cash used in operating activities was $77.6 million, which primarily consisted of a net loss of $113.8 million and a net decrease of $6.3 million in operating assets and liabilities, offset by a net increase of $42.5 million in non-cash charges. The non-cash charges primarily consisted of depreciation and amortization of $8.0 million, share-based compensation expense of $24.3 million, interest paid-in-kind of $0.9 million related to the Term Loan 2024, loss on disposal of property and equipment of $2.1 million, non-cash lease expense of $0.4 million, amortization of debt discounts and issuance costs of $1.4 million, a change in fair value of warrant liability of $2.6 million, provision for uncollectible accounts receivable of $2.7 million, and deferred income tax expense of $0.1 million. The net change in our operating assets and liabilities consisted of increases in accounts payable of $2.8 million, accrued liabilities of $4.6 million driven by increases in accrued compensation due to increased headcount and a reserve for claims repayments, and operating lease liabilities of $0.4 million, partially offset by increases in account receivables of $8.8 million, disposable medical equipment supplies of $3.4 million, and prepaid expenses and other current assets of $1.9 million related to prepayments for insurance, commercial materials, and software licenses and fees.

For the fiscal year ended April 30, 2024, cash used in operating activities was $72.2 million, which primarily consisted of a net loss of $94.1 million, offset by a net increase of $3.9 million in operating assets and liabilities and $18.0 million in non-cash charges. The non-cash charges primarily consisted of depreciation and amortization of $11.6 million, share-based compensation expense of $1.5 million, interest paid-in-kind of $1.1 million related to the Term Loan 2024 and the Term Loan, loss on disposal of property and equipment of $1.1 million, non-cash loss on extinguishment of debt related to the Term Loan of $0.9 million, non-cash lease expense of $0.7 million, amortization of debt discounts and issuance costs of $0.6 million, and provision for uncollectible accounts receivable of $0.5 million. The net change in our operating assets and liabilities consisted of changes in accounts payable of $7.4 million, accrued liabilities of $0.4 million driven by increases in accrued compensation due to increased headcount, and prepaid expenses and other current assets of $0.3 million related to prepayments for commercial materials and software licenses and fees, partially offset by changes in account receivables of $2.5 million, disposable medical equipment supplies of $1.2 million, and operating lease liabilities of $0.5 million.

Cash Flows from Investing Activities

For the fiscal year ended April 30, 2025, cash used in investing activities was $23.3 million, which primarily consisted of $22.9 million of purchases of property and equipment such as medical rental equipment, computer hardware, test equipment and other research and development activities, and leasehold improvements, $0.7 million deposits paid for medical rental equipment and $0.3 million refund of deposits for medical rental equipment received.

For the fiscal year ended April 30, 2024, cash used in investing activities was $12.2 million, which primarily consisted of purchases of property and equipment such as medical rental equipment, computer hardware, test equipment and other research and development activities, and leasehold improvements.

Cash Flows from Financing Activities

For the fiscal year ended April, 2025, cash provided by financing activities was $330.2 million, which primarily consisted of $215.8 million in proceeds from the IPO net of underwriting discounts and commissions, $103.4 million in proceeds from the issuance of redeemable preferred stock, $17.1 million in proceeds from the issuance of stock to a non-controlling interest, and $2.4 million in proceeds from a capital contribution by West Affum Holdings, L.P. The increase in cash provided by financing activities was offset by offering and reorganization costs of $3.5 million, equity issuance costs of $3.3 million, and deemed dividend payments of $1.7 million.

For the fiscal year ended April 30, 2024, cash provided by financing activities was $77.7 million, which primarily consisted of $75.0 million in proceeds from the issuance of redeemable preferred stock and $45.0 million in proceeds from the initial draw on the Term Loan 2024 in September 2023. The increase in cash provided by financing activities was offset by re-payments of long-term debt of $39.1 million, debt issuance costs of $2.4 million and deemed dividend payments of $0.8 million.

Off-Balance Sheet Arrangements

As of April 30, 2025, we had two irrevocable standby letters of credit issued by Silicon Valley Bank, a division of First Citizens Bank, that total $0.1 million related to our office leases and Cash Pledge Agreement of $0.2 million as collateral for the Company credit card program. We did not have any other obligations, assets or liabilities that would be considered off-balance sheet arrangements. We do not participate in transactions that create relationships with unconsolidated entities or financial partnerships, often referred to as variable interest entities, which would have been established for the purpose of facilitating off-balance sheet arrangements. We have not entered into any off-balance sheet financing arrangements, established any special purpose entities, guaranteed any debt or commitments of other entities, or entered into any non-financial agreements involving assets.

Critical Accounting Policies and Significant Management Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses and related disclosures. We base our estimates on historical experience, known trends and events and various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ materially from these estimates under different assumptions or conditions, could have a material impact on the Company's business, financial condition, results of operations and prospects. While our significant accounting policies are described in more detail in Note 2 of our audited consolidated financial statements included elsewhere in this Annual Report, we believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue

The Company generates revenue from the leases of our ASSURE WCD. ASSURE WCD leases are classified as operating leases at lease commencement in accordance with Accounting Standards Codification Topic 842, *Leases* ("ASC Topic 842"). Under ASC Topic 842, we recognize lease revenue on operating leases on a straight-line basis over the contractual lease term, when collectability of the lease payments is deemed to be probable. The lease term begins on the date the device is made available to the patient.

If collectability of the lease payments is not probable, then lease income is limited to the lesser of the income that would have been recognized if collectability was probable, or the lease payments collected. Collectability of all lease payments, which includes amounts reimbursed by third-party payors or amounts covered by the patient, is assessed for each type of contract upon lease commencement and is subject to subsequent reassessment throughout the lease term, as necessary.

We have elected the practical expedient provided under ASC Topic 842 to combine the lease of our ASSURE WCD with the non-lease components of our Cardiac Recovery System platform, which include the digital healthcare platform. Our ASSURE WCD is the predominant component and, as a result, we account for the combined components under ASC Topic 842.

Due to the nature of the industry and the reimbursement environment in which we operate, we evaluate the need to record a general reserve under Accounting Standards Codification Topic 450, *Contingencies*, for a portfolio of operating lease receivables that are probable of collection. Inherent in the reserve estimates is the risk that they will have to be revised or updated as additional information becomes available. Specifically, the complexity of many third-party billing arrangements and the uncertainty of reimbursement amounts for certain services from certain payors may result in adjustments to amounts originally recorded. Such adjustments are expected to be identified and recorded at the point of cash application or claim denial.

Impairment of Long-Lived Assets

The Company's long-lived assets consist of property and equipment, which includes leasehold improvements and right-of-use assets. The Company does not have long-lived assets held for sale. Long-lived assets are reviewed for potential impairment at such time that events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When evaluating long-lived assets for potential impairment, the Company will first compare the carrying amount of the assets to estimated future net undiscounted cash flows expected to result from the use of the assets, including cash flows from disposition. If the estimated future cash flows are less than the carrying amounts of the assets, an impairment loss is recognized and measured based upon the excess of the carrying value of the asset over its estimated fair value. There were no impairments of long-lived assets during the fiscal years ended April 30, 2025 and 2024.

Valuation of Equity

Prior to the completion of our IPO, the fair value of the common units underlying our share-based awards was determined by the Board of Directors. The valuations of our common units prior to the completion of our IPO were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. In the absence of a public trading market, the Board of Directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common units as of the date of each option grant, including the following factors:

- our stage of development;
- our history and the timing of the introduction of new technology;
- our actual operating results and performance and financial condition, including our levels of available capital resources;
- current business conditions and projections;
- the prices, rights, preferences, and privileges of our redeemable preferred stock relative to those of our common equity;
- market and economic conditions;
- conditions of the medical device industry;
- the stock price performance, volatility, and valuation multiples of comparable publicly-traded companies;
- the likelihood and timing of achieving a liquidity event, such as an initial public offering, given prevailing market conditions;
- the prices of redeemable preferred stock sold by us to third-party investors in arms-length transactions;
- recent stock transactions in shares of our preferred and common equity;
- relevant mergers and acquisitions in targeted industries;
- the lack of marketability of our common equity; and
- contemporaneous valuations performed by third-party valuation firms.

We determined that the Probability-Weighted Expected Returns Method ("PWERM") approach is the most appropriate method for estimating our enterprise value. This method considers various exit scenarios including an initial public offering (the "IPO Scenario"), potential merger or acquisition (the "M&A Scenario"), or staying private, and assigns a probability weight to each scenario. Using the PWERM, the enterprise value under each potential exit scenario and the timing of each scenario were weighted based on our estimated probability of occurrence for such scenario. Our equity values under the IPO Scenario and M&A Scenario were each estimated using the market approach based on the valuation of comparable public companies. We then allocated the equity value to our outstanding common stock based on the estimated timing, valuation and probability of each scenario. The stay private scenario estimated our equity value using an income approach based on our financial projections.

The scenario-specific values were probability-weighted and discounted to present value to arrive at an overall estimated equity value. After the equity value was determined, we applied a discount for lack of marketability to reflect the lack of marketability associated with our common shares, which is not traded on public exchanges. For financial reporting purposes, we considered the amount of time between the valuation date and the grant date of any stock options to determine whether to use the latest common stock valuation or a straight-line interpolation between the latest valuation date and the grant date. This determination included an evaluation of whether any significant events or changes had occurred between the previous valuation date and the grant date that could materially change our equity value determined at the latest valuation date.

For valuations after the completion of our IPO, the fair value of each share of underlying common stock is based on the closing price of our common shares as reported on the date of grant on Nasdaq.

Share-Based Compensation

We maintain an equity incentive plan to provide long-term incentives for employees, consultants and members of the Board of Directors. We are required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards granted, including employee stock options. We account for share-based compensation awards, including stock options to employees and non-employees, based on their estimated grant date fair value. We estimate the fair value of our stock options using the Black-Scholes option-pricing model. We recognize fair value of stock options, which vest based on continued service, on a straight-line basis over the requisite service period. Forfeitures are recognized as they occur.

Prior to our IPO, we incurred share-based compensation expense related to equity incentive units of West Affum Holdings, L.P., which was allocated to us. Share-based compensation related to equity incentive units of West Affum Holdings, L.P. is measured at the grant date based on the fair value of the award and is recognized as share-based compensation expense on a straight-line basis over the requisite service period. We estimated the fair value of the equity incentive units of West Affum Holdings, L.P. using the Black-Scholes option pricing model. Forfeitures were recognized as they occurred.

The Black-Scholes option pricing model requires the use of subjective assumptions to determine the fair value of equity incentive awards. These assumptions include:

- *Fair value of common equity.* The fair value of our common units (prior to IPO) or common shares (following the IPO) on the date of the grant.

- *Expected term.* Expected term represents the period that share-based awards are expected to be outstanding. We estimated the expected term based on an average of the midpoint of the requisite service period and the contractual term.

- *Expected volatility.* Since we had been a privately held company prior to our IPO, we did not have any trading history for our common units and we have limited trading history for our common shares. Therefore, the expected volatility is estimated based on the average volatility for comparable publicly traded medical technology companies over a period equal to the expected term. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

- *Expected dividend.* The dividend yield assumption is zero, as we have no history of, or plans to make, dividend payments on our common units or our common shares.

The Black-Scholes option pricing model requires the use of subjective assumptions to determine the fair value of the equity incentive awards. These assumptions include:

- *Fair value of common shares.* The fair value of common units is determined by the Board of Directors as of the date of award grant, with input from management, considering contemporaneous independent third-party valuations of common units, and the Board of Directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant.

- *Expected term.* Expected term represents the period that share-based awards are expected to be outstanding. The expected term for incentive units is the expected time to liquidity.

- *Expected volatility.* Since we have been a privately held company and do not have any trading history for our common units, the expected volatility is estimated based on the average volatility for comparable publicly traded medical technology companies over a period equal to the expected term. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

- *Expected dividend.* We have never paid dividends on our common shares and have no plans to pay dividends on our common units. Therefore, we used an expected dividend yield of zero.

- *Discount for lack of marketability.* We applied a discount for lack of marketability ("DLOM") based on two widely accepted models: the 2012 Finnerty Model and the Asian Put. The DLOM was assessed by applying a low range based on a time-to-liquidity assumption of 0.50 years and a volatility assumption of 70.0%, and a high range based on a time-to-liquidity assumption of 1.50 years and a volatility assumption of 90.0%. After evaluating the results from both models, we selected a DLOM range and selected a final DLOM at the low end of the selected range.

Contemporaneously with the IPO, vesting of all incentive units of West Affum Holdings LP were accelerated and the Company recognized share-based payment costs of $2.8 million. The equity incentive units were converted into shares of Kestra Medical Technologies, Ltd. contemporaneously with the IPO. Equity incentive units are no longer issued.

Income Taxes

We account for income taxes using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences representing future deductible amounts are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized. As a result of the valuation allowances, our net deferred tax position has historically been immaterial.

We recognize the effect of income tax positions only if those positions are more likely than not of being sustained upon an audit. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being recognized. Changes in recognition or measurement are reflected in the period in which the change in judgement occurs.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act. We will remain an emerging growth company until the earliest to occur of (i) the last day of the fiscal year that follows the fifth anniversary of the completion of our IPO; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer," as defined in Rule 12b-2 under the Exchange Act, which will occur when the market value of our common shares held by non-affiliates exceeds $700.0 million as of the most recently completed second quarter; and (iv) the date on which we have issued more than $1 billion in non-convertible debt over a three-year period.

Pursuant to the JOBS Act, an emerging growth company is provided the option to adopt new or revised accounting standards that may be issued by the Financial Accounting Standards Board or the SEC either (i) within the same periods as those otherwise applicable to non-emerging growth companies or (ii) within the same time periods as private companies. We have elected to take advantage of the exemption for complying with new or revised accounting standards within the same time periods as private companies. Accordingly, the information contained herein may be different than the information you receive from other public companies.

We have elected to take advantage of some of the reduced regulatory and reporting requirements of emerging growth companies pursuant to the JOBS Act so long as we qualify as an emerging growth company, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and reduced disclosure obligations regarding executive compensation.

We are also a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act. We may continue to be a smaller reporting company for so long as either (1) the market value of our common shares held by non-affiliates is less than $250.0 million as of the last business day of our most recently completed second fiscal quarter or (2) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our common shares held by non-affiliates is less than $700.0 million as of the last business day of our most recently completed second quarter. Any loss of our status as a smaller reporting company takes effect in the first quarter after the fiscal year in which we cease to qualify as a smaller reporting company. To the extent that we continue to qualify as a smaller reporting company at the time we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently Adopted and Issued Accounting Pronouncements

Recently issued and adopted accounting pronouncements are described in Note 2 to our audited consolidated financial statements.

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

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates.

Interest Rate Risk

We had cash, cash equivalents and restricted cash balances of $237.9 million and $8.6 million as of April 30, 2025 and 2024, respectively. Cash consists of deposits with financial institutions. Interest income is sensitive to changes in the general level of interest rates. However, our exposure to interest rate risk as a result of our cash deposits with financial institutions is not significant, and a hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements included elsewhere in this Annual Report.

We also are subject to interest rate risk under the Term Loan. All amounts outstanding under the Term Loan accrue interest at an annual rate equal to the greater of (a) forward-looking one-month term SOFR as posted by the CME group and (b) 4.75% per annum, plus an applicable margin of 7.25% of which up to 2.00% may be paid-in-kind through March of 2025. However, our exposure to interest rate risk is not significant, and a hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements included elsewhere in this Annual Report.

We do not currently engage in nor do we plan to enter into investments for trading or speculative purposes.

Concentrations of Credit Risk

We are subject to credit risk from cash balances we maintain that are in excess of federal depository insurance limits of $250,000 and certain cash balances in accounts located in the Cayman Islands and Ireland which are not insured. As of April 30, 2025, we maintained cash, cash equivalents and restricted cash balances of $237.9 million, with $0.3 million in accounts located in the Cayman Islands. As of April 30, 2024, we maintained cash, cash equivalents and restricted cash balances of $8.6 million, $0.3 million of which was in accounts located in the Cayman Islands. Cash, cash equivalents and restricted cash balances as of April 30, 2025 and 2024 were in excess of federal depository insurance limits. We have not experienced any losses in such accounts as of the date of this Annual Report, and we believe that we are not exposed to significant credit risk on our cash balances.

Inflation Risk

Our consolidated results of operations and financial condition are presented based on historical cost. While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we believe the effects of inflation, if any, on our results of operations and financial condition have been immaterial. There can be no assurance that future inflation will not have an adverse impact on our results of operations and financial condition.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements and notes thereto, referred to in Item 15(a) of this Annual Report, are filed as part of this Annual Report and appear in this Annual Report beginning on page F-1.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of April 30, 2025, because of the material weaknesses in our internal control over financial reporting described below.

Material Weaknesses in Internal Control over Financial Reporting

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 consolidated financial statements will not be prevented or detected on a timely basis.

We did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of resources in the accounting, finance and IT functions to appropriately analyze, record and disclose accounting matters timely and accurately. This material weakness contributed to the following additional material weaknesses.

We did not design and maintain effective controls to ensure the financial statements were properly presented and classified for certain non-routine or complex transactions. Specifically, we did not design and maintain controls to appropriately account for the classification of selling, general and administrative expenses, paid-in-kind interest, restricted cash, right of use lease assets, and the cash flow presentation of leases. This material weakness resulted in immaterial audit adjustments to the aforementioned accounts, which were recorded in previous years, prior to the issuance of the consolidated financial statements.

We did not design and maintain effective controls to verify personnel would not have the ability to prepare and post manual journal entries or review account reconciliations without an independent review by someone without the ability to prepare and post manual journal entries. This material weakness did not result in adjustments to the consolidated financial statements.

Additionally, these material weaknesses could result in a misstatement of substantially all of the financial statement accounts and disclosures that would result in a material misstatement to our annual or interim consolidated financial statements that would not be prevented or detected.

We did not design and maintain effective controls over IT general controls for information systems that are relevant to the preparation of our consolidated financial statements. Specifically, we did not design and maintain: (i) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately; (ii) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate Company personnel; (iii) computer operations controls to ensure that data backups are authorized and monitored; and (iv) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

These IT deficiencies did not result in adjustments to our consolidated financial statements; however, the deficiencies, when aggregated, could impact maintaining effective segregation of duties, as well as the effectiveness of IT-dependent controls (such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports) that could result in misstatements potentially impacting all financial statement accounts and disclosures that would not be prevented or detected. Accordingly, we have determined these deficiencies in the aggregate constitute a material weakness.

Remediation Plans

We continue to make progress towards remediating these material weaknesses. These remediation measures are ongoing as of the date of this Form 10-K and include: hiring additional personnel, such as financial planning and accounting, compliance, information technology, and other professionals with appropriate levels of knowledge and experience; engaging third parties to assist with technical accounting and in designing and implementing controls related to period-end financial reporting, segregation of duties and IT general controls; designing and implementing controls to properly present and classify non-routine or complex transactions; and enhancing IT governance processes.

We intend to evaluate current and projected resource needs on a regular basis and hire additional qualified resources as needed. Our ability to maintain qualified and adequate resources to support the Company and our projected growth will be a critical component of our internal control environment.

The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

Management's Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act during the quarter ended April 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Disclosure Controls and Procedures and Internal Control over Financial Reporting

Our management team, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives. The effectiveness of any systems of controls is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to completely eliminate all potential for misconduct. 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, if any, have been detected. The design of any system of controls is based in part on 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 deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in any cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

During the fiscal year ended April 30, 2025, none of our directors or officers adopted, modified, or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2025 Annual Meeting of Shareholders within 120 days after the end of the fiscal year ended April 30, 2025. Information relating to our executive officers is found at Item 1, "Business—Executive Officers of the Company" and is incorporated by reference herein.

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. A current copy of the code is posted on the Investors—— Corporate Governance section of our website, which is located at www.kestramedical.com.

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of the Nasdaq Global Select Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

We have adopted insider trading policies and procedures governing the purchase, sale, and other dispositions of our securities by directors, officers, and employees that are designed to promote compliance with insider trading laws, rules, and regulations, and applicable Nasdaq Global Select Market listing standards, as well as procedures designed to further the foregoing purposes. A copy of our insider trading policy is filed with this Annual Report as Exhibit 19.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2025 Annual Meeting of Shareholders within 120 days after the end of the fiscal year ended April 30, 2025.

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

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2025 Annual Meeting of Shareholders within 120 days after the end of the fiscal year ended April 30, 2025.

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

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2025 Annual Meeting of Shareholders within 120 days after the end of the fiscal year ended April 30, 2025.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our 2025 Annual Meeting of Shareholders within 120 days after the end of the fiscal year ended April 30, 2025.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this Annual Report:

(a) Financial Statements. See Index to Financial Statements included in the financial statements in this Annual Report.

(b) Financial Statement Schedules. All financial statement schedules are omitted because they are not applicable or required, or the information required to be set forth therein is included in the financial statements or notes thereto included in the Index to Financial Statements of this Annual Report.

(c) Exhibits. The exhibits required to be filed as part of this Annual Report are listed in the Exhibit List attached hereto and are incorporated herein by reference (numbered in accordance with Item 601 of Regulation S-K).

Item 16. Form 10-K Summary.

None.

Exhibit Index

Exhibit Number	Description
3.1	Certificate of Incorporation (previously filed as Exhibit 3.1 to the Registration Statement on Form S-1 (File No. 333-284807) filed on February 10, 2025 and incorporated herein by reference).
3.2	Memorandum of Association (previously filed as Exhibit 3.2 to the Registration Statement on Form S-1 (File No. 333-284807) filed on February 10, 2025 and incorporated herein by reference).
3.3	Amended and Restated Bye-laws of the Registrant (previously filed as Exhibit 3.1 to the Current Report on Form 8-K (File No. 001-42549) filed on March 7, 2025 and incorporated herein by reference).
3.4	Certificate of Deposit of Memorandum of Increase of Share Capital (previously filed as Exhibit 3.2 to the Current Report on Form 8-K (File No. 001-42549) filed on March 7, 2025 and incorporated herein by reference).
4.1	Warrant to Purchase 62,325 Common Shares issued to Kennedy Lewis Capital Partners Master Fund II LP, dated March 7, 2025, by and among Kestra Medical Technologies, Ltd., West Affum Holdings, L.P. and Kennedy Lewis Capital Partners Master Fund II LP (previously filed as Exhibit 10.1 to the Current Report on Form 8-K filed on March 7, 2025 and incorporated herein by reference).
4.2	Warrant to Purchase 46,744 Common Shares issued to Kennedy Lewis Capital Partners Master Fund II LP, dated March 7, 2025, by and among Kestra Medical Technologies, Ltd., West Affum Holdings, L.P. and Kennedy Lewis Capital Partners Master Fund II LP (previously filed as Exhibit 10.2 to the Current Report on Form 8-K filed on March 7, 2025 and incorporated herein by reference).
4.3	Warrant to Purchase 325,847 Common Shares issued to Perceptive Credit Holdings IV, LP, dated March 7, 2025, by and among Kestra Medical Technologies, Ltd., West Affum Holdings, L.P. and Perceptive Credit Holdings IV, LP (previously filed as Exhibit 10.3 to the Current Report on Form 8-K filed on March 7, 2025 and incorporated herein by reference).
4.4*	Description of Share Capital.
10.1	Assignment and Assumption of Registration Rights Agreement, dated as of February 26, 2025, by and between West Affum Holdings, L.P. and Kestra Medical Technologies, Ltd. (previously filed as Exhibit 10.1 to Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-284807) filed on February 26, 2025 and incorporated herein by reference).
10.2 +	Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan (previously filed as Exhibit 10.4 to the Current Report on Form 8-K filed on March 7, 2025 and incorporated herein by reference).
10.3 +	Forms of Equity Award Agreements under Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan (previously filed as Exhibit 10.3 to Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-284807) filed on February 26, 2025 and incorporated herein by reference).
10.4	Amended and Restated Credit Agreement and Guaranty, dated as of February 25, 2025, among Kestra Medical Technologies, Inc. and West Affum Holdings Corp., as borrowers, the guarantors from time to time thereto, the lenders from time to time party thereto and Perceptive Credit Holdings IV, LP, as administrative agent and as a lender (previously filed as Exhibit 10.12 to Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-284807) filed on February 26, 2025 and incorporated herein by reference).
10.5+	Form of Indemnification Agreement (previously filed as Exhibit 10.4 to Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-284807) filed on February 26, 2025 and incorporated herein by reference).
10.6+	Employment Agreement, dated as of October 17, 2016, between Kestra Medical Technologies, Inc. and Brian Webster (previously filed as Exhibit 10.6 to the Registration Statement on Form S-1 (File No. 333-284807) filed on February 10, 2025 and incorporated herein by reference).
10.7+	Employment Agreement, dated as of September 10, 2021, between Kestra Medical Technologies, Ltd. and Vaseem Mahboob (previously filed as Exhibit 10.7 to the Registration Statement on Form S-1 (File No. 333-284807) filed on February 10, 2025 and incorporated herein by reference).
10.8+	Employment Agreement, dated as of October 26, 2016, between Kestra Medical Technologies, Inc. and Traci S. Umberger (previously filed as Exhibit 10.8 to the Registration Statement on Form S-1 (File No. 333-284807) filed on February 10, 2025 and incorporated herein by reference).
10.9*+	Amendment to Employment Agreement, dated as of June 4, 2025, by and between Kestra Medical Technologies, Inc. and Brian Webster.
10.10*+	Amendment to Employment Agreement, dated as of June 4, 2025, by and between Kestra Medical Technologies, Inc. and Vaseem Mahboob.
10.11*+	Amendment to Employment Agreement, dated as of June 4, 2025, by and between Kestra Medical Technologies, Inc. and Traci S. Umberger.
10.12*+	Employment Agreement, dated as of June 4, 2025, by and between Kestra Medical Technologies, Inc. and Al Ford.
10.13*+	Form of Restricted Stock Unit Grant Notice and Award Agreement (Non-employee Directors) under the Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan.
10.14*+	Form of Restricted Stock Unit Grant Notice and Award Agreement (Executive Officers) under the Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan.

10.15*+	Form of Performance Stock Unit Grant Notice and Award Agreement under the Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan.
10.16*+	Form of Performance Stock Unit Grant Notice and Award Agreement (RTSR) under the Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan.
19*	Insider Trading Policy of Kestra Medical Technologies, Ltd.
21*	List of Subsidiaries.
23*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of 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*	Certification 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*	Executive Compensation Recovery Policy.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

+ Includes a management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements 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.

Kestra Medical Technologies, Ltd.

Date: July 17, 2025 By: /s/ Brian Webster
Brian Webster
President and Chief Executive Officer

Date: July 17, 2025 By: /s/ Vaseem Mahboob
Vaseem Mahboob
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Brian Webster Brian Webster	President and Chief Executive Officer, and Director *(Principal Executive Officer)*	July 17, 2025
/s/ Vaseem Mahboob Vaseem Mahboob	Chief Financial Officer *(Principal Financial Officer)*	July 17, 2025
/s/ Traci Umberger Traci Umberger	General Counsel and CAO, and Director	July 17, 2025
/s/ Jeff Schwartz Jeff Schwartz	Chairman of the Board of Directors	July 17, 2025
/s/ Christopher Gordon Christopher Gordon	Director	July 17, 2025
/s/ Mary Kay Ladone Mary Kay Ladone	Director	July 17, 2025
/s/ Raymond W. Cohen Raymond W. Cohen	Director	July 17, 2025
/s/ Toby AuWerter Toby AuWerter	Director	July 17, 2025
/s/ Kevin Reilly Kevin Reilly	Director	July 17, 2025
/s/ Maxwell Bikoff Maxwell Bikoff	Director	July 17, 2025
/s/ Conor Hanley Conor Hanley	Director	July 17, 2025

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Kestra Medical Technologies, Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kestra Medical Technologies, Ltd. and its subsidiaries (the "Company") as of April 30, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of changes in redeemable preferred stock and shareholders' equity (deficit) and of cash flows for the years then ended, including 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 April 30, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

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.

Emphasis of Matter

As discussed in Note 1 to the consolidated financial statements, the Company has incurred negative operating cash flows and significant losses from operations since its inception. Management's evaluation of the events and conditions and management's plans to mitigate these matters are also described in Note 1.

/s/ PricewaterhouseCoopers LLP
Irvine, California
July 17, 2025

We have served as the Company's auditor since 2016.

KESTRA MEDICAL TECHNOLOGIES, LTD. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	April 30, 2025	April 30, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 237,595	$ 8,249
Accounts receivable, net	8,081	1,998
Disposable medical equipment supplies	6,572	3,290
Prepaid expenses and other current assets	3,080	1,370
Total current assets	255,328	14,907
Right-of-use assets	2,078	2,286
Deposits	2,021	1,710
Restricted cash	334	334
Property and equipment, net	34,830	26,105
Other long-term assets	1,153	607
Total assets	$ 295,744	$ 45,949
Liabilities, Redeemable Preferred Stock and Shareholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 23,961	$ 23,892
Accrued liabilities	13,829	9,079
Operating lease liabilities, current portion	187	—
Total current liabilities	37,977	32,971
Operating lease liabilities, net of current portion	3,026	2,633
Warrant liabilities	8,097	—
Other long-term liabilities	140	76
Long-term debt, net	41,098	42,536
Total liabilities	90,338	78,216
Commitments and contingencies (Note 14)		
Redeemable preferred stock, $0.01 par value; 0 and 5,000,000 shares authorized as of April 30, 2025 and April 30, 2024, respectively; 0 and 177,110 shares issued and outstanding as of April 30, 2025 and April 30, 2024, respectively	—	177,110
Shareholders' equity (deficit)		
Common stock, $0.01 par value; 5,000,000 shares authorized as of April 30, 2024; 105,808 shares issued and outstanding as of April 30, 2024	—	19,909
Common shares, $1.00 par value; 100,000,000 shares authorized as of April 30, 2025; 51,348,656 shares issued and outstanding as of April 30, 2025	51,349	—
Additional paid-in capital	674,306	177,149
Accumulated deficit	(520,249)	(406,435)
Total shareholders' equity (deficit)	205,406	(209,377)
Total liabilities and shareholders' equity (deficit)	$ 295,744	$ 45,949

The accompanying notes are an integral part of these consolidated financial statements.

KESTRA MEDICAL TECHNOLOGIES, LTD. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Year Ended April 30,	
	2025	**2024**
Revenue	$ 59,815	$ 27,814
Cost of revenue	35,605	27,452
Gross profit	24,210	362
Operating expenses:		
Research and development	15,652	15,490
Selling, general and administrative	114,936	69,935
Total operating expenses	130,588	85,425
Loss from operations	(106,378)	(85,063)
Other expense (income):		
Interest expense	7,734	6,230
Interest income	(3,199)	—
Other expense	2,766	2,803
Net loss before provision for income taxes	(113,679)	(94,096)
Provision for income taxes	135	24
Net loss and comprehensive loss	(113,814)	(94,120)
Less: Undeclared preferred stock dividends	12,321	6,721
Net loss attributable to common shareholders, basic and diluted	$ (126,135)	$ (100,841)
Net loss per share attributable to common shareholders, basic and diluted	$ (5.13)	$ (5.07)
Weighted-average shares of common shares outstanding, basic and diluted[1]	24,583,745	19,885,382

The accompanying notes are an integral part of these consolidated financial statements.

[1]Weighted-average shares of common shares outstanding, basic and diluted, has been adjusted on a retrospective basis. Refer to Note 16 "*Net Loss Per Share Attributable to Common Shareholders*" for additional disclosure.

KESTRA MEDICAL TECHNOLOGIES, LTD. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)

	Redeemable Preferred Stock		Common Shares		Additional Paid-In	Accumulated	Non-controlling	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	Equity (Deficit)
Balances at April 30, 2023[2]	102,110	$102,110	19,909,281	$ 19,909	$ 174,828	$ (312,315)	$ —	$ (117,578)
Share-based compensation expense	—	—	—	—	1,488	—	—	1,488
Issuance of redeemable preferred stock	75,000	75,000	—	—	—	—	—	—
Deemed dividend for payments to third party on behalf of shareholder	—	—	—	—	(799)	—	—	(799)
Capital contribution from West Affum LP related to warrant obligation	—	—	—	—	1,632	—	—	1,632
Net loss and comprehensive loss	—	—	—	—	—	(94,120)	—	(94,120)
Balances at April 30, 2024	177,110	$177,110	19,909,281	$ 19,909	$ 177,149	$ (406,435)	$ —	$ (209,377)

	Redeemable Preferred Stock		Common Shares		Additional Paid-In	Accumulated	Non-controlling	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Interests	Equity (Deficit)
Balances at April 30, 2024	177,110	$ 177,110	19,909,281	$ 19,909	$ 177,149	$ (406,435)	$ —	$ (209,377)
Share-based compensation expense	—	—	—	—	24,271	—	—	24,271
Conversion of Incentive Units to common shares on IPO	—	—	651,577	652	(652)	—	—	—
Capital contribution from West Affum LP	—	—	—	—	2,374	—	—	2,374
Warrant modification upon IPO	—	—	—	—	(1,171)	—	—	(1,171)
Issuance of redeemable preferred stock	103,400	103,400	—	—	—	—	—	—
Conversion of redeemable preferred stock to common shares on IPO	(280,510)	(280,510)	15,444,716	15,445	265,065	—	—	280,510
Issuance of stock to non-controlling interest	—	—	—	—	—	—	17,100	17,100
Conversion of non-controlling interest to common shares on IPO	—	—	1,645,893	1,646	15,454	—	(17,100)	—
Issuance of restricted share awards	—	—	32,485	32	(32)	—	—	—
Issuance of common shares upon IPO, net of underwriter discounts and issuance costs of $21,909	—	—	13,664,704	13,665	196,726	—	—	210,391
Deemed dividend for payments to third party on behalf of shareholder	—	—	—	—	(4,878)	—	—	(4,878)
Net loss and comprehensive loss	—	—	—	—	—	(113,814)	—	(113,814)
Balances at April 30, 2025	—	$ —	51,348,656	$ 51,349	$ 674,306	$ (520,249)	$ —	$ 205,406

The accompanying notes are an integral part of these consolidated financial statements.

[2]The number and amount of shares of common shares of Intermediate Holdings at a par value of $0.01 prior to the IPO has been retrospectively recast based on the number of Common Shares at a par value of $1.00 of Kestra Medical Technologies, Ltd. into which they were exchanged in connection with the Organizational Transactions prior to the IPO. Refer to Note 1 "*The Company*" for additional disclosure.

KESTRA MEDICAL TECHNOLOGIES, LTD. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended April 30,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (113,814)	$ (94,120)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,968	11,560
Loss on disposal of property and equipment	2,094	1,070
Provision for uncollectible accounts receivable	2,694	500
Interest paid-in-kind	855	1,098
Amortization of debt discounts and issuance costs	1,400	610
Share-based compensation expense	24,270	1,488
Non-cash lease expense	416	729
Deferred income tax expense	64	12
Non-cash loss on debt extinguishment	—	930
Change in fair value of warrant liability	2,648	—
Changes in operating assets and liabilities:		
Disposable medical equipment supplies	(3,443)	(1,177)
Prepaid expenses and other current assets	(1,852)	331
Accounts receivable	(8,777)	(2,498)
Accounts payable	2,842	7,340
Accrued liabilities	4,617	371
Operating lease liabilities	370	(469)
Other long-term assets	40	(10)
Net cash used in operating activities	(77,608)	(72,235)
Cash flows from investing activities		
Purchases of property and equipment	(22,936)	(12,226)
Deposits for medical rental equipment	(655)	(288)
Refund of deposits for medical rental equipment	283	285
Net cash used in investing activities	(23,308)	(12,229)
Cash flows from financing activities		
Proceeds from issuance of redeemable preferred stock	103,400	75,000
Deemed dividend for payments to third party on behalf of shareholder	(1,654)	(799)
Proceeds from issuance of stock to non-controlling interest	17,100	—
Proceeds from issuance of long-term debt	—	45,000
Proceeds from issuance of Common Shares	215,789	—
Proceeds from capital contributions	2,374	—
Payment of debt issuance costs	—	(2,353)
Payment of equity issuance costs	(3,224)	—
Repayment of long-term debt	—	(39,123)
Payments of IPO offering costs	(3,523)	—
Net cash provided by financing activities	330,262	77,725
Net increase (decrease) in cash, cash equivalents and restricted cash	229,346	(6,739)
Cash, cash equivalents and restricted cash		
Beginning of period	8,583	15,322
End of period	$ 237,929	$ 8,583

Reconciliation of cash, cash equivalents and restricted cash reported in the consolidated balance sheets				
Cash and cash equivalents	$	237,595	$	8,249
Restricted cash		334		334
Cash, cash equivalents and restricted cash	$	237,929	$	8,583
Non-cash investing and financing activities:				
Purchases of property and equipment in accrued liabilities and accounts payable	$	7,029		11,066
Capital contribution from West Affum LP to settle warrant obligation		—		1,632
IPO offering costs incurred but not yet paid		1,875		—
Issuance of warrants related to long-term debt		5,449		—
Conversion of redeemable preferred stock into Common Shares on completion of IPO		280,510		—
Supplemental disclosure of cash flow information				
Income taxes paid (refunds received)	$	83		(30)
Interest paid		4,851		3,630

The accompanying notes are an integral part of these consolidated financial statements.

1. The Company

Kestra Medical Technologies, Ltd. is a commercial stage medical device company, which principally generates revenue through leasing the ASSURE© System, which consists of a Wearable Cardioverter Defibrillator, to patients.

Kestra Medical Technologies, Ltd. was formed as a limited company in Bermuda on May 20, 2021 as a wholly owned subsidiary of West Affum Holdings, L.P. ("West Affum LP"), a company in the Cayman Islands. Kestra Medical Technologies, Ltd. was formed for the purpose of completing a public offering and related transactions to carry on the business of West Affum Intermediate Holdings Corp. and its subsidiaries.

West Affum Intermediate Holdings Corp., a Cayman Islands exempted company ("Intermediate Holdings"), was incorporated on August 6, 2020, in order to carry on the business of West Affum Holdings Corp. ("WAH Corp.") and its consolidated subsidiaries. Except as otherwise indicated or the context requires, references to the "Company" are to Intermediate Holdings for transactions occurring in periods prior to the consummation of the initial public offering of Kestra Medical Technologies, Ltd., and references to the "Company" are to Kestra Medical Technologies, Ltd. and its consolidated subsidiaries for transactions occurring in periods following the consummation of the initial public offering.

The Company and its consolidated subsidiaries own certain intellectual property related to the development of personal Wearable Cardioverter Defibrillators ("WCD") approved by the U.S. Food and Drug Administration ("FDA") in July of 2021.

Initial Public Offering

On March 7, 2025, Kestra Medical Technologies, Ltd. completed an initial public offering of 11,882,352 common shares, par value $1.00 per share ("Common Shares") at an offering price to the public of $17.00 per Common Share ("IPO"). On March 14, 2025, the underwriters purchased an additional 1,782,352 Common Shares at an offering price to the public of $17.00 per Common Share.

In connection with the IPO, organizational transactions were effected whereby Kestra Medical Technologies, Ltd. delivered 37,683,952 Common Shares to West Affum LP and its unitholders, including 19,885,382 Common Shares delivered to West Affum LP in exchange for West Affum LP's contribution of its 105,808 shares of common stock, in Intermediate Holdings to Kestra Medical Technologies, Ltd., and the remainder of which Common Shares, including 32,485 Common Shares of Kestra Medical Technologies, Ltd. that are subject to vesting conditions, were delivered to holders of West Affum LP's class A common units (the "Class A Common Units") and equity incentive units (the "Incentive Units"), including a third-party investor in West Affum Holdings Designated Activity Company, a subsidiary of Intermediate Holdings (collectively, the "Organizational Transactions").

Following the Organizational Transactions, pre-existing interests in Intermediate Holdings, as well as non-controlling interests of its subsidiaries, were exchanged into Common Shares. Kestra Medical Technologies, Ltd. now directly owns 100% of Intermediate Holdings and indirectly owns 100% of each of Intermediate Holdings' direct and indirect subsidiaries.

The IPO, together with the Organizational Transactions, represent a business combination between entities under common control under the principles of ASC Topic 805, *Business Combinations*. As such, the exchange of Intermediate Holdings common stock into Common Shares of Kestra Medical Technologies, Ltd. have been reflected on a retrospective basis. Other transactions that closed contemporaneously with the Organizational Transactions, including conversions of preferred stock, non-controlling interests, and equity awards were accounted for prospectively beginning on the date such transactions occurred, and were not given retrospective effect.

Liquidity

As of April 30, 2025, the Company's principal sources of liquidity consisted of $237,595 of cash and cash equivalents.

The Company has incurred negative operating cash flows and significant losses from operations since its inception. For the years ended April 30, 2025 and 2024, the Company incurred net losses of $113,814 and $94,120, respectively. Cash used in operating activities was $77,608 and $72,235 for the years ended April 30, 2025 and 2024, respectively. As of April 30, 2025, the Company had an accumulated deficit of $520,249.

In March 2025, the Company raised $215,789 in proceeds in the IPO after deducting underwriting discounts and commissions and before deducting IPO offering costs of $5,398.

Based on the Company's current operating plan, the Company believes that its existing cash and cash equivalents will be sufficient to fund the Company's planned operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these financial statements.

However, the Company may experience lower than expected cash generated from operating activities or greater than expected capital expenditures, cost of revenue or operating expenses and may require additional funding to execute on its growth plans, which may include funding raised through future equity and debt financings. Management cannot predict with certainty that adequate funding will be available on acceptable terms or at all. If the Company cannot obtain sufficient funds on acceptable terms when needed, the Company may experience a material and adverse effect on its business, financial condition, results of operations and prospects.

Emerging Growth Company Status

The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), enacted in 2012. Under the JOBS Act, EGCs can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an EGC or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

2. Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and generally accepted accounting principles in the United States of America ("US GAAP") and include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. The Company's reporting currency is the U.S. dollar.

Certain prior period amounts in the consolidated statements of cash flows have been reclassified to conform to the current period presentation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Estimates are required as part of determining the collectability of lease payments for revenue recognition, estimated useful lives of property and equipment, losses for unreturned property and equipment, share-based compensation expense, fair value of warrants and valuation allowance for deferred tax assets.

The Company bases its estimates on historical experience and other market-specific or relevant assumptions that it believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents are recorded at cost, which approximates fair value. Restricted cash consists of amounts related to the Company's office lease agreement and credit card collateralization. In lieu of a cash security deposit, the landlord required an irrevocable standby letter of credit upon execution of the lease be

maintained throughout the term of the lease agreement in the amount of $109 as of April 30, 2025 and 2024. The Company also had restricted cash of $225 for credit card collateralization as of April 30, 2025 and 2024.

Disposable Medical Equipment Supplies

Disposable medical equipment supplies consist of equipment parts, consumables, and associated product supplies that are expensed to the cost of revenue at the time of order delivery to the patient or first use. Disposable medical equipment supplies are valued at cost.

Accounts Receivable

Accounts receivable and net revenues are based on contractually agreed-upon rates for leases for the ASSURE© System, reduced by contractual adjustments. Inherent in these estimates is the risk that they will have to be revised or updated as additional information becomes available. The complexity of third-party billing arrangements and laws and regulations governing Medicare may result in adjustments to amounts originally recorded.

The Company performs a periodic analysis to review the valuation of accounts receivable and collectability of outstanding balances. These estimates are determined utilizing historical realization data under a portfolio approach which is then assessed by management to evaluate whether adjustments should be made based on accounts receivable aging trends, other operating trends, and relevant business conditions such as governmental and managed care payor claims processing procedures.

The Company records a reserve for estimated probable losses as part of net revenue adjustments in reporting revenue at an expected collectable amount based on the total portfolio of receivables for which collectability has been deemed probable. Accounts receivable is presented on the consolidated balance sheets net of the adjustments.

Receivables are considered past due when not collected by established due dates. Specific patient balances are written off after collection efforts have been followed and the account has been determined to be uncollectible. Changes to reserve estimate impacts are recorded as an adjustment to net revenue in the period during which changes in circumstances support a change to the estimate. The estimates of the allowance for uncollectible accounts receivable were $3,193 and $500 as of April 30, 2025 and 2024, respectively.

Property and Equipment

Property and equipment consist of medical rental equipment, test equipment, computer software and equipment, and leasehold improvements. Medical rental equipment used in the delivery of the ASSURE® WCD system consists of therapy cables, batteries, battery chargers, assistants and WCD monitors, all of which have different useful lives. Upon completion of use by a patient, medical rental equipment is returned to the Company's third-party manufacturing and supply partner and inspected, tested and recertified for use by another patient. When not in use by patients, medical rental equipment resides with the Company's third-party manufacturing and supply partner, at third-party warehouses or with the Company's territory managers. Physical counts of components are conducted at least annually at the third-party manufacturing and supply partner locations and at least quarterly at other locations.

Property and equipment are stated at cost less accumulated depreciation. Depreciation of medical rental equipment commences at the date when it becomes available for service, which represents the date that the asset is ready for intended use by the patients and continues through the estimated useful life of the asset. Expenditures for major renewals and betterments that extend the useful lives of property and equipment are capitalized. Expenditures for maintenance and repairs, including planned major maintenance activities, are expensed as incurred.

Property and equipment are depreciated using the straight-line method based on the following estimated useful lives:

	April 30, 2025	April 30, 2024
Asset Classification	**Estimated Useful Lives**	**Estimated Useful Lives**
Computer software and equipment	3 years	3 years
Test equipment	5 years	5 years
Leasehold improvements	Lesser of useful life or lease-term	Lesser of useful life or lease-term
Medical rental equipment	2 - 8 years	1.5 - 7 years

During the year ended April 30, 2025, the estimated useful life of the medical rental equipment asset class was changed prospectively from 1.5 - 7 years to 2 - 8 years. This change was the result of an FDA approval allowing therapy cables to be repaired up to three times, which increased the estimated useful life of this component from two

years to eight years. The impact was a reduction of depreciation expense, which is included within cost of revenue, by $1,208 in the year ended April 30, 2025, compared to if the useful life of therapy cables had remained at two years. In addition, during the year ended April 30, 2025, the estimated useful lives of batteries was extended from two years to six years and was applied prospectively. This change was a result of the better-than-expected performance of the batteries. The impact was a reduction of depreciation expense, which is included within cost of revenue, by $198 in the year ended April 30, 2025, compared to if the useful life of batteries had remained at two years. This change in estimated useful life reduced net loss and comprehensive loss by the same amount.

When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts, and any resulting gain or loss is recognized in the consolidated statements of operations and comprehensive loss for the period.

Deposits

Deposits represent advance payments to contracted suppliers for medical rental equipment. These payments are classified as long-term assets in the consolidated balance sheets.

Leases

The Company determines if an arrangement is a lease at inception and on the lease commencement date, the Company recognizes an asset for the right to use a leased asset and a liability based on the present value of remaining lease payments over the lease term.

The Company determines whether a contract contains a lease at the inception of a contract. If the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration, the Company considers the contract to contain a lease.

The Company determines whether a contract conveys the right to control the use of an identified asset for a period of time if the contract contains both the right to obtain substantially all of the economic benefits from use of the identified asset and the right to direct the use of the identified asset.

The Company's leases do not provide an implicit rate. As such, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments.

Lease and non-lease components are combined for all leases. The measurement of lease right-of-use assets and liabilities includes amounts related to lease payments made prior to the lease commencement date, incentives from landlords received by the Company for signing a lease, including tenant improvement allowances or deferred lease credits paid to the Company by landlords, fixed payments related to lease components, such as rent escalation payments schedules at the lease commencement date, and fixed payments related to non-lease components, such as taxes, insurance and maintenance costs. The measurement of lease right-of-use assets and liabilities excludes amounts related to variable payments related to lease components, such as contingent rent payments.

Variable payments related to non-lease components, such as taxes, insurance and maintenance costs, are expensed as incurred in the consolidated statements of operations and comprehensive loss. The Company has elected not to recognize right-of use-assets and lease liabilities for leases with a term of twelve months or less. Lease costs for short-term leases are recognized on a straight-line basis over the lease term.

Certain of the Company's leases may include options to extend the lease or to terminate the lease. The Company assesses these leases and, depending on the facts and circumstances, has not included these options in the measurement of the Company's lease right-of-use assets and liabilities since extending the lease under an option is not reasonably certain of such option being exercised.

Non-cash amortization related to the lease right-of-use assets and liabilities is calculated on a straight-line basis over the lease term and is reflected in research and development expenses and selling, general and administrative expense in the consolidated statements of operations and comprehensive loss. Operating lease payments are classified as cash flows from operating activities in the consolidated statements of cash flows.

Impairment of Long-Lived Assets

The Company periodically reviews its long-lived assets, including property and equipment and right-of-use assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable.

The Company compares the carrying value of the long-lived assets (asset group) with the estimated future net undiscounted future cash flows expected to result from the use of the assets (asset group), including cash flows from disposition. An impairment loss is measured as the amount by which the carrying value exceeds the fair value of the long-lived assets (asset group). No impairment of long-lived assets was recorded during the years ended April 30, 2025 and 2024.

Warrant Liabilities

The Company accounts for certain warrants as liabilities in accordance with ASC 815-40, *Derivatives and Hedging*. The warrants are presented as a warrant liability in the consolidated balance sheets and are measured at fair value, with gains or losses recognized in the consolidated statements of operations and comprehensive loss.

Revenue

The Company generates revenue from the leases of ASSURE© System, which consists of a Wearable Cardioverter Defibrillator combined with a proprietary digital healthcare platform, to at-risk patients for a fixed amount on a month-to-month basis. The lease payments generally consist of the contracted amounts based on reimbursement arrangements with third-party payors including Medicare, Medicaid and private commercial payors, and/or certain patient co-payments. The patient has the right to cancel the lease at any time during the rental period.

The equipment leases are classified as operating leases at lease commencement, and the Company recognizes the revenue associated with ASSURE© rentals in accordance with Accounting Standards Codification Topic 842, *Leases* ("ASC Topic 842"). The Company elected the practical expedient provided under ASC Topic 842 to combine the lease of ASSURE© System with the non-lease components, which includes the digital healthcare platform. The ASSURE© System is expected to be the predominant component and, as a result, the Company accounts for the combined revenue components under ASC Topic 842. Revenue is recognized on a straight-line basis over the contractual non-cancellable lease term, which is one month, when collectability of the lease payments is deemed to be probable. If collectability of the lease payments is not deemed to be probable, the lease income is limited to the lesser of the income that would have been recognized if collectability was probable or the lease payments collected. Collectability of all lease payments, which includes amounts reimbursed by third-party payors and/or amounts covered by the patient, is assessed for each contract upon lease commencement and is subject to subsequent reassessment throughout the lease term, as necessary.

Due to the nature of the industry and the reimbursement environment in which the Company operates, the Company periodically evaluates the need to record a general reserve under ASC 450, *Contingencies,* for a portfolio of operating lease receivables that are probable of collection. Inherent in the reserve estimates is the risk that they will have to be revised or updated as additional information becomes available. Specifically, the complexity of many third-party billing arrangements and the uncertainty of reimbursement amounts for certain services from certain payors may result in adjustments to amounts originally recorded. Such adjustments are expected to be identified and recorded at the point of cash application or claim denial.

Cost of Revenue

Cost of revenue consists of direct material, labor and rental equipment costs and indirect costs related to rental performance of ASSURE© System. It includes the cost of disposable WCD device components, depreciation cost of medical rental equipment reusable components, shipping, and order fulfillment costs, as well as other indirect costs incurred to support the manufacture and medical rental equipment delivery to and ongoing support for the patient's costs incurred in connection with providing the ASSURE© System to the patients.

Deferred IPO Offering Costs

The Company capitalized as deferred offering costs all direct and incremental legal, professional and other third-party fees incurred in connection with the Company's IPO within long-term assets. The Company recorded $5,398 in deferred offering costs through the IPO in March 2025 (see Note 1 *"The Company"*). The deferred offering costs were offset against the IPO proceeds upon closing of the IPO and were no longer deferred. As of April 30, 2025, $1,875 of the IPO offering costs were in accounts payable and accrued expenses.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established if it is more likely than not that some, or all of the net deferred tax assets will not be realized.

The Company recognizes the effect of income tax positions only if it is more likely than not that the tax position will be sustained upon examination by the tax authorities. Recognized income tax positions are measured at the largest amount that has a greater than 50% likelihood of being recognized. Changes in recognition or measurement are reflected in the period in which the change in judgement occurs.

Research and Development

Research and development expenses consist of salaries and related benefits of product development personnel, prototype materials and other expenses related to the development of new products. Research and development expenses are expensed as incurred.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. Patent-related legal costs are included as a component of selling, general and administrative expenses.

Share-Based Compensation

The Company accounts for share-based compensation for employee and non-employee awards in accordance with ASC 718, *Compensation - Stock Compensation.* ASC 718 requires the recognition of compensation expense using a fair value-based method for costs related to all share-based awards, including stock options.

Share-based compensation expense for share-based payments is measured at the grant date based on the fair value of the award and recognized as compensation expense over the period of service. The Company uses the Black-Scholes option pricing model to determine the fair value of share-based payments. The model requires various assumptions involving the judgement of management, including the fair value of common units or common shares, volatility in price, time to liquidity (prior to the IPO) and risk-free interest rate. As the Company did not have sufficient trading history for share-based awards issued prior to the IPO, the expected volatility was derived from the average historical volatilities of several comparable public companies within the Company's industry over a period equivalent to the expected term of the share-based awards. The Company will continue to analyze the volatility assumptions as additional data for the Company's Common Share becomes available. Due to the lack of historical exercise history, the expected term of the Company's stock options is determined using the "simplified" method. The risk-free interest rate is rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to expected term of the stock options. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The Company classifies share-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Payments on Behalf of Shareholder

During the year ended April 30, 2025, and 2024, the Company paid administrative costs to third parties on behalf of one of its shareholders of $4,878 and $799, respectively. The payments to third parties on behalf of the Company's shareholder were recorded as a deemed dividend in the consolidated statements of changes in redeemable preferred stock and shareholders' equity (deficit).

Concentrations of Risk

Credit Risk

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash. The Company's cash is mainly held in financial institutions. Amounts on deposit may at times exceed federally insured limits. The Company has not experienced any losses on its deposits of cash and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Further, the Company holds a small cash balance in its account located in the Cayman Islands, which is not insured.

Business Risk

The Company relies and expects to continue to rely on a small number of vendors to manufacture supplies, materials, and rental equipment for its use in the commercial product and the clinical trial programs. These programs could be adversely affected by a significant interruption in these manufacturing services.

Customer Risk

The Company earns revenues by seeking reimbursement for the product from governmental healthcare programs and private health insurance companies, including the federal Medicare program. If the Medicare program were to slow payments of the receivables for any reason, the Company would be adversely impacted. In addition, both governmental healthcare programs and private health insurance companies may seek ways to avoid or delay reimbursement, which could adversely affect the Company's cash flow and revenues.

Segment Information

The Company has a single operating and reportable segment. The Company has determined that its Chief Executive Officer is its chief operating decision maker. The Company's Chief Executive Officer reviews financial information presented on a consolidated basis and in a consistent manner with that is included in the consolidated statements of operations and comprehensive loss for purposes of assessing performance and making decisions on how to allocate resources. As the Company operates as one operating segment, all required segment financial information, such as revenues and significant operating expenses, is found in the accompanying consolidated financial statements. For the periods presented, all of the Company's long-lived assets were located in the United States, and all revenues from leasing of ASSURE© System devices to patients were earned in the United States. The accounting policies for segment reporting are the same as for the Company as a whole.

The chief operating decision maker utilizes the Company's financial information such as net loss and comprehensive loss derived from revenues and operating expenses included in the Company forecast, performance metrics, and budget versus actual analyses for purposes of evaluating financial performance and how to best allocate resources when developing and reviewing the annual budget to achieve the Company's long-term objectives. Significant expenses within loss from operations include cost of revenue, research and development, selling, general and administrative expenses, which are each separately presented on the Company's Consolidated Statements of Operations and Comprehensive Loss.

Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants as of the measurement date. There are three levels of inputs that may be used to measure fair value:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities
- Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Comprehensive Loss

Comprehensive loss consists of net loss and other gains or losses affecting shareholders' equity that, under accounting principles generally accepted in the United States of America, are excluded from net loss. For the years ended April 30, 2025 and 2024, there were no items which qualify as components of other comprehensive loss and therefore, the Company's comprehensive loss was the same as its reported net loss.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU No. 2023-07"). ASU 2023-07 requires that an entity disclose significant segment expenses, a description of "other segment items," and the title and position of the chief operating decision maker along with an explanation of how the reported segment profit or loss is assessed and allocated. The amendments in this ASU were applied retrospectively for all prior periods presented in the financial statements. The Company adopted ASU 2023-07 during the year ended April 30, 2025. The adoption of the amendments in ASU 2023-07 impacted the Company's disclosures in the notes to the consolidated financial statements and did not have a material impact on its consolidated balance sheets, results of operations or cash flows.

Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which enhances transparency and decision usefulness of income tax disclosures, primarily related to the income tax rate reconciliation and income taxes paid information. The guidance is effective for private business entities for annual reporting periods beginning after December 15, 2025. The Company does not anticipate a material impact to the required financial statement disclosure as a result of this ASU.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40) ("ASU 2024-03")*, requiring disclosure in the notes to the financial statements for specified information about certain costs and expenses. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027; however early adoption is permitted and can be applied either prospectively or retrospectively. The Company is evaluating the impact that this ASU will have on its financial statement disclosures.

The Company has reviewed other recent accounting pronouncements and concluded that they are either not applicable to the business, or that no material effect is expected on the consolidated financial statements as a result of future adoption.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at:

	April 30,	
	2025	**2024**
Prepaid software fees	$ 1,387	$ 951
Other	1,693	419
Prepaid expenses and other current assets	$ 3,080	$ 1,370

4. Property and Equipment

Property and equipment consisted of the following at:

	April 30,	
	2025	2024
Medical rental equipment	$ 52,670	$ 38,097
Computer software and equipment	1,446	1,439
Test equipment	3,115	1,564
Leasehold improvements	919	891
Work in progress	635	1,660
Total property and equipment	$ 58,785	$ 43,651
Less: accumulated depreciation	(23,955)	(17,546)
Property and equipment, net	$ 34,830	$ 26,105

The Company recorded $7,968 and $11,560 of depreciation expense for the years ended April 30, 2025 and 2024, respectively.

5. Leases

The Company had two operating leases for office space that commenced on May 1, 2020 and January 1, 2021 with a 48-month term and 40-month term, respectively. The Company determined at the commencement of both leases that it is reasonably certain that the Company will not exercise the option to extend the terms of either lease. The office leases have variable lease payments to reimburse the lessor for costs, such as insurance and taxes but do not depend on an index rate and are excluded from the measurement of the lease liability and are recognized in operating expense.

In June 2021, the Company amended its office lease that began on May 1, 2020 to expand the leased space, commencing on September 1, 2021. The amendment is subject to all terms and conditions of the original office lease agreement and were set to expire in April 2024. In October 2023, the Company amended the existing office lease to expire in April 2029. The Company has the option to renew for 3 or 5 years upon expiration of the extended term at prevailing market rates.

The October 2023 office lease amendment provided rent abatement from November 1, 2023 through April 30, 2024. The same amendment further provided a tenant improvement allowance of $943 to be used as rent abatement or tenant improvement reimbursement by June 2026, and $786 specifically for tenant improvement reimbursement. In August 2024, the Company amended its office lease to allow for two additional months of rent abatement and for the amount to be used specifically for tenant improvement reimbursement to be used for rent abatement or tenant improvements.

In February 2025, the Company further amended its office lease to expand the leased space, commencing on April 1, 2025.

Operating lease expense was as follows for the periods below:

	Year Ended April 30,	
	2025	2024
Operating lease expense	$ 758	$ 991
Variable lease expense	636	602
Total operating lease expense	$ 1,394	$ 1,593

Operating lease expense includes amortization and interest expense associated with operating lease right-of-use assets and liabilities. Variable lease expense includes payments related to taxes, insurance and maintenance costs as required by the lease.

Cash paid for operating leases was $655 and $1,269 for the years ended April 30, 2025 and 2024, respectively.

The weighted average remaining lease term for the Company's operating leases was 48 months as of April 30, 2025, and 60 months as of April 30, 2024. The weighted average discount rate used to calculate the net present value of the Company's operating lease liabilities was 15.2% as of April 30, 2025 and 2024.

Maturities of operating lease liabilities (net reimbursements) were as follows as of April 30, 2025:

	2025
Fiscal Year:	
2026	$ 333
2027	1,364
2028	1,405
2029	1,447
Total future lease payments	$ 4,549
Less: imputed interest	(1,336)
Total lease liability balance	$ 3,213
Less: current portion of lease liability	(187)
Total lease liability, net of current portion	$ 3,026

6. Accrued Liabilities

Accrued liabilities consisted of the following at:

	April 30,	
	2025	2024
Bonuses and commissions	$ 6,368	$ 4,291
Other expenses	3,547	1,191
Paid time off	2,305	1,903
Professional services	1,141	1,460
Payroll and payroll taxes	468	234
Accrued liabilities	$ 13,829	$ 9,079

7. Long-Term Debt

On September 24, 2020, West Affum Holdings Corp. and Kestra Medical Technologies, Inc. (subsidiaries of West Affum Intermediate Holdings Corp.) entered into the Loan and Security Agreement (the "Loan Agreement") with a lender, which provided for a Senior Secured Delayed-Draw Term Loan in an aggregate principal amount of up to $50.0 million (as amended, the "Term Loan"). Borrowings under the original Term Loan were made available in up to three tranches, which were subject to the Company achieving certain funding, regulatory or revenue milestones as defined in the Loan Agreement. The term loan included certain six-month trailing revenue targets beginning in July of 2022, which, if breached, would increase the interest rate on the Term Loan by 1.0% and require the then outstanding balance to accelerate to be repaid over a 24-month period.

On December 28, 2020, the Company drew the first tranche of the Term Loan pursuant to the terms of the Loan Agreement in the amount of $20.0 million. The Company incurred a 1.0% facility fee of the total available loan amount of $50.0 million upon the drawing of the first tranche and legal fees of $832 for both the Company and the lender. The Company recognized a portion of the facility fee and legal fees as a discount to the long-term debt liability and a portion in other long-term assets, relative to the tranche draws, both of which were amortized as interest expense over the term of the loan on a straight-line basis.

In conjunction with the draw on the first tranche, West Affum LP issued a warrant to the lender to purchase up to 49,044 shares of West Affum LP's common units at an exercise price of $22.63 per share. The fair value of the warrant was $320 and was recognized as a debt discount and as a capital contribution, and the debt discount was amortized over the term of the loan to interest expense.

On January 21, 2022, the Company drew the second tranche of the Term Loan pursuant to the terms of the Loan Agreement in the amount of $15.0 million. Relative to the second tranche draw, the Company reclassified a portion

of the facility fee and legal fees from other long-term assets to the long-term debt liability as a debt discount, with both facility and legal fees being amortized as interest expense over the term of the loan on a straight-line basis.

In conjunction with the draw of the second tranche, West Affum LP issued a warrant to the lender to purchase up to 36,783 shares of West Affum LP's common units at an exercise price of $26.24 per share. The fair value of the warrant was $375 and was recognized as a debt discount and as a capital contribution, and the debt discount was amortized over the term of the loan to interest expense.

The Term Loan originally bore interest on outstanding balances of 14.5% per annum, all of which could be paid-in-kind, accrued and added to the principal balance and compounded quarterly until the earlier of the repayment or maturity date of the Term Loan. Following achievement of Premarket Approval from the FDA of the Company's ASSURE® WCD system, the Term Loan would bear interest of 12.5% per annum, up to 6.5% of which could be paid-in-kind, accrued and added to the principal and compounded quarterly until the earlier of either the repayment or maturity date of the Term Loan. On July 27, 2021, the Company received FDA Premarket Approval for the ASSURE®WCD system and submitted evidence of the FDA Premarket Approval to the lender of the Term Loan. As such, the Term Loan began to bear interest on outstanding balances of 12.5% per annum, up to 6.5% of which could be paid-in-kind, accrued and added to the principal and compounded quarterly until the earlier of either the repayment or maturity date of the Term Loan. On April 11, 2022, the Company and the lender entered into a First Amendment to Loan and Security Agreement (the "Amendment"), pursuant to which the parties agreed to amend the existing Loan Agreement to (i) provide for additional funding under additional tranche Loan ("Tranche D Draw") in the amount of $10.0 million, (ii) increase the aggregated principal amount by $10.0 million, to a total of $60.0 million, (iii) increase the portion of paid-in-kind interest to 100% of a stated interest rate at 12.5% for the period starting February 1, 2022 through April 30, 2023 and thereafter at a rate of 6.5% in accordance with the terms of the loan agreement, and (iv) modify the certain revenue targets and defer the first measurement date to October of 2022. The Amendment included the ability to draw on the third tranche of the debt until March 24, 2023, provided the Company could achieve $9.0 million in three-month trailing revenue. Further, the Tranche D Draw for $10.0 million was available until July 24, 2023, upon achievement of a six-month trailing revenue of $25.0 million. The original loan maturity date of September 24, 2025, under the loan modification remained unchanged. The Company evaluated the Amendment to the Term Loan under accounting guidance ASC 470, *Debt*, and determined that the amendment should be treated as a debt modification, as such no gain or loss was recognized in the year ended April 30, 2022.

As of October 31, 2022, the Company did not meet the required revenue target for the preceding six-months trailing revenue. As a result, the Company began to make principal payments over a 24-month period, payable at the beginning of the following quarter and the interest rate increased by 1% to 13.5%. The Company made its first principal payment of $5,333 on February 1, 2023. The Company did not meet its revenue target for the preceding six months as of January 31, 2023, and principal payments continued. The Company made a second principal payment on May 1, 2023, for $5,511. The Company did not meet its revenue target for the preceding six months as of April 30, 2023, and the next principal payment was due on August 1, 2023.

On July 28, 2023, the Company entered into an agreement with the holder of the Term Loan, to defer a principal payment that was due on August 1, 2023, to extend the payment date to September 1, 2023. On August 31, 2023, the Company entered into an agreement to defer the principal payment that was due on August 1, 2023, to October 31, 2023. The agreement also changed the loan prepayment fee of 6% through from September 24, 2022, to September 24, 2023, to a loan prepayment fee of 5% from September 24, 2022, through December 31, 2023, and for the prepayment fee to be changed to 3% beyond December 31, 2023. On September 29, 2023, the Company terminated the Term Loan by paying off the loan balance of $34,209, accrued interest of $757, a prepayment fee of $1,710 and a loss on extinguishment of debt of $1,006, including the non-cash portion of $930. Loss on extinguishment of debt is included in other expense on the consolidated statements of operations and comprehensive loss.

On September 29, 2023, the Company entered into a Credit Agreement with a separate lender which provided a Senior Secured Delayed Draw Term Loan Facility (as amended, the "Term Loan 2024") in an aggregate principal amount of up to $60.0 million which matures on September 29, 2028. Borrowings are made available in up to three tranches, the first of which is available upon closing of the agreement, which included committed equity funding of at least $75 million, and two follow on tranches of $7.5 million which become available before November 1, 2024, and February 1, 2025, and are dependent on upon achievement of revenue milestones of trailing twelve-month revenues of $50.0 million and $70.0 million, respectively. The Term Loan 2024 bears interest equal to the sum of Term Secured Overnight Financing Rate plus 7.25% for each interest period which is measured monthly and is

payable on the last day of each fiscal quarter. Through March 31, 2025, the Company has the ability to pay-in-kind up to 2% of the payable interest. The Term Loan 2024 requires a minimum level of cash of $3.0 million and certain revenue thresholds based upon trailing twelve-month revenue results. The revenue covenant began to be measured on April 30, 2024. As of April 30, 2024, the Company was in compliance with both financial covenants.

On September 29, 2023, the Company drew the initial $45.0 million. In connection with the first draw, the Company incurred a 1% facility fee of the total available loan amount of $60.0 million upon the draw of the first tranche of $600 and legal fees of $1,753 for both the Company and the lender. The Company recognized the facility fee and legal fees as a discount of $1,765 to the Term Loan 2024 for the initial draw on the loan, and $588 as an Other long-term asset, for the remainder available to draw. Each of these will be amortized as interest expense over the term of the loan on a straight-line basis.

As of October 31, 2024, the Company determined that the revenue milestone related to the second tranche was not met and the third tranche was not probable of being achieved. As a result, the Company expensed the asset related to debt issuance costs and facility fees in the amount of $462.

In conjunction with the draw of the first tranche, West Affum LP issued a warrant to the lender to purchase up to 256,410 shares of West Affum LP's common units at an exercise price of $17.55 per share. The fair value of the warrant was $1,632 and was recognized as a debt discount and as a capital contribution, and the debt discount is amortized over the term of the loan to interest expense.

On February 25, 2025, the Company amended the Term Loan 2024 facility to adjust the revenue milestones applicable to the debt covenants therein and amend the ability to draw additional loans under the third tranche to allow for the ability to draw an additional $15.0 million through July 31, 2026 upon the achievement of revenue of at least $60.0 million for any twelve consecutive month period prior to the third tranche borrowing date. As of April 30, 2025, the Company was in compliance with all financial covenants.

In connection with the IPO, the warrant issued to the lender on September 29, 2023 was cancelled and exchanged for a new warrant to purchase up to 325,847 Common Shares of Kestra Medical Technologies, Ltd. with an exercise price of $11.54. The new warrant expires on September 29, 2033. The warrant is classified as a liability and is recorded as a discount to the Term Loan 2024. Upon the funding of additional amounts under the third tranche of Term Loan 2024, the Company will issue additional warrants to the lender equal to 10% of the amount funded.

The Company's long-term debt consisted of the following at:

	April 30,	
	2025	2024
Term loans	$ 45,000	$ 45,000
Accumulated paid-in-kind interest applied to term loan balance	1,395	540
Less: unamortized debt issuance costs and debt discount	(5,297)	(3,004)
Total long-term debt	$ 41,098	$ 42,536
Less: Current portion of long-term debt	—	—
Total long-term debt, net of current portion	$ 41,098	$ 42,536

The Company recognized expenses related to the Term Loan 2024 as follows:

	Year Ended April 30,	
	2025	2024
Cash interest expense	$ 4,851	$ 2,860
Amortization of the facility fee and legal fees	874	271
Amortization of the debt discount recognized in connection with the warrant	526	438
Interest expense paid-in-kind and applied to the Term Loan 2024 balance	855	540
Total expense recognized related to the Term Loan 2024	$ 7,106	$ 4,109

The Company recognized expenses related to the Term Loan as follows:

	Year Ended April 30,	
	2025	2024
Cash interest expense	$ —	$ 771
Amortization of the facility fee and legal fees	—	93
Amortization of the debt discount recognized in connection with the warrant	—	56
Interest expense paid-in-kind prior to the extinguishment of the Term Loan	—	1,141
Total expense recognized related to the Term Loan	$ —	$ 2,061

8. Fair Value Measurement

The following table presents the Company's fair value hierarchy for its classified assets and liabilities measured at fair value on a recurring basis as of April 30, 2025 and 2024.

	Level 1	Level 2	Level 3
April 30, 2025			
Assets			
Cash and cash equivalents	$ 237,595	$ —	$ —
Restricted cash	334	—	—
Total assets	$ 237,929	$ —	$ —
Liabilities			
Warrant liabilities	—	—	8,097
Total liabilities	$ —	$ —	$ 8,097
April 30, 2024			
Assets			
Cash and cash equivalents	$ 8,249	$ —	$ —
Restricted cash	334	—	—
Total assets	$ 8,583	$ —	$ —

The Company classifies its money market funds, which are valued based on quoted market prices in active markets with no valuation adjustment, as cash and cash equivalents within the fair value hierarchy.

As of April 30, 2025 and 2024, the fair value of the long-term debt, net of discounts, approximated $47,330 and $43,870, respectively. The fair value of long-term debt was determined using quoted market prices, when available, or discounted cash flows based on various factors, including maturity schedules and current market rates. Long-term debt has been classified as Level 2 of the fair value hierarchy.

The Term Loan was transferred out from the Level 2 fair value hierarchy during the year ended April 30, 2024 when the Company paid off and terminated the Term Loan. In the same period, the Term Loan 2024 was transferred into the Level 2 fair value hierarchy. Other than those items, there were no transfers into or out of the Level 1, 2 or 3 fair value hierarchies during the years ended April 30, 2025 and 2024.

Warrant Liabilities

As of April 30, 2025, the Company recorded warrant liabilities from issuance of warrants to the lender of the Term Loan 2024 in connection with the amendment on February 25, 2025. The warrant liabilities are based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The Company's valuation of the warrant liabilities utilized the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value the warrants.

As of April 30, 2025, the quantitative elements associated with the Company's Level 3 inputs impacting the fair value measurement of the warrant liabilities included the fair value per share of the underlying Common Shares, the remaining contractual term of the warrant, risk-free interest rate, expected dividend yield and expected volatility of

the price of the underlying Common Shares. The expected volatility is derived from comparable public companies as the Company did not have sufficient trading history for the Company's Common Shares. The change in fair value of warrant liability was $2,648 for the year ended April 30, 2025, which is included in other expense within the consolidated statements of operations and comprehensive loss.

The following table presents the significant inputs and assumptions used in the Black-Scholes option pricing model to determine the fair value of the warrant liabilities as of April 30, 2025:

	April 30, 2025
Strike price	$ 11.54
Expected term (in years)	8.42
Expected volatility	65.0%
Risk free rate	4.21%
Dividend yield	0.0%

A reconciliation of the Level 3 liabilities is as follows:

Fair value of warrant liabilities at issuance on March 7, 2025	$ 5,449
Change in fair value of warrant liabilities	2,648
Fair value of Level 3 liabilities as of April 30, 2025	$ 8,097

9. Common Shares

The Company had 100,000,000 Common Shares authorized and 51,348,656 Common Shares issued and outstanding with a par value of $1.00 as of April 30, 2025. Each Common Share is entitled to one vote. The Company had 5,000,000 shares of common stock authorized and 105,808 shares issued and outstanding with a par value of $0.01 as of April 30, 2024. Each share of common stock was entitled to one vote. Contributions are recorded to additional paid-in capital.

10. Redeemable Preferred Stock

In May 2022, Intermediate Holdings amended and restated its Memorandum and Articles of Association, according to which Intermediate Holdings' existing share capital of 5,000,000 shares can upon the discretion of Intermediate Holdings be issued in the form of either common and/or preferred stock with a par value of $0.01 each.

For the years ended April 30, 2025 and 2024, Intermediate Holdings issued to West Affum LP a total of 103,400 and 75,000 shares of preferred stock for proceeds of $103,400 and $75,000, respectively. Following the Organizational Transactions, pre-existing interests in Intermediate Holdings, as well as non-controlling interests of its subsidiaries, were exchanged into Common Shares. Kestra Medical Technologies, Ltd. now directly owns 100% of Intermediate Holdings and indirectly owns 100% of each of Intermediate Holdings' direct and indirect subsidiaries. There were no shares of preferred stock outstanding as of April 30, 2025. Outstanding preferred stock was $177,110 as of April 30, 2024.

Preferred stock issued is considered non-voting and is subject to a preferred dividend accrued daily with a set payment "yield" capped at 4.7% for issuances prior to April 30, 2023 and at 6.0% for issuances on or after May 1, 2023. No dividends were declared as of the year ended April 30, 2025 or 2024. Cumulative unpaid dividends were factored into the value of the preferred stock when exchanged for Common Shares of Kestra Medical Technologies, Ltd. in connection with the Organizational Transactions.

11. Non-Controlling Interest

In July 2024, West Affum Holdings Designated Activity Company (the "DAC"), a subsidiary of the Company, received a $17,100 investment from a third party (the "Investor") in exchange for shares. The DAC sold the Investor 171 Class A redeemable ordinary shares ("Class A Redeemable Ordinary Shares") of the DAC at a price per share equal to $100,000 for an aggregate cash purchase price of $17,100. Concurrently with the execution and delivery of the agreement governing the Investor's investment into DAC, Intermediate Holdings entered into an agreement with the Investor and West Affum LP wherein, at the discretion of the Investor, the DAC's Class A Redeemable Ordinary

Shares held by the Investor can be exchanged into common stock of Intermediate Holdings, and subsequently exchanged into Class A Common Units of West Affum LP. The exchange ratio is calculated based on the DAC price per share of $100,000 and the Class A Common Unit price of $14.67 as of July 2024 which allows the Investor to exchange 171 DAC Class A Redeemable Ordinary Shares into 1,165,644.17 Class A Common Units of West Affum LP.

In connection with the IPO, all Class A Redeemable Ordinary Shares were exchanged for common stock of Intermediate Holdings, which common stock were exchanged for common units of West Affum LP immediately after. West Affum LP contributed all of its Intermediate Holdings common stock to Kestra Medical Technologies, Ltd. for its Common Shares.

12. Equity Incentive Plan

Incentive Units

Prior to the IPO, certain employees and contractors of Intermediate Holdings were granted Incentive Units of West Affum LP. The Incentive Units allow the holder to participate in the equity of West Affum LP subject to participation thresholds as defined by West Affum LP. Upon termination of employment or services, West Affum LP has the right but not the obligation to repurchase vested Incentive Units at fair market value within seven months following termination.

Incentive Units vest based on continued service on a straight-line basis over the applicable service periods. Any unvested Incentive Units are automatically forfeited upon a separation. Incentive Units do not expire and have no exercise price. Compensation cost of Incentive Units is estimated on the date of grant.

As of April 30, 2024, total Incentive Units vested were 1,262,180 and total Incentive Units unvested were 867,963. Also as of April 30, 2024, unrecognized compensation cost for outstanding Incentive Units was $3,389, with the weighted-average period over which this cost is expected to be recognized at 3.18 years.

In connection with the IPO, vesting was accelerated for all unvested Incentive Units and all Incentive Units were exchanged into Common Shares of Kestra Medical Technologies, Ltd. The Company recorded $2,783 in share-based compensation related to the acceleration of the vesting of the unvested Incentive Units. The following table summarizes Incentive Units activity:

	Incentive Units
Outstanding at April 30, 2023	2,087,651
Granted	141,800
Forfeited / repurchased	(99,308)
Outstanding at April 30, 2024	2,130,143
Granted	1,192,999
Forfeited / repurchased	(192,405)
Exchanged into Common Shares	(3,130,737)
Outstanding at April 30, 2025	—

The weighted average grant date fair value of Incentive Units outstanding as of April 30, 2024 was $5.65 per share.

Restricted Common Units and Restricted Class A Common Units

Certain directors and advisors of the Company were granted 17,149 shares of restricted common units of West Affum LP between September 1, 2022 and October 16, 2024, with a vesting period of 3 years. As of April 30, 2025, 8,575 and 8,575 restricted common units were vested and unvested, respectively. As of April 30, 2024, 2,858 and 14,291 restricted common units were vested and unvested, respectively.

Certain directors and advisors of the Company were granted 35,787 shares of restricted Class A Common Units of West Affum LP between July 24, 2024 and November 3, 2024, with a vesting period of 3 years. In connection with the IPO, Class A Common Units were automatically exchanged into restricted Common Shares of Kestra Medical Technologies, Ltd., subject to continued vesting under the directors' original grant agreements. After the acceleration of 12,994 Class A Common Units in connection with the IPO, as of April 30, 2025, there were 32,485 shares of unvested restricted Common Shares outstanding.

Share-based compensation expense associated with restricted common units and restricted Common Shares is immaterial and recorded within selling, general and administrative expense.

Stock Options and Restricted Stock Units

In connection with the IPO, the Company entered into the 2025 Omnibus Incentive Plan to grant eligible individuals incentive equity awards, including stock options ("Stock Options"), in order to attract, retain and reward such individuals and strengthen the mutuality of interests between such individuals and Kestra Medical Technologies, Ltd.'s shareholders. The Company has granted 4,658,300 Stock Options to directors, active employees, and former employees since the IPO date. The Board of Directors determines the terms and conditions of the Stock Options, including the number of Stock Options to be granted and vesting criteria at the time of grant. The terms of each Stock Option are stated in the agreements. As of April 30, 2025, total vested Stock Options were 1,658,100. None of the vested Stock Options are exercisable due to the lock-up agreements which will expire in September 2025, thus, no Stock Options are exercised as of April 30, 2025.

Stock Options activity for the year ended April 30, 2025 is as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Balance at April 30, 2024	**—**	$ —	**—**	$ —
Options granted	4,658,300	17.04		
Options forfeited	(9,200)	17.00		
Balance at April 30, 2025	**4,649,100**	**17.04**	**9.85**	**32,640**
Options vested at April 30, 2025	1,658,100	17.07	9.85	11,600
Options exercisable at April 30, 2025	—	$ —	—	$ —

Also as of April 30, 2025, unrecognized compensation cost for outstanding Stock Options was $28,293, with the weighted-average period over which this cost is expected to be recognized at 1.77 years. The aggregate intrinsic value of Stock Options is calculated as the difference between the exercise price of the Stock Options and the fair value of the Company's Common Shares for those Stock Options that had exercise prices lower than the fair value of the Company's Common Shares.

The weighted average grant date fair value of Stock Options outstanding as of April 30, 2025 was $10.20 per share.

The 2025 Omnibus Incentive Plan also allows for the grants of restricted shares and restricted stock units. No Restricted Common Shares or restricted stock units have been granted through April 30, 2025, except as described under "*—Restricted Common Units and Restricted Class A Common Units*."

Share-Based Compensation

The Company recorded share-based compensation in the following expense categories of its consolidated statements of operations and comprehensive loss:

	Year Ended April 30,	
	2025	2024
Research and development	$ 1,964	$ 174
Selling, general and administrative	22,307	1,314
Total share-based compensation expense	$ 24,271	$ 1,488

In determining the compensation cost of the Incentive Units, the fair value for each Incentive Unit has been estimated at the date of grant using the Black-Scholes or probability-weighted expected return method ("PWERM") models.

For Incentive Units, the Company's PWERM approach estimated its enterprise value. This method considered various exit scenarios including an initial public offering, or staying private, and assigned a probability weight to each scenario. Using the PWERM, the enterprise value under each potential exit scenario and the timing of each scenario were weighted based on the estimated probability of occurrence for such scenario. The Company's equity values under the initial public offering scenarios were each estimated using the market approach based on the valuation of comparable public companies.

There is no intrinsic value or exercise price associated with these Incentive Units as they are participation units rather than options. The weighted average significant assumptions used in calculating the value of the Incentive Units were summarized as follows:

	April 30, 2024
Expected volatility	90.0%
Expected term	1.5 years
Risk free rate	4.04%
Dividend yield	0.0%
Estimated fair value	$ 5.27

The Company used Black-Scholes model to value Stock Options as the Company's Common Stock is traded in the public markets. The volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have sufficient trading history for the Company's Common Shares. The expected time to liquidity is based on the midpoint of the option vesting term and the contractual term. The Company will continue to analyze the expected volatility and expected term assumptions as additional data for the Company's Common Share becomes available. The risk-free interest rate assumption is based on the U.S. Constant Maturity Treasury rates, interpolated for the expected term of the Company's Stock Options. The dividend yield assumption is based on the Company's history and expectation of no dividend payouts. The weighted average significant assumptions used in calculating the value of the Stock Options were summarized as follows:

	April 30, 2025
Expected volatility	65.0%
Expected term	5.41 years
Risk free rate	4.04%
Dividend yield	0.0%

13. Income Taxes

The components of net loss before provision for income taxes are as follows:

	April 30,	
	2025	2024
U.S. operations	$ (105,417)	$ (75,374)
Foreign operations	(8,262)	(18,722)
Net loss before provision for income taxes	$ (113,679)	$ (94,096)

Prior to the consummation of the IPO, the Company's business was conducted through Intermediate Holdings and its consolidated subsidiaries. As a result of the Organizational Transactions effected in connection with the IPO, Kestra Medical Technologies, Ltd. became the top holding company, and operates and controls all of the business and affairs and consolidates the financial results of Intermediate Holdings. Kestra Medical Technologies, Ltd. is based in Bermuda and is a resident of Ireland for tax purposes. The Company has subsidiaries in the Cayman Islands, Ireland and the U.S. Under the current laws of Bermuda and the Cayman Islands, the Company is not subject to tax on income. However, the Company and its subsidiaries are subject to taxation in Ireland, the U.S. federal government, and various states. The Company accounts for the provision for income taxes in accordance

with ASC 740, Income Taxes, which requires an estimate of the annual effective tax rate for the full year to be applied to the interim period, taking into account year-to-date amounts and projected results for the full year.

Due to the current year restructuring effectuated in connection with its IPO, the Company's effective tax rate varies from the statutory Irish tax rate due to the effect of U.S. federal income taxes, state income taxes and research and development credits. The Company's effective tax rate could fluctuate from quarter to quarter based on variations in the estimated and actual level of pre-tax income or loss by jurisdiction, changes in enacted tax laws and regulations, and changes in estimates regarding the realizability of deferred tax assets. As of April 30, 2025 and 2024, the Company provided a full valuation allowance against its net deferred tax assets that are not more likely than not to be realized based on the weight of available evidence.

For purposes of the reconciliation between the provision (benefit) for income taxes at the statutory rate and the effective tax rate, an Irish 25% rate is applied to pretax income as a result of the following for the year ended April 30, 2025. The U.S. statutory rate of 21% was used for the period ending April 30, 2024 due to the Company's structure for that year:

	April 30,	
	2025	2024
Tax benefit at U.S. statutory rate	$ (28,420)	$ (19,760)
Non-taxable foreign income	4,719	(373)
State tax (net of federal tax benefit)	(4,110)	(2,325)
Non-deductible expenses	3,561	719
R&D credit (net of reserve)	(402)	(704)
Other	—	23
Change in valuation allowance	24,787	22,444
Provision for income taxes	$ 135	$ 24

Significant components of the deferred tax assets and liabilities are as follows:

	April 30,	
	2025	2024
Deferred tax assets		
Loss carryforwards	$ 52,281	$ 34,572
Interest carryforward	7,211	5,786
Accrued liabilities	4,553	2,261
Operating lease liability	539	354
Disposable medical equipment supplies	224	161
U.S. research and development credits	5,517	5,116
Intangible asset	35,375	35,375
Share-based compensation	4,998	—
Total deferred tax assets	$ 110,698	$ 83,625
Less: valuation allowance for deferred tax assets	(103,815)	(79,028)
Net deferred tax assets	$ 6,883	$ 4,597
Deferred tax liabilities		
Property and equipment	$ (6,233)	$ (4,161)
Prepaid expenses	(533)	(228)
Right-of-use assets	(257)	(284)
Total deferred tax liabilities	$ (7,023)	$ (4,673)
Net deferred tax liabilities	$ (140)	$ (76)

The Company does not accrue a deferred tax liability on stock basis of its subsidiaries since the tax basis exceeds the book basis. There are no unremitted foreign earnings.

Utilization of some of the federal and state net operating losses and credit carryforwards may be subject to annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986 ("Internal Revenue Code") and similar state provisions. The Tax Reform Act of 1986 limits the use of net operating loss and tax credit

carryforwards in certain situations where changes occur in the stock ownership of a company. A study has not yet been performed. If there was an ownership change, there could be an annual limitation that may result in the expiration of net operating losses and credits before utilization.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, carry back opportunities and tax planning strategies in making the assessment. The Company believes it is more likely than not it will not realize the benefits of these deductible differences and has applied a full valuation allowance against them.

Net operating losses and tax credit carryforwards as of April 30, 2025 are as follows:

	2025	Expiration Years
Net operating losses, federal	$ 201,189	Indefinite
Net operating losses, state	110,475	Various
Tax credits, federal	6,336	2039 - 2043
Net operating losses, foreign	34,307	Indefinite

The Company determines whether a tax position is more likely than not to be sustained upon examination based on the technical merits of the position in accordance with ASC 740. For tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant taxing authority.

The following table summarized the activity related to unrecognized tax benefits for the years ended:

	April 30,	
	2025	2024
Unrecognized tax benefits at beginning of year	$ (774)	$ (696)
Additions based on tax positions taken in the current year	(45)	(78)
Additions based on tax positions taken in the prior year	—	—
Decreases based on tax positions taken in prior years	—	—
Unrecognized tax benefits at end of year	$ (819)	$ (774)

All of the unrecognized tax benefits as of April 30, 2025 are accounted for as a reduction in deferred tax assets. Due to the valuation allowance, none of the $(819) of unrecognized tax benefits would affect the effective tax rate, if recognized. The Company does not believe it is reasonably possible that the unrecognized tax benefits will significantly change in the next twelve months. The Company recognizes interest and penalties related to unrecognized tax benefits as income tax expense. There were no accrued interest or penalties related to unrecognized tax benefits for the year ended April 30, 2025 or April 30, 2024. The Company does not expect any significant change in the unrecognized tax benefits during the next twelve months.

The Company files Irish, U.S. federal and U.S. state income tax returns. The Company is not currently under examination but is open to audit by the I.R.S. and state tax authorities for tax years beginning in 2019. The resolutions of any examinations are not expected to be material to these financial statements. As of April 30, 2025, there are no penalties or accrued interest recorded in the financial statements.

On July 4, 2025, the One Big Beautiful Bill Act (2025 US tax reform) was enacted into law. The 2025 US tax reform contains several key tax laws, including extensions and modifications of the Tax Cuts and Jobs Act. In accordance with Accounting Standards Codification (ASC) 740, Income Taxes, the Company is required to recognize the effect of the tax law changes in the period of enactment, such as remeasuring the estimated U.S. deferred tax assets and liabilities. The Company is in the process of assessing the impacts from the 2025 US tax reform.

14. Commitments and Contingencies

From time to time, the Company may become involved in litigation relating to claims arising from the ordinary course of business. The Company considers the likelihood of loss or impairment of an asset, or the incurrence of a liability, as well as the ability to reasonably estimate the amount of loss, in determining loss contingencies. An estimated loss contingency is accrued when information available prior to issuance of the consolidated financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the consolidated financial statements, and the amount or range of loss can be reasonably estimated. Legal costs are expensed as incurred. Gain contingencies are not recognized until they are realized or realizable.

The Company enters into indemnification agreements with its officers and directors, and the Company's certificate of incorporation and bylaws include similar indemnification obligations to its officers and directors. To date, there have been no claims under any indemnification provisions, therefore there is no accrual of such amounts as of April 30, 2025 and 2024. The Company is unable to determine the maximum potential impact of these indemnifications on the future results of operations.

Management believes that there are currently no other claims or actions pending against the Company where the ultimate disposition could have a material effect on the Company's results of operations, financial condition or cash flows.

15. Defined Contribution Plan

The Company sponsors a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code of 1986, as amended (the "401(k) Plan"), for its full-time employees, which covers all eligible employees in the United States. The 401(k) Plan provides for matching and discretionary contributions by the Company. For the years ended April 30, 2025 and 2024, matching and discretionary contributions by the Company totaled $1,660 and $1,345, respectively.

16. Net Loss Per Share Attributable to Common Shareholders

The Organizational Transactions represent a business combination between entities under common control under the principles of ASC Topic 805, *Business Combinations*. In connection with the Organizational Transactions, West Affum LP contributed its 105,808 shares of common stock in Intermediate Holdings for 19,885,382 Common Shares of Kestra Medical Technologies, Ltd. ("Exchange"). Under the principles of ASC 260, *Earnings Per Share*, the Exchange was applied retrospectively for purposes of calculating basic and diluted net loss per share. Other transactions that closed contemporaneously with the Organizational Transactions, including conversions of preferred stock, non-controlling interests, and equity awards were accounted for prospectively beginning on the date such transactions occurred, and were not given retrospective treatment as they changed the relative subordination characteristics of the securities owned by the respective holders after the effective date of the Organizational Transactions. Similarly, the shares issued upon the IPO and exercise of the underwriters' overallotment option were accounted for prospectively beginning on the date such shares were issued and were not given retrospective treatment. The total number of outstanding shares disclosed on the face of the audited consolidated balance sheets and audited consolidated statements of changes in redeemable preferred stock and shareholders' equity (deficit) represents the number of shares legally outstanding as of the latest audited consolidated balance sheet date. This differs from the number of outstanding shares disclosed for basic and diluted net loss per share, which has been retrospectively adjusted for common shares outstanding but not yet vested.

Basic net loss per share attributable to common shareholders is calculated by dividing net loss by the weighted average number of Common Shares outstanding during the period and excludes any dilutive effects of employee share-based awards and warrants. Diluted net loss per share attributable to common shareholders is computed giving effect to all potentially dilutive common shares, including common shares issuable upon vesting of share-based payment awards and/or upon exercise of the warrants. For the years ended April 30, 2025 or 2024, the Company did not have any dilutive shares. For both periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

Potentially anti-dilutive shares excluded from the calculation of diluted net loss per share for the year ended April 30, 2025 include 4,649,100, 434,916, and 32,485 shares of common shares underlying stock options, warrants,

and restricted stock, respectively. Potentially anti-dilutive shares excluded from the calculation of diluted net loss per share for the year ended April 30, 2024 include 23,899 shares of restricted stock.

The following table sets forth the computation of basic and diluted net loss per share attributable to common shareholders for the years ended April 30, 2025 and 2024:

	Year Ended April 30,	
	2025	**2024**
Numerator:		
Net loss attributable to Kestra Medical Technologies, Ltd.	$ (113,814)	$ (94,120)
Undeclared preferred dividends	(12,321)	(6,721)
Net loss attributable to common shareholders	$ (126,135)	$ (100,841)
Denominator:		
Weighted average shares of common share outstanding – basic and diluted	24,583,745	19,885,382
Net loss per share attributable to common shareholders		
– basic and diluted	$ (5.13)	$ (5.07)

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