# 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, 2026**

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

The aggregate market value of the Registrant's Common Shares held by non-affiliates, based upon the closing price of the Common Shares on October 31, 2025, as reported by the Nasdaq Stock Market LLC, was approximately $618.7 million. Common Shares held by each executive officer and director and by each person who is deemed to be an affiliate of the Registrant have been excluded from such computation. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the Registrant's Common Shares outstanding as of July 9, 2026 was 58,602,497.

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 2026, 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 ("Annual Report") 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. We caution you that the foregoing list does not contain all of the forward-looking statements made in this Annual Report.

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, 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.

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.

**Trademarks and Service Marks**

ASSURE, CARDIAC RECOVERY SYSTEM, KESTRA, KESTRA CARESTATION and ASSURE ASSIST and other trademarks and service marks appearing in this Annual Report are the property of the Company. This Annual Report also contains trade names, trademarks and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this Annual Report may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names.

## 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 2026 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.

## 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;

- we are actively expanding our sales force and customer service resources, and if we are unable to effectively manage this growth, including hiring, training and retaining qualified personnel and scaling our commercial operations, our business, operating results and prospects could be adversely affected;

- 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;

- 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;

- 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;

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

## 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 through connected monitoring, therapeutic intervention, and data-driven clinical insights. We have developed and are commercializing the Cardiac Recovery System platform, an integrated cardiac recovery ecosystem designed to support patients at elevated risk of sudden cardiac arrest ("SCA") during vulnerable periods of recovery.

Our Cardiac Recovery System platform is anchored by the ASSURE® Wearable Cardioverter Defibrillator ("WCD"), which continuously monitors patient heart rhythms and automatically delivers defibrillation therapy when life-threatening ventricular arrhythmias are detected. The platform also includes digital patient engagement and clinical workflow solutions designed to improve patient adherence, support care coordination, and provide actionable clinical insights throughout the recovery process.

We believe the ASSURE WCD is differentiated by its patient-centered design, including comfort, wearability, and low false alarm rates, which are intended to improve patient compliance during extended wear periods. In addition, our integrated platform generates continuous cardiac rhythm data and clinically actionable insights that may assist healthcare providers in managing patients during vulnerable recovery periods. We believe these capabilities position Kestra to participate in the growing cardiac recovery market and support future platform expansion opportunities. As of April 30, 2026, our ASSURE WCD has protected nearly 40,000 patients since commercial launch.

### Market Overview and Opportunity

There are three primary types of defibrillators used to treat life-threatening ventricular arrhythmias: implantable cardioverter defibrillators ("ICDs"), external defibrillators, and wearable cardioverter defibrillators ("WCDs"). ICDs are permanently implanted devices intended for long-term protection, while external defibrillators are typically used in acute emergency settings and require intervention by another individual. WCDs provide continuous, non-invasive protection during temporary periods of elevated sudden cardiac arrest risk.

Many patients recovering from recent myocardial infarction, newly diagnosed cardiomyopathy, or other cardiac events are not immediate candidates for ICD implantation due to clinical guidelines, reimbursement requirements, or the need for optimization of guideline-directed medical therapy. During this recovery period, patients may remain at meaningful risk for life-threatening arrhythmias.

We believe WCD therapy plays an important role during this vulnerable interval by providing continuous protection while supporting clinical decision-making throughout the recovery process. We further believe the combination of therapy delivery, patient engagement, and clinically actionable cardiac insights positions our Cardiac Recovery System platform to address an important unmet need in cardiac recovery management. The expected wear duration of the WCD varies based on the patient indication, with most patients being prescribed the WCD for three months or longer.

#### *Limitations of Other Commercially Available WCDs*

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 other commercially available WCDs, 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.

#### *Our Market Opportunity*

Since the approval of the first WCD in 2001, global WCD revenues have grown significantly, reaching approximately $1.1 billion in 2025, with over 80% of the revenues coming from the United States. Based on our commercial results and publicly reported financial data from our competitor, we estimate the WCD market grew in the low to mid-teens in 2025, an acceleration from high single digit growth in recent years. We expect that growth to continue, driven by increased awareness and education about WCD therapy, a growing body of clinical evidence, and the rapidly growing heart failure population. Despite being available for over 25

years and proven effective in treating dangerous cardiac rhythms when worn by patients, WCD therapy reached just 16% of eligible U.S. patients in 2025, highlighting a significant opportunity for growth. We attribute this low penetration to poor patient compliance, driven by the limitations of our leading 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 other commercially available WCDs.

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 left ventricular ejection fraction ("LVEF") and a recent myocardial infarction (MI), recent revascularization procedure or newly diagnosed nonischemic cardiomyopathy with heart failure symptoms. In addition, patients with documented ventricular tachycardia ("VT") or ventricular fibrillation ("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 Americal Heart Association ("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 $3,589 per patient per month, 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., 18% of global WCD revenues in 2025 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. as of 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 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.

**Our Solution**

***Our Product***

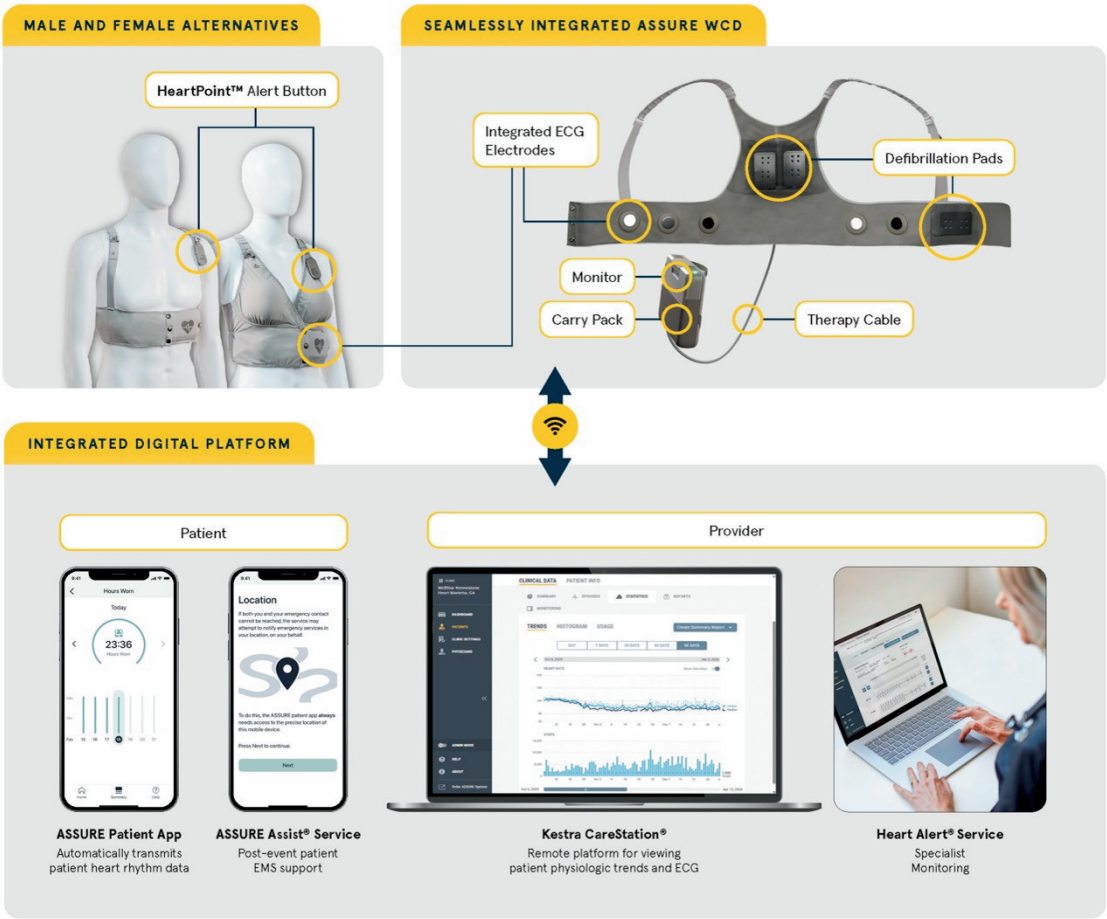
The ASSURE WCD serves as the foundation our Cardiac Recovery System platform, which pairs proven protection with clinically informed insights to support patients throughout the recovery journey. The ASSURE WCD automatically monitors elevated risk patients and, if needed, delivers a defibrillation shock to return the patient's heart to normal rhythm. It was purpose-built to enhance patient comfort and compliance and directly address the key barriers to adoption associated with the other commercially available WCDs. 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.

***Our Platform***

Building on this foundation, the Cardiac Recovery System platform includes a suite of digital and clinical support solutions designed to provide a more connected approach to patient management. Integrated solutions—including the ASSURE patient application, Kestra CareStation® remote patient management platform, Heart Alert Services, and ASSURE Assist®—provide clinicians with greater visibility into patient status and support informed care decisions.

The ASSURE patient application engages patients through real-time mobile connectivity and facilitates communication between patients and healthcare providers. The Kestra CareStation remote patient management platform equips providers with alert-based notifications and patient data that may support timely clinical decision-making. Heart Alert Services and ASSURE Assist work together to enhance patient safety by notifying healthcare providers of significant arrhythmias and facilitating emergency response when therapy is delivered. ASSURE Assist is designed to notify emergency services when a therapeutic shock is administered, helping to support timely post-event care.

In April 2026, we announced the release of the Enhanced ASSURE Detection Algorithm, a software enhancement to the ASSURE WCD that incorporates insights derived from the ASSURE WCD Clinical Evaluation Post-Approval Study ("ACE-PAS") registry dataset. The Enhanced ASSURE Detection Algorithm was designed to further improve rhythm discrimination and reduce unnecessary alarms while maintaining the device's ability to identify and treat life-threatening ventricular arrhythmias. The graphic below provides an overview of the integrated components of our Cardiac Recovery System platform and how they support patients and healthcare providers:




***Key Benefits of Our Solution***

We believe 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 Sensorfit 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 (“ACE-PAS”) which demonstrate a median wear time of greater than 23 hours per day. In addition to improving comfort and wearability, our unique Sensorfit 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. Reduction in false alarms may lead to lower patient anxiety, improved patient satisfaction and increased patient compliance. 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. Primary results from ACE-PAS, announced in November 2025, which enrolled 21,612 patients across the United States, reported a low false alarm rate with only 6% of our patients experiencing a false alarm. The latest updates to the ASSURE WCD include the Enhanced ASSURE Detection Algorithm, whose projected impact is estimated to result in only 3% of ASSURE patients experiencing a false alarm. This compares to 46% of patients experiencing a false alarm for the leading competitor's device, as reported in the Journal of Interventional Cardiac Electrophysiology Study.

- ***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 leading 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 who experience multiple cardiac events within a short period of time, such as a VT storm—a condition characterized by repeated episodes of sustained VT requiring intervention.

***Our Product Portfolio***

In addition to our commercialized products, we continue to invest in expanding our offerings and product portfolio. For example, in January 2026, we announced a strategic collaboration with Biobeat Technologies ("Biobeat"), which has developed the only clinically validated, FDA-cleared cuffless, patch-worn ambulatory blood pressure monitoring ("ABPM") device. The device leverages photoplethysmography-based sensing to deliver continuous, noninvasive blood pressure measurement over a 24-hour period for hypertension diagnosis and management in the outpatient cardiac recovery setting. We intend to integrate Biobeat's technology into its product portfolio to make ABPM data available for patients prescribed the ASSURE WCD.

**Our Strategy**

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

- Large, growing, and underpenetrated WCD market;

- Highly innovative Cardiac Recovery System platform designed to protect patients from SCA and improve patient compliance and healthcare provider adoption;

- Comprehensive and fully integrated suite of mission critical digital solutions and services for driving patient and healthcare provider engagement;

- Material investments in infrastructure to support rapid growth and scale;

- Established reimbursement and favorable payor coverage;

- Strong and compelling body of clinical evidence;

- Broad research and development capabilities and a robust intellectual property portfolio; and

- Highly experienced management team and board with proven commercial growth success.

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.;
- Expand adoption of our Cardiac Recovery System platform in the U.S. to increase the penetration of the U.S. total addressable WCD market;
- Build upon our strong base of clinical evidence;
- Continue our payor engagement to broaden coverage and increase reimbursement;
- Innovate our system and bolster our digital healthcare platform and data management capabilities;
- Drive gross profit expansion and operating leverage;
- Pursue expansion in international markets; and
- Strategically pursue adjacent markets with new products offerings and differentiated services.

**Clinical Trials**

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, with 10 publications completed to date. We believe our ongoing clinical initiatives will further validate the benefits of our system and may support stronger guideline recommendations for WCD therapy.

Preclinical and human clinical safety and effectiveness data provided the basis for PMA approval of the ASSURE WCD in July 2021. That 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. Our ASSURE Patient Registry continues to serve as a cornerstone for generating real-world evidence on our ASSURE WCD's performance. All patients prescribed the ASSURE WCD in the U.S. after August 5, 2022 are included in the Registry. As of April 30, 2026, our ongoing registry has enrolled approximately 40,000 patients.

Most recently, we announced the primary results of primary results from the ASSURE WCD Clinical Evaluation Post-Approval Study ("ACE-PAS") in November 2025, which underscored the ASSURE WCD's competitive advantages in wearability, usability, and patient compliance, providing strong support for continued adoption. ACE-PAS has been the largest prospective real-world study of wearable defibrillators to date. Key outcomes from ACE-PAS include 100% successful conversion rate for VT and VF events and an inappropriate-shock rate of 0.0065 per patient-month, with only 6% of our patients experiencing a false alarm, compared to 46% for our leading competitor's device. Among 16,441 patients who completed wear at data cut-off, median daily use was more than 23 hours per day, with one third of patients in the study continuing use beyond 90 days. The study also revealed that 2.6% of patients experienced at least one life-threatening VT or VF event within only a few months of being prescribed the ASSURE WCD, highlighting the need for the product. The ASSURE system facilitated the detection of high-rate atrial fibrillation in 4.2% of patients (35% previously undiagnosed) and severe bradycardia or asystole in 0.3% of patients, enabling the potential for more timely intervention.

**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 290 million lives as of April 30, 2026. 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. Code K0606 falls under the Capped Rental monthly reimbursement rate for lease payments. K0606 is an active 2026 HCPCS code defined as an automated external defibrillator, with integrated ECG analysis, garment type. The Medicare allowable for code K0606 is approximately $3,589 per month for months one to three and reduces 25% to $2,692 for months four to thirteen published in the CMS DMEPOS Fee Schedule in January 2026, while the maximum Medicare allowable over the course of their lease is approximately $37,683. 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 consistent, favorable trends, with published Medicare reimbursement rates having increased at a CAGR of over 2.5% from 2016 to 2026.

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 future international expansion.

**Sales and Marketing**

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 130 direct sales representatives as well as more than 40 sales and clinical support professionals as of April 30, 2026. 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 500 Assure Patient Specialists ("APS") 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.

We have initially focused on establishing key customer accounts and expansion into high WCD-volume areas. Our commercial team has been successful at driving adoption of the ASSURE WCD with hospitals ranging from top academic medical centers to community hospitals, and we plan to continue to further scale our commercial team to reach a wider range of healthcare providers across the entire U.S. Long term, we plan to expand internationally, and we believe 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, 2026, 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.

**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. In addition, in January 2026, we announced a strategic collaboration with Biobeat Technologies, which has developed the only clinically validated, FDA-cleared cuffless, patch-worn ABPM device. The device leverages photoplethysmography-based sensing to deliver continuous, noninvasive blood pressure measurement over a 24-hour period for hypertension diagnosis and management in the outpatient cardiac recovery setting. We intend to integrate Biobeat's technology into its product portfolio to make ABPM data available for patients prescribed the ASSURE WCD.

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.

**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 of 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 20 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**

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, which is marketed by ZOLL Medical, a wholly owned subsidiary of Asahi Kasei Corporation. In May 2025, a new market entrant received FDA approval for an adhesive-based external defibrillator.

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 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.

We believe 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. However, our competitors, current and future, may have greater financial and personnel resources than we have and may have advantages over us in any of the aforementioned factors. For a discussion of risks related to our competition, see 'Item 1A. Risk Factors – *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*."

**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, 2026, we have rights to 264 issued U.S. and foreign patents, consisting of 229 issued patents in the U.S., 17 issued patents in the European Union, 8 issued patents in Japan, 5 issued patents in Australia and 5 issued patents in China. Additionally, as of April 30, 2026, we had 125 pending published and unpublished U.S. and foreign patent applications, consisting of 114 pending published and unpublished patent applications in the U.S., 5 pending published patent applications in the European Union, 2 pending published patent applications in Japan, 1 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 February 2031.

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, KESTRA CARESTATION and ASSURE ASSIST to distinguish our products from the products of our competitors. We have registered or applied for each of these marks in the United States and, for certain markets, in 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 Quality System Regulation (“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 (“510(k)”) under Section 510(k) of the FDCA or approval of a premarket approval application (“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 clearance 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 an 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 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, which may include 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 submission of a PMA application, the FDA conducts an initial filing review to determine whether the application is sufficiently complete to permit substantive review. If the application is accepted for filing, the FDA's review goal under the FDCA is 180 days; however, actual review timelines are typically longer and may extend well beyond this timeframe depending on the complexity of the application, the need for Advisory Committee input, and the number and scope of FDA information requests. During the review process, the FDA frequently issues requests for additional information or clarification (e.g., deficiency letters), and the sponsor's responses to these requests can significantly impact the overall review timeline. 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 QSR. PMA applications are also subject to the payment of user fees, which for 2026 includes a standard application fee of $579,272.

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 in July 2021. Most recently, we announced results from the post-approval clinical study of the ASSURE WCD in November 2025, and we 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.

Advertising and promotion of medical devices is regulated by the FDA, as well as the Federal Trade Commission depending on the type of device and by state regulatory and enforcement authorities. Promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. Furthermore, under the federal U.S. Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

***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 ("ACA"). Specifically, under the Anti-Kickback Statute, the government must prove the defendant acted "knowingly" to prove a violation occurred. The ACA 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 ACA 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 was fully implemented on January 1, 2025 and regulates how any organization in Bermuda may use personal information through 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 and Cost Containment Measures***

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, 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. Since its enactment, there have been numerous judicial, administrative, executive and legislative challenges to certain aspects of the ACA. For example, various portions of the ACA have faced legal and constitutional challenges, including in the United States Supreme Court; the Trump administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress introduced several pieces of legislation aimed at significantly revising or repealing the ACA. While the ACA remains in effect, it continues to be subject to modification through legislative, regulatory and administrative actions, the impact of which on our business cannot be predicted.

Other legislative changes have been proposed and adopted since the ACA was enacted, include the Budget Control Act of 2011, which among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 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. In January 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.

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.

**Team Members and Human Capital Resources**

As of April 30, 2026, we had over 443 full time team members, substantially all of which are located in the U.S. 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, equity compensation awards, including performance-based equity, 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 through connected monitoring, therapeutic intervention, and data-driven clinical insights. 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, and therefore do not have a long history operating as a commercial 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 primary competitor 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, and developing and maintaining 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 our markets and new markets we may enter into. We are continuing to invest in and grow our 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. We may not be able to do this 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.

***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. More recently, we have also incurred expenses relating to operating as a public company. We had net losses of $131.6 million and $113.8 million for the fiscal years ended April 30, 2026 and 2025, respectively, and as of April 30, 2026, we had an accumulated deficit of $651.9 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 and potential partnerships 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.

While we believe that our existing cash, cash equivalents and investments 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. Fundraising efforts can divert

management from their day-to-day activities, which may adversely affect our ability to further commercialize our ASSURE WCD and otherwise grow our business. 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 by leasing 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 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 requires 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 ASSURE 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 U.S., 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 U.S., 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 among 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 U.S. 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.

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

Macroeconomic conditions, such as inflationary pressure, changes to monetary policy, fluctuations in 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 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. 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. 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.

We may at times experience supply chain constraints, including difficulties obtaining a sufficient supply or increased prices of component materials used in our products, due to macroeconomic factors. 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.

***We are actively expanding our sales force and customer service resources, and if we are unable to effectively manage this growth, including hiring, training and retaining qualified personnel and scaling our commercial operations, our business, operating results and prospects could be adversely affected.***

As we continue to commercialize our ASSURE WCD, we are expanding the size and geographic scope of our sales, marketing, and clinical support and customer service organizations in order to develop broad brand awareness and increase market penetration. Our commercial team is comprised of approximately 130 direct sales representatives as well as more than 40 sales and clinical support professionals as of April 30, 2026, up from 80 direct sales representatives and 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 500 APSs as of April 30, 2026 who assist patients with fitting and training, up from 300 APSs as of April 30, 2025.

Our continued growth requires us to recruit, hire, onboard, train, manage and retain a significant number of qualified sales, clinical and customer service personnel. In particular, there is significant competition for qualified and experienced sales force personnel, as well as healthcare personnel with the relevant technical and clinical expertise 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 requires significant time, expense and management attention. New hires and newly contracted APSs require substantial training and time before achieving desired productivity levels, developing customer relationships and completing patient fittings at the levels of quality and efficiency we expect.

As we continue to expand our commercial organization, we expect to incur substantial costs, including increased compensation, commissions, benefits, training and support expenses. We have in the past entered, and expect to continue 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. If we are unable to effectively manage the growth of our commercial operations, successfully integrate and train new personnel, or achieve anticipated productivity and revenue growth from these investments, our business and operating results could be adversely affected.

This growth may also cause operational and managerial challenges, including maintaining consistent sales practices, customer support quality, compliance oversight and coordination across geographies. Management will need to spend additional time and attention recruiting and integrating additional employees. Rapid expansion in personnel could also result in less experienced people marketing and offering 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. 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.

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.

We also utilize, and may in the future further utilize, third parties to support certain sales, billing, collections, marketing, patient support and distribution activities. For example, we have executed a distribution agreement with a DME supplier to facilitate billing and collections relating to the utilization of ASSURE WCD. We may have limited control over the performance of such third parties, and they may fail to devote sufficient resources or attention to supporting ASSURE WCD effectively. If we are unable to expand and manage our sales and customer service capabilities successfully, either on our own or in collaboration with third parties, 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.

***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 we can experience issues that may lead to production or service delays or shortfalls, 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 we continue to scale our commercial operations, we have and may in the future experience issues that can lead to 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
- our ability to attract, hire, train and retain qualified personnel in order to scale our services.

In addition to the above factors, 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 there are delays with our third party providers, 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. 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.

***Our continued growth depends on our ability to successfully scale manufacturing, service, quality assurance and other operational capabilities, and failure to do so could adversely impact our business.***

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.

***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 can 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 or other health crises;
- 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 a material adverse effect on our business, financial condition, results of operations and prospects. 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.

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.

***If our suppliers' manufacturing facilities or our research and development facilities are damaged, inoperable, or otherwise unavailable, we could experience manufacturing disruptions, delays in research and development activities, increased costs, and adverse effects on our business and 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 natural disasters or 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 results of operations. 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 our existing products and other products we are developing. Additionally, it may be costly and time-consuming to repair or replace the facilities and 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. This in particular 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 can 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, due to trade restrictions or otherwise, 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.

***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. There is no assurance of whether we will be able to complete patient enrollment for any clinical trials and delays in completing patient enrollment may result in increased costs or affect the timing or outcome of our 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 U.S., 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 ("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.

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

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 primary 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 this 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, as any perception of our involvement could dilute, tarnish or otherwise adversely affect our reputation and brand.

The availability 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. Information on these platforms may be inaccurate, and 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.

The revenue we can generate from the lease of our ASSURE WCD depends in large part on the availability of reimbursement from third-party payors, namely Medicare, Medicaid and private 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 involves 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 payors 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.

***We are subject to audits, investigations and recoupment actions by governmental and commercial payors, which could adversely affect our business, financial condition and results of operations.***

Federal and state governmental agencies and commercial payors conduct audits, investigations and other reviews to identify potential overpayments and other perceived irregularities in claims submitted to government healthcare programs and private payors. These activities may include reviews conducted by Recovery Audit Contractors (responsible for auditing Medicare claims), Unified Program Integrity Contractors (responsible for the identification of suspected fraud through medical record review), and Medicaid Integrity Contractors (responsible for auditing Medicaid claims). We are regularly subject to audits, inquiries, and investigations from these and other contractors from time to time in the ordinary course of our business and may become subject to increased scrutiny from governmental agencies and commercial payors in the future.

Responding to and defending against audits, investigations and similar inquiries may require substantial management time and attention, result in significant legal and administrative costs, and divert resources from the operation of our business. Moreover, an adverse determination resulting from an audit or investigation could damage our reputation and result in repayment obligations, claim denials, fines, penalties, and other sanctions. Public disclosure of audits, investigations or enforcement actions also could adversely affect our reputation and business.

Documentation and medical necessity requirements applicable to reimbursement claims are complex, frequently changing and often subject to varying interpretation by governmental agencies, contractors and commercial payors. In many instances, there are limited publicly-available guidelines or methodologies for determining error rates or evaluating compliance with documentation standards. For example, certain CMS guidance manuals, local coverage determinations, and the Durable Medical Equipment Medicare Administrative Contractor ("DME MAC") supplier guidance require clinical information contained in a patient's medical record to support medical necessity determinations for DMEPOS claims. Some contractors and payors have interpreted these requirements to mean that documentation maintained by treating healthcare providers, rather than documentation generated by suppliers, must support reimbursement claims. As a result, our ability to successfully defend claims may depend in part on the adequacy, completeness and timely availability of records maintained by third-party healthcare providers over whom we have limited control.

If treating healthcare providers fail to maintain sufficient supporting documentation, or if governmental agencies or commercial payors disagree with our interpretation of applicable requirements, we may experience increased claim denials, repayment obligations, audits or enforcement activity. In addition, auditors and payors may apply inconsistent interpretations of applicable policies, which may contribute to increased perceived error rates and additional audit activity across our industry. Any requirement to repay amounts previously reimbursed, or any significant increase in denied claims, audit activity or compliance obligations, could adversely affect our revenue, cash flows, financial condition and results of operations.

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 predict the scope, frequency or outcome of any future audits, investigations or reimbursement disputes, and any adverse outcome could materially adversely affect our business, financial condition and results of operations.

***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. Prior to our entrance, the WCD market had been served by a single incumbent commercial product, the LifeVest WCD, marketed by ZOLL Medical, a wholly-owned subsidiary of Asahi Kasei Corporation, our primary competitor. In May 2025, a new market entrant also obtained FDA approval for an adhesive-based external defibrillator. As we continue to scale our business, competitors 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 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. These 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 are no longer indicated for a WCD but who still require ongoing support. 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, 2026, 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 "2024 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. On July 10, 2026, we entered into the Loan Agreement, dated as of July 10, 2026 (as may be further amended from time to time, the "Term Loan"), with BPCR Limited Partnership and BioPharma Credit Investments V (Master) LP, as lenders, BioPharma Credit PLC, as collateral agent, Kestra Medical Technologies, Inc., as borrower, and the guarantors party thereto. In connection with entering the Term Loan, the 2024 Term Loan was paid off and terminated and our obligations thereunder were discharged.

We must make significant quarterly interest payments under the Term Loan, 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, incur additional indebtedness, incur liens, pay dividends and other restricted payments, and enter into mergers and similar transactions, 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. Additionally, there are certain non-financial covenants. See Note 7, "*Long-Term Debt*" and Note 17, "*Subsequent Event*" 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.

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 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 a material adverse effect on our business, financial condition, results of operations and prospects. Cybersecurity incidents affecting our information technology systems, or those of our vendors or partners, including ransomware, malware, phishing, distributed denial-of-service attacks, credential compromise, unauthorized access, software vulnerabilities, insider threats and other malicious or accidental acts, 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, have been and will continue to be vulnerable to malicious cyber activity 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.

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 compromise 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.

***Product liability claims, misuse or off-label use of our products, or allegations that we improperly promoted off-label uses could result in litigation, regulatory enforcement actions, reputational harm, and increased costs.***

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 are misused, we may become subject to costly litigation initiated by healthcare providers, the hospitals and clinics where healthcare providers who prescribe 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;
- increased regulatory scrutiny or enforcement actions;
- 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 or invest in 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. For example, in January 2026, we announced an exclusive license and co-development arrangement with and investment in Biobeat Technologies. Potential and completed acquisitions, strategic investments, licenses and other partnerships 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 and other investment opportunities 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 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 or investing in 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 a target 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.

***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 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.***

We have identified material weaknesses in our internal control over financial reporting, and we may identify additional material weaknesses in the future. If we are unable to remediate these material weaknesses, or if we otherwise 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 adversely affect our business and the value of our common shares.

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. Based on our assessment, we concluded that our internal control over financial reporting was not effective as of April 30, 2026 due to the material weaknesses described below.

- 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 the Company's consolidated financial statements for the year ended April 30, 2021.

- 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.

- 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 professionals, 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 continue to evaluate current and projected resource needs on a regular basis, hire additional qualified resources as needed and have engaged third parties and other professionals to assist with the resolution of IT general controls and governance processes. 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. 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.

***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 identified material weaknesses in our internal control over financial reporting in previous years; remediation of these material weaknesses is ongoing. More information relating to these material weaknesses is detailed in the risk factor above. 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 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" or "smaller reporting 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.

***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, among 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.

***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 will 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 to maintaining compliance with these requirements and the additional reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. Changing 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. 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 securities or industry analysts do not continue publishing 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, our business, or our competitors. We do not have any control over these analysts or the contents and opinions in their reports. A number of securities and industry analysts currently publish research and reports about our company, but we may not continue to receive adequate research coverage. If one or more analysts who cover us 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, publish unfavorable commentary about us or our industry, or if our results of operations do not meet their expectations, our share price could decline. Additionally, if analysts' expectations regarding our financial performance, operating results or business prospects differ from our actual results, our common share price could experience increased volatility.

**Risks Related to Our Tax Structure and Taxation**

***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, liabilities, and taxes which could adversely affect our business, financial condition, results of operations and prospects.***

We engage independent contractors in certain aspects of our operations for whom we do not pay or withhold any federal, state or other employment tax. The legal standards governing worker classification are complex, fact-specific, and subject to evolving federal, state and foreign laws, regulations, agency guidance, and judicial interpretations. 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. In some instances, reclassification of independent contractors as employees may also result in liability for unpaid wages, overtime, employment taxes, penalties, workers' compensation premiums and other liabilities.

***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 Columbia;
- an 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.

**Risks Related to 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. A summary of our intellectual property portfolio is in the section entitled "*Business—Intellectual Property.*" However, legal measures cannot assure full protection. The process of applying for and obtaining a patent is also 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 any existing or future products, components we may pursue in the future. 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 countries outside the United States is 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 such as 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. The use of remote working arrangements, collaboration technologies, digital communications and third-party hosted systems can increase the risk of unauthorized access, disclosure or misuse of confidential information and trade secrets. Additionally, the use of generative artificial intelligence tools may also increase the risk of inadvertent disclosure of proprietary information.

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, but 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 matters are generally governed by 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, CARDIAC RECOVERY SYSTEM, 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 and we may, at times, 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 U.S. 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, regulations or evolving judicial interpretations relating to patent eligibility, patent scope, patent enforcement or remedies may impact our ability to obtain maintain or enforce 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. The Leahy-Smith America Invents Act enacted in September 2011 (the "Leahy-Smith Act") implemented significant changes to U.S. patent law, including changes affecting patent prosecution, post-grant proceedings and patent enforcement. The USPTO has developed and continues to develop regulations and procedures to govern administration of the Leahy-Smith Act, and courts continue to interpret its provisions. As a result, the Leahy-Smith Act and related development may increase the costs, uncertainties and complexities associated with the prosecution, enforcement and defense of our patents and patent applications, 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, certain of our European patents may be subject to the jurisdiction of the European United Patent Court ("UPC"). Because the UPC is relatively new, there remains uncertainty regarding its procedures, the scope of patent rights and remedies available through the UPC and how the UPC will interpret and enforce patent rights.

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 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. In some cases, we may only be able to patent 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, and a competitor or other third party may review our published patent filings and arrive at the same or similar technology advances for our assets as we developed. If another party 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 that party, 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 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, and subsequent legislation have resulted in ongoing reductions to Medicare payments to providers and suppliers, and these reductions could continue to apply unless modified or suspended by future legislation. 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. In June 2024, the U.S. Supreme Court issued its decision in *Loper Bright Enterprises v. Raimondo* (the "Loper decision"), overturning the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision has resulted, and may continue to 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 other federal and foreign regulatory agencies. Any such legal challenges or resulting changes in agency interpretations, guidance or rulemaking could materially affect our business operations and regulatory compliance obligations.

***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. 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, among 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 adversely 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. 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 planning to pursue CE Mark approval in Europe in the future and intend to strategically commercialize in selected international markets. We anticipate Western Europe to be our initial focus and our goal is to obtain regulatory approvals to begin distributing our ASSURE WCD in certain markets in Western Europe. There is no assurance of when we will successfully obtain the CE Mark, if at all. In addition, regulatory requirements for medical devices in the United Kingdom and the European Union have diverged following the United Kingdom's exit from the European Union, which may require additional time and resources to obtain and maintain relevant approvals. 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.

The Affordable Care Act and related healthcare reform measures have been subject to legislative, regulatory and judicial challenges, and there continue to be ongoing efforts to modify or repeal all or certain provisions of the Affordable Care Act. 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. Changes in the priorities of presidential administrations, Congress, CMS, HHS, the FDA and other governmental authorities may result in changes to the healthcare and regulatory landscape. Congress and other government authorities have and may in the future consider reductions in healthcare spending or other cost-containment measures affecting government healthcare programs. 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. As our business evolves and expands geographically and operationally, we are periodically subject to new, revised or additional licensing, certification and enrollment requirements. 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 have implemented compliance controls, monitoring processes and personnel dedicated to maintaining required licenses, 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. We maintain DME accreditation and Medicare DMEPOS supplier enrollment, each of which is subject to ongoing compliance obligations, periodic review, renewal and potential reinspection. 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 condition.

***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. If an open source software component that is important in our products becomes unavailable, unsupported, subject to unfavorable licensing changes, or otherwise infeasible for our use, we may be required to replace such component with alternative software. Identifying, validating and implementing a replacement could be costly and divert management and engineering resources.

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.

***We are subject to increasingly stringent, 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 ability to market our products, as well as our overall business and prospects.***

The regulatory landscape for medical device cybersecurity is rapidly evolving. For example, in February 2026, the FDA issued updated guidance, "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions," which sets stricter requirements for device design, labeling, and documentation. Failure to align our platform, products, and features with the latest FDA cybersecurity standards, including requirements for a robust Software Bill of Materials (SBOM) and coordinated vulnerability disclosure (CVD) programs, could result in delays in regulatory clearances, enforcement actions, or a loss of competitive advantage.

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.

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"), as amended by the California Privacy Rights Act ("CPRA"), imposes obligations relating to the collection, processing and sharing of personal information and provides for civil penalties and a private right of action in certain circumstances. In addition, the My Health My Data Act of 2023 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 privacy and data protection laws, such as the General Data Protection Regulation, will 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.

**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 43% of our common shares and controls approximately 43% of the voting power represented by our outstanding common shares, as of April 30, 2026. This 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 Bain Charger 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 shareholder 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 any 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.

***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, 2026, approximately 39.3 million of our common shares are held by our directors, executive officers and other affiliates, approximately 25.2 million shares of which are held by Bain Capital. If Bain Capital 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, under the Exchange

Control Act 1972 and related regulations, the Bermuda Monetary Authority permits 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, including the Nasdaq Global Select Market, where we are listed. The general permission is conditioned on our continued listing 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.

**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 13 years of experience leading information security functions, including over eight 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, 2026, our properties included:

- 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.

- 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.

- 221 E Southlake Blvd, Southlake, TX: 350 square feet of general and administrative office space. The lease term will expire on May 31, 2027, and we may extend the term of the lease or move to a different leased premise.

- 28 Fitzwilliam Place, Dublin 2, Ireland: 300 square feet of general and administrative office space. The lease will expire on July 31, 2026, 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 9, 2026, there were 276 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 through connected monitoring, therapeutic intervention, and data-driven clinical insights. We have developed and are commercializing the Cardiac Recovery System platform, an integrated cardiac recovery ecosystem designed to support patients at elevated risk of SCA during vulnerable periods of recovery. Our Cardiac Recovery System platform is anchored by the ASSURE® WCD, which continuously monitors patient heart rhythms and automatically delivers defibrillation therapy when life-threatening ventricular arrhythmias are detected. The platform also includes digital patient engagement and clinical workflow solutions designed to improve patient adherence, support care coordination, and provide actionable clinical insights throughout the recovery process. We believe the ASSURE WCD is differentiated by its patient-centered design, including comfort, wearability, and low false alarm rates, which are intended to improve patient compliance during extended wear periods. In addition, our integrated platform generates continuous cardiac rhythm data and clinically actionable insights that may assist healthcare providers in managing patients during vulnerable recovery periods. We believe these capabilities position Kestra to participate in the growing cardiac recovery market and support future platform expansion opportunities.

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. 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. 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 $131.6 million and $113.8 million for the fiscal years ended April 30, 2026 and 2025, respectively. For the fiscal year ended April 30, 2026, we generated revenue of $95.1 million, with a gross profit of $48.9 million, compared to revenue of $59.8 million, with a gross profit of $24.2 million, for the fiscal year ended April 30, 2025. As of April 30, 2026 , we had cash, cash equivalents, and investments of $262.2 million. As of April 30, 2025, we had cash and cash equivalents of $237.6 million. As of April 30, 2026 and 2025, we had an accumulated deficit of $651.9 million and $520.2 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). 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.

In December 2025, we completed a public underwritten offering and issued an aggregate of 6,900,000 Common Shares at a price of $23.00 per share, resulting in net proceeds of $149.3 million, after deducting underwriting discounts but before expenses. The aggregate number of Common Shares offered pursuant to the public offering included 900,000 Common Shares issued pursuant to the exercise in full of the underwriters' option to purchase additional shares.

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, cash equivalents, investments, 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 30, 2026, we had approximately 130 territories in the United States compared to 80 as of April 30, 2025. 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 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 consists 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 loan as well as interest received from various interest-bearing bank accounts and marketable securities. The non-cash component consists of interest expense recognized from the amortization of debt discounts, debt issuance costs, and warrant fair value adjustments.

***Provision for Income Taxes***

To date, we have recorded a limited amount of United States federal and state income tax expense. As of April 30, 2026, significant deferred tax assets include net operating loss carryforwards of $81.0 million, intangible assets of $35.4 million, interest carryforwards of $6.7 million, United States research and development credits of $5.9 million, and share-based compensation expense of $6.2 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 our deferred tax assets.

**Results of Operations**

The following tables set forth our results of operations for the fiscal years ended April 30, 2026 and 2025. We have derived the data for the fiscal years ended April 30, 2026 and 2025 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.

| | Year Ended April 30, | | | |
|---|---|---|---|---|
| **(in thousands)** | **2026** | **2025** | **$ Change** | **% Change** |
| Revenue | $ 95,126 | $ 59,815 | $ 35,311 | 59% |
| Cost of revenue | 46,263 | 35,605 | 10,658 | 30% |
| Gross profit | 48,863 | 24,210 | 24,653 | 102% |
| Operating expenses: | | | | |
| Research and development | 19,484 | 15,652 | 3,832 | 24% |
| Selling, general and administrative | 164,120 | 114,936 | 49,184 | 43% |
| Total operating expenses | 183,604 | 130,588 | 53,016 | 41% |
| Loss from operations | (134,741) | (106,378) | (28,363) | 27% |
| Other expense (income): | | | | |
| Interest expense | 7,546 | 7,734 | (188) | (2%) |
| Interest income | (8,351) | (3,199) | (5,152) | 161% |
| Other expense (income) | (2,618) | 2,766 | (5,384) | NM |
| Net loss before provision for income taxes | (131,318) | (113,679) | (17,639) | 16% |
| Provision for income taxes | 294 | 135 | 159 | 118% |
| Net loss | (131,612) | (113,814) | (17,798) | 16% |
| Less: Undeclared preferred stock dividends | — | 12,321 | (12,321) | (100%) |
| Net loss attributable to common shareholders, basic and diluted | $ (131,612) | $ (126,135) | $ (5,477) | 4% |

NM = Percentage not meaningful

***Comparison of the Fiscal Years Ended April 30, 2026 and 2025***

***Revenue***

Revenue increased by $35.3 million, or 59%, to $95.1 million for the fiscal year ended April 30, 2026, from $59.8 million for the fiscal year ended April 30, 2025, primarily driven by a 58% increase in the number of patients using our product.

***Cost of Revenue***

Cost of revenue increased by $10.7 million, or 30%, to $46.3 million for the fiscal year ended April 30, 2026, from $35.6 million for the fiscal year ended April 30, 2025. The increase in cost of revenue was primarily driven by an increase of $7.7 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, a $1.8 million increase in depreciation expense due to an increased number of systems and equipment in use, and an increase of $1.5 million in our reserve for lost or damaged equipment, partially offset by a $1.1 million decrease in depreciation expense due to the changes in useful life of our components.

***Gross Profit***

Gross profit increased by $24.7 million to $48.9 million for the fiscal year ended April 30, 2026, from $24.2 million for the fiscal year ended April 30, 2025. 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. The increase in gross profit was also driven by a decrease in cost of revenues per patient by 18% for the fiscal year ended April 30, 2026 compared to the fiscal year ended April 30, 2025, due to further improvements in the utilization of our rental pool of medical equipment and lower disposable costs driven by volume and implementation of manufacturing cost improvement programs, and longer useful lives of our medical rental equipment.

***Research and Development Expenses***

Research and development costs for the year ended April 30, 2026 increased by $3.8 million, or 24%, to $19.5 million from $15.7 million for the fiscal year ended April 30, 2025. The increase was primarily driven by a $2.4 million increase in personnel expenses such as salaries, benefits and share-based compensation expense, and a $1.4 million increase in contractor costs.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses increased by $49.2 million, or 43%, to $164.1 million for the fiscal year ended April 30, 2026, from $114.9 million for the fiscal year ended April 30, 2025. The increase was primarily driven by a $33.2 million increase in personnel expenses such as salaries, benefits and share-based compensation, resulting from an increase in headcount to support commercial growth, a $0.9 million increase in professional service fees, and insurance related to our transition to a public company, a $3.5 million increase in travel and entertainment expenses due to an increase in headcount, a $3.2 million increase in commercial support costs including contractors and external recruitment costs, a $2.1 million increase in commercial training costs, a $2.0 million increase related to shipping and logistics costs, a $1.7 million increase related to increased software licensing fees driven by increased headcount, a $0.9 million increase related to conference fees, and $1.4 million increase in other costs.

***Interest and Other Expense (Income)***

Interest expense was largely flat in the fiscal year ended April 30, 2026 compared to the prior year.

Interest income increased by $5.2 million, or 161%, to $8.4 million for the fiscal year ended April 30, 2026, from $3.2 million for the fiscal year ended April 30, 2025, primarily due to higher cash and investment balances following the IPO and secondary offering.

Other expense (income) for the year ended April 30, 2026 increased by $5.4 million compared to the year ended April 30, 2025. The increase was primarily due to the remeasurement of the warrant liability.

***Provision for Income Taxes***

For each of the fiscal years ended April 30, 2026 and 2025, the tax provision was less than $0.3 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 was $131.6 million and $113.8 million for the fiscal years ended April 30, 2026, and 2025, respectively. As of April 30, 2026, we had an accumulated deficit of $651.9 million. For the fiscal years ended April 30, 2026, and 2025, we generated negative operating cash flows of $81.7 million and $77.6 million, respectively.

On December 4, 2025, we completed a public underwritten offering and issued an aggregate of 6,900,000 Common Shares at a price of $23.00 per share, resulting in net proceeds of $149.3 million, after deducting underwriting discounts but before expenses. The aggregate number of Common Shares offered pursuant to the public offering included 900,000 Common Shares issued pursuant to the exercise in full of the underwriters' option to purchase additional shares.

As of April 30, 2026, our principal sources of liquidity consisted of $262.2 million of cash, cash equivalents, and investments. As of April 30, 2025, our principal sources of liquidity consisted of $237.6 million of cash and cash equivalents. Based on our current operating plan, we believe that our existing cash, cash equivalents, and investments, which includes the net proceeds from our IPO and follow on offering, 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, and investments, 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 our revenues. We expect the proceeds from our IPO and secondary offering, 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, 2026, the outstanding principal amount under the Term Loan 2024 was approximately $45.0 million. 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, 2026, we had cash, cash equivalents, and investments of $262.2 million and an accumulated deficit of $651.9 million.

On December 4, 2025, we completed a public underwritten offering and issued an aggregate of 6,900,000 Common Shares at a price of $23.00 per share, resulting in net proceeds of $149.3 million, after deducting underwriting discounts but before expenses. The aggregate number of Common Shares offered pursuant to the public offering included 900,000 Common Shares issued pursuant to the exercise in full of the underwriters' option to purchase additional shares.

In May and July of 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 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"). 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 would have become available before November 1, 2024 and February 1, 2025, 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 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 entered into the Second Amendment to Credit Agreement and Guaranty, by and among Kestra Medical Technologies, Inc., the Company, the guarantors party thereto, the lenders party thereto and Perceptive Credit Holdings IV, LP, as administrative agent (the "Second Amendment to Credit Agreement") which amended the Term Loan 2024 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 (the "2033 Warrant") to purchase up to 325,847 of our common shares with an exercise price of $11.54 per share. On September 4, 2025, Perceptive Credit Holdings IV, LP fully exercised the 2033 Warrant to purchase Common Shares on a cashless basis, resulting in the issuance of 100,397 Common Shares and the cancellation of the 2033 Warrant.

On July 10, 2026, Kestra Medical Technologies, Inc. and other credit parties thereto, entered into a Loan Agreement with BPCR Limited Partnership and BioPharma Credit Investments V (Master) LP, as lenders, and BioPharma Credit PLC, as collateral agent. The Loan Agreement provides for a five-year senior secured term loan facility of up to $200.0 million, divided into four tranches: (i) a committed Tranche A Loan in an aggregate principal amount of $75.0 million (the "Tranche A Loan") which was funded on July 10, 2026 (the "Tranche A Closing Date"); (ii) a committed Tranche B Loan in an aggregate principal of $25.0 million (the "Tranche B Loan") which may be requested, subject to certain limited conditions, at our option through July 31, 2027; (iii) a committed Tranche C Loan in an aggregate principal amount of $50.0 million (the "Tranche C Loan") which is available to us upon reaching a trailing twelve-month revenue of $150.0 million and which may be requested on or prior to June 30, 2028 and (iv) an uncommitted Tranche D Loan for acquisitions at our option in aggregate principal amount of $50.0 million (the "Tranche D Loan" and collectively with the Tranche A Loan, the Tranche B Loan, and the Tranche C Loan, the "Term Loans"), subject to certain limited conditions and upon approval of the Lenders, on such date mutually agreed upon between us and the lenders.

Net proceeds from the Tranche A Loan were approximately 20.0 million, after deducting estimated debt issuance costs, fees and expenses, and repaying in full the obligations under Term Loan 2024 on July 10, 2026. The remaining proceeds will be used to fund our general corporate and working capital requirements.

For further information, see Note 7, "*Long-Term Debt,*" to our consolidated financial statements for the fiscal years ended April 30, 2026 and 2025 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:

| | Twelve Months Ended April 30, | |
|---|---|---|
| **(in thousands)** | **2026** | **2025** |
| Net cash used in operating activities | $ (81,703) | $ (77,608) |
| Net cash used in investing activities | (203,277) | (23,308) |
| Net cash provided by financing activities | 147,095 | 330,262 |
| Increase (decrease) in cash, cash equivalents and restricted cash | $ (137,885) | $ 229,346 |

*Cash Flows from Operating Activities*

For the fiscal year ended April 30, 2026, cash used in operating activities was $81.7 million, which primarily consisted of a net loss of $131.6 million and a net decrease of $1.8 million in operating assets and liabilities, offset by a net increase of $48.0 million in non-cash charges. The non-cash charges primarily consisted of share-based compensation expense of $33.6 million, depreciation and amortization of $8.7 million, loss on disposal of property and equipment of $1.2 million, non-cash lease expense of $0.3 million, amortization of debt discounts and issuance costs of $1.9 million, a change in fair value of warrant liability of $2.7 million, provision for uncollectible accounts receivable of $2.6 million. The net change in our operating assets and liabilities consisted of increases in accounts payable of $4.3 million, accrued liabilities of $8.2 million driven by increases in accrued compensation due to increased headcount and a reserve for claims repayments, and operating lease liabilities of $0.7 million, partially offset by increases in account receivables of $9.1 million, disposable medical equipment supplies of $0.5 million, and prepaid expenses and other current assets of $0.6 million.

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 $6.2 million in operating assets and liabilities, offset by a net increase of $42.4 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.

*Cash Flows from Investing Activities*

For the fiscal year ended April 30, 2026, cash used in investing activities was $203.3 million, which primarily consisted of $163.0 million in purchases of marketable securities, $5.0 million for the purchase of an equity security, $34.9 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, $0.5 million deposits paid for medical rental equipment and $0.2 million refund of deposits for medical rental equipment received.

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.

*Cash Flows from Financing Activities*

For the year ended April 30, 2026, cash provided by financing activities was $147.1 million, which primarily consisted of proceeds of $149.3 million from the secondary offering offset by $2.5 million of payments of equity offering costs and $0.6 million in proceeds from stock option exercises. The increase in cash provided by financing activities was partially offset by deemed dividend payments of $0.3 million.

For the fiscal year ended April 30, 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.

**Off-Balance Sheet Arrangements**

As of April 30, 2026, 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***

Our long-lived assets consist of property and equipment, which includes leasehold improvements and right-of-use assets. We do 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, we 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, 2026 and 2025.

***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 investment balances of $262.2 million as of April 30, 2026. The primary goals of our investment policy are liquidity and capital preservation. We do not enter into investments for trading or speculative purposes. The carrying amount of our cash equivalents reasonably approximates fair value, due to the short maturities of these instruments. Our investments are exposed to market risk due to a fluctuation in interest rates, which may affect the fair market value of our investments in marketable securities. As of April 30, 2026, the effect of a hypothetical 1.00% (100 basis point) change in interest rates would have changed the fair value of our marketable securities by $1.5 million. Such change would only be realized if we sold the marketable securities prior to maturity.

We also are subject to interest rate risk under the Term Loan. All amounts outstanding under the Term Loan bear interest as a variable rate per annum equal to 5.50% plus three-month Secured Overnight Financing Rate (“SOFR”) with a SOFR floor of 3.25%. 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.

***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 Ireland which are not insured. As of April 30, 2026, we maintained cash, cash equivalents and investments of $262.2 million. As of April 30, 2025, we maintained cash, cash equivalents and restricted cash balances of $237.6 million. Cash, cash equivalents and restricted cash balances as of April 30, 2026 and 2025 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, 2026, because of the material weaknesses in our internal control over financial reporting described below.

***Management's Report on Internal Control over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based upon criteria established in *Internal Control Integrated Framework* (2013) by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that our internal control over financial reporting was not effective as of April 30, 2026 due to the material weaknesses described below:

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. The material weaknesses are as follows:

- 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 the Company's consolidated financial statements for the year ended April 30, 2021.

- 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.

- 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.

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.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this Annual Report.

***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 professionals, 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 continue to evaluate current and projected resource needs on a regular basis, hire additional qualified resources as needed and have engaged third parties and other professionals to assist with the resolution of IT general controls and governance processes. 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.

***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, 2026 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 quarter ended April 30, 2026, 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 2026 Annual Meeting of Shareholders within 120 days after the end of the fiscal year ended April 30, 2026. 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 2026 Annual Meeting of Shareholders within 120 days after the end of the fiscal year ended April 30, 2026.

### 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 2026 Annual Meeting of Shareholders within 120 days after the end of the fiscal year ended April 30, 2026.

### 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 2026 Annual Meeting of Shareholders within 120 days after the end of the fiscal year ended April 30, 2026.

### 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 2026 Annual Meeting of Shareholders within 120 days after the end of the fiscal year ended April 30, 2026.

## 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 | Description of Share Capital (previously filed as Exhibit 4.4 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 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 + | Kestra Medical Technologies, Ltd. 2025 Employee Stock Purchase Plan (previously filed as Exhibit 10.1 to the Quarterly Report on Form 10-Q on March 17, 2026 and incorporated herein by reference). |
| 10.4* | Loan Agreement, dated as of July 10, 2026, between Kestra Medical Technologies, Inc. and the guarantors signatory therein, BioPharma Credit PLC, BPCR Limited Partnership, and BioPharma Credit Investments V (Master) LP. |
| 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 (previously filed as Exhibit 10.9 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 10.10+ | Amendment to Employment Agreement, dated as of June 4, 2025, by and between Kestra Medical Technologies, Inc. and Vaseem Mahboob (previously filed as Exhibit 10.10 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 10.11+ | Amendment to Employment Agreement, dated as of June 4, 2025, by and between Kestra Medical Technologies, Inc. and Traci S. Umberger (previously filed as Exhibit 10.11 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 10.12+ | Employment Agreement, dated as of June 4, 2025, by and between Kestra Medical Technologies, Inc. and Al Ford (previously filed as Exhibit 10.12 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 10.13+ | Employment Agreement, dated as of October 17, 2025, between Kestra Medical Technologies, Inc. and Timothy Moran (previously filed as Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on December 11, 2025 and incorporated herein by reference). |
| 10.14*+ | Kestra Medical Technologies, Ltd. Director Compensation Policy. |

| | |
|---|---|
| 10.15+ | Forms of Option Grant Notice 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). |
| 10.16+ | Form of Restricted Stock Unit Grant Notice and Award Agreement (Non-employee Directors) under the Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan (previously filed as Exhibit 10.13 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 10.17+ | Form of Restricted Stock Unit Grant Notice and Award Agreement (Executive Officers) under the Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan (previously filed as Exhibit 10.14 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 10.18+ | Form of Performance Stock Unit Grant Notice and Award Agreement (revenue PSU) under the Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan (previously filed as Exhibit 10.15 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 10.19+ | Form of Performance Stock Unit Grant Notice and Award Agreement (rTSR PSU) under the Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan (previously filed as Exhibit 10.16 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 19 | Insider Trading Policy of Kestra Medical Technologies, Ltd (previously filed as Exhibit 19 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 21 | List of Subsidiaries (previously filed as Exhibit 21 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 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 (previously filed as Exhibit 97 to the Annual Report on Form 10-K filed on July 17, 2025 and incorporated herein by reference). |
| 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 14, 2026 By: /s/ Brian Webster
Brian Webster
President and Chief Executive Officer

Date: July 14, 2026 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<br>Brian Webster | President and Chief Executive Officer, and Director<br>*(Principal Executive Officer)* | July 14, 2026 |
| /s/ Vaseem Mahboob<br>Vaseem Mahboob | Chief Financial Officer<br>*(Principal Financial and Accounting Officer)* | July 14, 2026 |
| /s/ Traci Umberger<br>Traci Umberger | General Counsel and CAO, and Director | July 14, 2026 |
| /s/ Jeff Schwartz<br>Jeff Schwartz | Chairman of the Board of Directors | July 14, 2026 |
| /s/ Raymond W. Cohen<br>Raymond W. Cohen | Director | July 14, 2026 |
| /s/ Mary Kay Ladone<br>Mary Kay Ladone | Director | July 14, 2026 |
| /s/ Kevin Reilly<br>Kevin Reilly | Director | July 14, 2026 |
| /s/ Conor Hanley<br>Conor Hanley | Director | July 14, 2026 |
| /s/ Elizabeth Kwo<br>Elizabeth Kwo | Director | July 14, 2026 |

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS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## 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, 2026 and 2025, 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, 2026 and 2025, 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 14, 2026

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, 2026 | April 30, 2025 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 99,710 | $ 237,595 |
| Short-term investments | 96,724 | — |
| Accounts receivable, net | 14,542 | 8,081 |
| Disposable medical equipment supplies | 6,706 | 6,572 |
| Prepaid expenses and other current assets | 4,677 | 3,080 |
| Total current assets | 222,359 | 255,328 |
| Long-term investments | 65,767 | — |
| Right-of-use assets | 3,364 | 2,078 |
| Deposits | 1,761 | 2,021 |
| Restricted cash | 334 | 334 |
| Property and equipment, net | 59,090 | 34,830 |
| Other long-term assets | 5,790 | 1,153 |
| Total assets | $ 358,465 | $ 295,744 |
| **Liabilities and Shareholders' Equity** | | |
| Current liabilities | | |
| Accounts payable | $ 27,295 | $ 23,961 |
| Accrued liabilities | 23,046 | 13,829 |
| Operating lease liabilities, current portion | 31 | 187 |
| Total current liabilities | 50,372 | 37,977 |
| Operating lease liabilities, net of current portion | 4,111 | 3,026 |
| Warrant liabilities | 1,369 | 8,097 |
| Other long-term liabilities | 306 | 140 |
| Long-term debt, net | 42,649 | 41,098 |
| Total liabilities | 98,807 | 90,338 |
| Commitments and contingencies (Note 14) | | |
| Shareholders' equity | | |
| Common Shares, $1.00 par value; 100,000,000 shares authorized as of April 30, 2026 and April 30, 2025; 58,383,924 issued and outstanding as of April 30, 2026 and 51,348,656 shares issued and outstanding as of April 30, 2025 | 58,384 | 51,349 |
| Additional paid-in capital | 853,353 | 674,306 |
| Accumulated other comprehensive loss | (218) | — |
| Accumulated deficit | (651,861) | (520,249) |
| Total shareholders' equity | 259,658 | 205,406 |
| Total liabilities and shareholders' equity | $ 358,465 | $ 295,744 |

*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, | |
|---|---|---|
| | **2026** | **2025** |
| Revenue | $ 95,126 | $ 59,815 |
| Cost of revenue | 46,263 | 35,605 |
| Gross profit | 48,863 | 24,210 |
| Operating expenses: | | |
| Research and development | 19,484 | 15,652 |
| Selling, general and administrative | 164,120 | 114,936 |
| Total operating expenses | 183,604 | 130,588 |
| Loss from operations | (134,741) | (106,378) |
| Other expense (income): | | |
| Interest expense | 7,546 | 7,734 |
| Interest income | (8,351) | (3,199) |
| Other expense (income) | (2,618) | 2,766 |
| Net loss before provision for income taxes | (131,318) | (113,679) |
| Provision for income taxes | 294 | 135 |
| Net loss | (131,612) | (113,814) |
| Less: Undeclared preferred stock dividends | — | 12,321 |
| Net loss attributable to common shareholders, basic and diluted | $ (131,612) | $ (126,135) |
| Net loss per share attributable to common shareholders, basic and diluted | $ (2.43) | $ (5.13) |
| Weighted-average shares of common shares outstanding, basic and diluted[1] | 54,184,698 | 24,583,745 |
| Other comprehensive loss: | | |
| Net loss | $ (131,612) | $ (113,814) |
| Unrealized loss on marketable securities | (218) | — |
| Comprehensive loss | $ (131,830) | $ (113,814) |

*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, 2024[2]** | 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 |

| | Common Shares | | Additional Paid-In Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Shareholders' Equity (Deficit) |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balances at April 30, 2025** | 51,348,656 | $ 51,349 | $ 674,306 | $ — | $ (520,249) | $ 205,406 |
| Share-based compensation expense | — | — | 33,644 | — | — | 33,644 |
| Issuance of common shares - exercise of warrant | 100,397 | 100 | 3,954 | — | — | 4,054 |
| Issuance of common shares - equity offering, net of underwriter discounts and issuance costs of $10,414 | 6,900,000 | 6,900 | 141,386 | — | — | 148,286 |
| Issuance of common shares - stock option exercises | 34,871 | 35 | 558 | — | — | 593 |
| Deemed dividend for payments to third party on behalf of shareholder | — | — | (495) | — | — | (495) |
| Other comprehensive loss | — | — | — | (218) | — | (218) |
| Net loss | — | — | — | — | (131,612) | (131,612) |
| **Balance at April 30, 2026** | 58,383,924 | $ 58,384 | $ 853,353 | $ (218) | $ (651,861) | $ 259,658 |

*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, | |
|---|---|---|
| | 2026 | 2025 |
| **Cash flows from operating activities** | | |
| Net loss | $ (131,612) | $ (113,814) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 8,709 | 7,968 |
| Loss on disposal of property and equipment | 1,161 | 1,340 |
| Reserve for equipment and supplies | 2,435 | 754 |
| Provision for uncollectible accounts receivable | 2,596 | 2,694 |
| Amortization (accretion) of premiums (discounts) on securities, net | (106) | — |
| Interest paid-in-kind | — | 855 |
| Amortization of debt discounts and issuance costs | 1,874 | 1,400 |
| Share-based compensation expense | 33,644 | 24,270 |
| Non-cash lease expense | 326 | 416 |
| Deferred income tax expense | 166 | 64 |
| Change in fair value of warrant liabilities | (2,673) | 2,648 |
| Changes in operating assets and liabilities: | | |
| Disposable medical equipment supplies | (458) | (3,443) |
| Prepaid expenses and other current assets | (563) | (1,852) |
| Accounts receivable | (9,056) | (8,777) |
| Accounts payable | 4,302 | 2,842 |
| Accrued liabilities | 8,197 | 4,617 |
| Operating lease liabilities | (685) | 370 |
| Other long-term assets | 40 | 40 |
| Net cash used in operating activities | (81,703) | (77,608) |
| **Cash flows from investing activities** | | |
| Purchases of property and equipment | (34,892) | (22,936) |
| Deposits for medical rental equipment | (528) | (655) |
| Refund of deposits for medical rental equipment | 184 | 283 |
| Investment in equity security | (5,000) | — |
| Purchase of marketable securities | (163,041) | — |
| Net cash used in investing activities | (203,277) | (23,308) |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of redeemable preferred stock | — | 103,400 |
| Proceeds from issuance of common stock | 149,291 | 215,789 |
| Proceeds from issuance of stock to non-controlling interest | — | 17,100 |
| Proceeds from capital contributions | — | 2,374 |
| Payment of IPO offering costs | — | (3,523) |
| Payment of equity issuance costs | (2,466) | (3,224) |
| Deemed dividend for payments to third party on behalf of shareholder | (323) | (1,654) |
| Proceeds from stock option exercises | 593 | - |
| Net cash provided by financing activities | 147,095 | 330,262 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | (137,885) | 229,346 |
| **Cash, cash equivalents and restricted cash** | | |
| Beginning of period | 237,929 | 8,583 |
| End of period | $ 100,044 | $ 237,929 |
| **Reconciliation of cash, cash equivalents and restricted cash reported in the consolidated balance sheets** | | |
| Cash and cash equivalents | $ 99,710 | $ 237,595 |
| Restricted cash | 334 | 334 |
| Cash, cash equivalents and restricted cash | $ 100,044 | $ 237,929 |
| **Non-cash investing and financing activities:** | | |
| Purchases of property and equipment in accrued liabilities and accounts payable | $ 8,314 | $ 7,029 |
| Exercise of liability classified warrant | 4,055 | — |
| Remeasurement of lease liability | 1,614 | — |
| Equity offering costs incurred but not yet paid | 415 | 1,875 |
| Deemed dividend for payments to third party on behalf of shareholder included in accrued liabilities and accounts payable | 172 | — |
| 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 | $ 13 | $ 83 |
| Interest paid | 5,645 | 4,851 |

*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 (“WCD”), 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. Effective on December 31, 2025, West Affum LP was dissolved and all of the Common Shares it had received at IPO were distributed to its unit holders.

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 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, 2026, the Company’s principal sources of liquidity consisted of $262,201 of cash, cash equivalents, and investments.

The Company has incurred negative operating cash flows and significant losses from operations since its inception. For the years ended April 30, 2026 and 2025, the Company incurred net losses of $131,612 and $113,814, respectively. Cash used in operating activities was $81,703 and $77,608 for the years ended April 30, 2026 and 2025, respectively. As of April 30, 2026, the Company had an accumulated deficit of $651,861.

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.

On December 4, 2025, the Company completed a public underwritten offering and issued an aggregate of 6,900,000 Common Shares at a price of $23.00 per share, resulting in net proceeds to the Company of $149,291, after deducting underwriting discounts but before expenses paid by the Company. The aggregate number of Common Shares offered in the public offering included 900,000 Common Shares issued pursuant to the exercise in full of the underwriters' option to purchase additional shares.

Based on the Company's current operating plan, the Company believes that its existing cash, cash equivalents, and investments 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.

## 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 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, 2026 and 2025. The Company also had restricted cash of $225 for credit card collateralization as of April 30, 2026 and 2025.

### *Investments*

The Company considers investments with an original maturity greater than three months and remaining maturities less than 12 months to be short-term investments. The Company classifies those investments that are not required for use in current operations and that mature in more than 12 months as long-term investments.

The Company classifies its marketable securities as available for sale and reports them at fair value, with unrealized gains and losses recorded in accumulated other comprehensive income (loss). For investments sold prior to maturity, the cost of investments sold is based on the specific identification method. Realized gains and losses on the sale of investments are recorded in other income (expense), net in the consolidated statement of operations.

If the estimated fair value of a marketable debt security is below its amortized cost basis, the Company evaluates whether it is more likely than not that the Company will be required to sell the security before its anticipated recovery in market value and whether credit losses exist for the related securities. Credit-related losses are recognized as an allowance for credit losses on the balance sheet with a corresponding adjustment to earnings. Unrealized gains and losses that are unrelated to credit deterioration are reported in accumulated other comprehensive income (loss).

The Company invests in equity securities that do not have readily determinable fair values. Equity investments that do not have readily determinable fair values are measured using the measurement alternative at cost minus impairment, if any. These investments are included in Other long-term assets on the consolidated balance sheet as of April 30, 2026. The carrying amount of this investment is $5,000 and there were no adjustments to the carrying amount during the year ended April 30, 2026.

***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).

***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. The 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 $5,789 and $3,193 as of April 30, 2026 and 2025, 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 a therapy cable, batteries, a battery charger, assistant and WCD monitor, 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 re-certified 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, 2026 | April 30, 2025 |
|---|---|---|
| **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 - 15 years | 2 - 8 years |

During the year ended April 30, 2026, the estimated useful life of the medical rental equipment asset class was changed prospectively from 2 - 8 years to 2 - 15 years. This change was the result of actual field experience, established preventive maintenance programs, and an extensive engineering study completed during the period relating to the WCD monitor and battery charger. As a result, the useful life of the battery charger was changed from five years to fifteen years and the useful life of the WCD monitor was changed from seven years to fifteen years. The impact of the change was a reduction of depreciation expense, which is included within cost of revenue, by $1,410 in the year ended April 30, 2026, as compared to the useful life of medical rental equipment had it remained at 2 - 8 years. The net loss per share impact of the change is not material.

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, 2026 and 2025.

***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 Other expense (income) line item of the consolidated statements of operations and comprehensive loss during the years ended April 30, 2026 and 2025.

***Revenue***

The Company generates revenue from the leases of ASSURE© System, which consists of a WCD 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.

***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 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, 2026 and 2025, the Company paid administrative costs to third parties on behalf of one of its shareholders. 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 Ireland, 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 expenses, and selling, general and administrative expenses, which are each separately presented on the Company's Consolidated Statements of Operations and Comprehensive Loss.

***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 year ended April 30, 2026, unrealized losses on marketable securities were included as a component of comprehensive loss. For the year ended April 30, 2025, 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 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 Company adopted ASU 2023-09 prospectively during the year ended April 30, 2026. The adoption of the amendments in ASU 2023-09 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 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 reporting 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.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets ("ASU 2025-05")*, requiring election of a practical expedient when estimating expected credit losses for current accounts receivable and current contract assets. ASU 2025-05 is effective for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. Early adoption is permitted in both interim and annual reporting periods. The Company is evaluating the impact that this ASU will have on its financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software* ("ASU 2025-06"), modernizing the accounting framework for internal-use software by eliminating the prior stage-based model and introducing a principles-based capitalization threshold. ASU 2025-06 is effective for fiscal years beginning after December 15, 2027, and interim periods within those annual reporting periods, with early adoption permitted. The Company is evaluating the impact that this ASU will have on its financial statements and related 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, 2026 | April 30, 2025 |
|---|---|---|
| Prepaid software fees | $ 1,693 | $ 1,387 |
| Other current assets | 2,984 | 1,693 |
| Total Prepaid expenses and other current assets | $ 4,677 | $ 3,080 |

**4. Property and Equipment**

Property and equipment consisted of the following at:

| | April 30, 2026 | April 30, 2025 |
|---|---|---|
| Medical rental equipment | $ 83,053 | $ 52,670 |
| Test equipment | 3,490 | 3,115 |
| Office equipment and furniture | 1,517 | 1,446 |
| Leasehold improvements | 919 | 919 |
| Work in progress | 1,538 | 635 |
| Total property and equipment | 90,517 | 58,785 |
| Less: accumulated depreciation | (31,427) | (23,955) |
| Total Property and equipment, net | $ 59,090 | $ 34,830 |

The Company recorded $8,709 and $7,968 of depreciation expense for the years ended April 30, 2026 and 2025, 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.

In December 2025, the Company amended its office leases to extend the lease term through April 2031. The extended lease term resulted in a re-measurement resulting in the increase of the lease liability and right of use asset by $1,585.

In May 2025, the Company entered into a new lease agreement for an office in Texas, commencing on May 15, 2025. The lease is set to expire on May 31, 2027.

Operating lease expense was as follows for the periods below:

| | Year Ended April 30, | |
|---|---|---|
| | **2026** | **2025** |
| Operating lease expense | $ 984 | $ 758 |
| Variable lease expense | 680 | 636 |
| Total operating lease expense | $ 1,664 | $ 1,394 |

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 $2,081 and $655 for the years ended April 30, 2026 and 2025, respectively.

The weighted average remaining lease term for the Company's operating leases was 60 months as of April 30, 2026, and 48 months as of April 30, 2025. The weighted average discount rate used to calculate the net present value of the Company's operating lease liabilities was 12.0% as of April 30, 2026 and 15.2% as of April 30, 2025.

Maturities of operating lease liabilities (net reimbursements) were as follows as of April 30, 2026:

| | | |
|---|---|---|
| Fiscal Year: | | |
| 2027 | | 43 |
| 2028 | | 1,346 |
| 2029 | | 1,477 |
| 2030 | | 1,424 |
| 2031 | | 1,589 |
| Total future lease payments | $ | 5,879 |
| Less: imputed interest | | (1,737) |
| Total lease liability balance | $ | 4,142 |
| Less: current portion of lease liability | | (31) |
| Total lease liability, net of current portion | $ | 4,111 |

**6. Accrued Liabilities**

Accrued liabilities consisted of the following at:

| | April 30, 2026 | April 30, 2025 |
|---|---|---|
| Bonuses and commissions | $ 10,885 | $ 6,368 |
| Other accrued liabilities | 5,486 | 3,547 |
| Paid time off | 3,050 | 2,305 |
| Professional services | 1,133 | 1,141 |
| Payroll and payroll taxes | 2,492 | 468 |
| Total Accrued liabilities | $ 23,046 | $ 13,829 |

**7. Long-Term Debt**

On September 29, 2023, the Company entered into a Credit Agreement with a lender that provided a Senior Secured Delayed Draw Term Loan Facility (as amended, the "Term Loan 2024") in an aggregate principal amount of up to $60,000 and 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 $75,000, and two follow on tranches of $7,500 which became available before November 1, 2024, and February 1, 2025, dependent upon achievement of revenue milestones of trailing twelve-month revenues of $50,000 and $70,000, 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 had the ability to pay-in-kind up to 2% of the payable interest. The Term Loan 2024 requires a minimum level of cash of $3,000 and certain revenue thresholds based upon trailing twelve-month revenue results. The revenue covenant began to be measured on April 30, 2024.

On September 29, 2023, the Company drew an initial $45,000. In connection with the first draw, the Company incurred a 1% facility fee of the total available loan amount of $60,000 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, 2026, 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 (the "2033 Warrant") to purchase up to 325,847 Common Shares of Kestra Medical Technologies, Ltd. with an exercise price of $11.54. The 2033 Warrant expires on September 29, 2033. The 2033 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 exercisable for Common Shares with a value equal to 10% of the amount funded.

On September 4, 2025, the lender fully exercised the 2033 Warrant to purchase Common Shares on a cashless basis, resulting in the issuance of 100,397 Common Shares and the cancellation of the 2033 Warrant.

The Company's long-term debt consisted of the following at:

| | April 30, 2026 | April 30, 2025 |
|---|---|---|
| Term loan | $ 45,000 | $ 45,000 |
| Accumulated paid-in-kind interest applied to term loan balance | 1,395 | 1,395 |
| Less: unamortized debt issuance costs and debt discount | (3,746) | (5,297) |
| Total long-term debt | $ 42,649 | $ 41,098 |

The Company recognized expenses related to the Term Loan 2024 as follows:

| | Year Ended April 30, | |
|---|---|---|
| | 2026 | 2025 |
| Cash interest expense | $ 5,645 | $ 4,851 |
| Amortization of the facility fee and legal fees | 380 | 874 |
| Amortization of the debt discount recognized in connection with the warrant | 1,521 | 526 |
| Interest expense paid-in-kind and applied to the Term Loan 2024 balance | — | 855 |
| Total expense recognized related to the Term Loan 2024 | $ 7,546 | $ 7,106 |

**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, 2026 and 2025.

| | Level 1 | Level 2 | Level 3 |
|---|---|---|---|
| **April 30, 2026** | | | |
| **Assets** | | | |
| Money market funds | $ 22,146 | $ — | $ — |
| U.S. treasury securities | — | 195,338 | — |
| Total assets | $ 22,146 | $ 195,338 | $ — |
| **Liabilities** | | | |
| Warrant liabilities | — | — | 1,369 |
| Total liabilities | $ — | $ — | $ 1,369 |
| **April 30, 2025** | | | |
| **Liabilities** | | | |
| Warrant liabilities | — | — | 8,097 |
| Total liabilities | $ — | $ — | $ 8,097 |

The Company classifies its money market funds, which are valued based on quoted market prices in active markets with no valuation adjustment, as cash equivalents within the fair value hierarchy.

The fair value and amortized cost of available-for-sale marketable securities as of April 30, 2026 are presented in the following table:

| | Amortized Cost Basis | Gross Unrealized | | Fair Value |
|---|---|---|---|---|
| | | Unrealized Gains | Unrealized Losses | |
| **Assets** | | | | |
| Money market funds | $ 22,146 | $ — | $ — | $ 22,146 |
| U.S. treasury securities | 195,556 | — | (218) | 195,338 |
| Total | $ 217,702 | $ — | $ (218) | $ 217,484 |

As of April 30, 2026 available-for-sale marketable securities are classified as follows in the consolidated balance sheet:

| ***Category:*** | |
|---|---|
| Cash and cash equivalents | $ 54,993 |
| Short-term investments | 96,724 |
| Long-term investments | 65,767 |
| Total | $ 217,484 |

Short-term investments have a contractual maturity date that is one year or less from the respective balance sheet date. Long-term investments have a contractual maturity date that is more than one year from the respective balance sheet date. The Company recognized no credit losses during the years ended April 30, 2026 and 2025, and had no allowance for credit losses as of April 30, 2026, and 2025.

As of April 30, 2026 and 2025, the fair value of the long-term debt, net of discounts, approximated $47,700 and $47,330, 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.

There were no transfers into or out of the Level 1, 2 or 3 fair value hierarchies during the years ended April 30, 2026 and 2025.

***Warrant Liabilities***

As of April 30, 2026, 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, 2026, 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 $2,673 for the year ended April 30, 2026, 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, 2026:

| | April 30, 2026 | April 30, 2025 |
|---|---|---|
| Strike price | $ 11.54 | $ 11.54 |
| Expected term (in years) | 7.42 | 8.42 |
| Expected volatility | 59.00% | 65.00% |
| Risk free rate | 4.20% | 4.21% |
| Dividend yield | 0% | 0% |

A reconciliation of the Level 3 liabilities is as follows:

| | | |
|---|---|---|
| Fair value of Level 3 liabilities as of April 30, 2025 | $ | 8,097 |
| Change in fair value of warrant liabilities | | (2,673) |
| Exercise of warrant | | (4,055) |
| Fair value of Level 3 liabilities as of April 30, 2026 | $ | 1,369 |

**9. Common Shares**

The Company had 100,000,000 Common Shares authorized and 58,383,924 and 51,348,656 Common Shares issued and outstanding with a par value of $1.00 per Common Share as of April 30, 2026 and April 30, 2025, respectively. Each Common Share is entitled to one vote.

**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.

In May and July of 2024, Intermediate Holdings issued to West Affum LP a total of 103,400 shares of preferred stock for proceeds $103,400. 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'. There were no shares of preferred stock outstanding as of April 30, 2026 and April 30, 2025.

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, 2026 or 2025. 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. Effective on December 31, 2025, West Affum LP was dissolved and all of the Common Shares it had received at IPO were distributed to its unit holders.

**12. Equity Incentive Plan and Share Based Compensation**

***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 separation. Incentive Units do not expire and have no exercise price. Compensation cost of Incentive Units is estimated on the date of grant.

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, 2024** | 2,130,143 |
| Granted | 1,192,999 |
| Forfeited / repurchased | (192,405) |
| Exchanged into common shares | (3,130,737) |
| **Outstanding at April 30, 2025** | — |

***Restricted Common Units and Restricted Shares***

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. In connection with the IPO, the restricted common units converted into 23,899 restricted Common Shares of Kestra Medical Technologies, Ltd., subject to continued vesting under the original grant agreements. As of April 30, 2026, 19,916 and 3,983 of these Common Shares were vested and unvested, respectively. As of April 30, 2025, 11,950 and 11,950 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 45,479 restricted Common Shares of Kestra Medical Technologies, Ltd., subject to continued vesting under the directors' original grant agreements. During the year ended April 30, 2026, 18,795 restricted Common Shares vested. As of April 30, 2026, there were 23,822 and 21,657 shares of vested and unvested restricted Common Shares outstanding. As of April 30, 2025, there were 12,994 and 32,485 shares of vested and 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.

In connection with the IPO, the Company entered into the Kestra Medical Technologies, Ltd. 2025 Omnibus Incentive Plan (the "2025 Omnibus Incentive Plan") to grant eligible individuals incentive equity awards, including stock options and restricted stock units. Stock option and restricted stock unit activity for the year ended April 30, 2026 is as follows:

***Stock Options***

Stock options activity for the year ended April 30, 2026 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, 2025** | 4,649,100 | $ 17.04 | 9.85 | $ 32,640 |
| Forfeited | (109,721) | 17.38 | | |
| Exercised | (34,871) | 17.00 | | |
| **Balance at April 30, 2026** | **4,504,508** | **17.04** | **8.85** | 16,675 |
| Vested and exercisable at April 30, 2026 | 3,182,286 | 17.04 | 8.85 | 11,768 |

Also as of April 30, 2026, unrecognized compensation cost for outstanding stock options was $12,539, with the weighted-average period over which this cost is expected to be recognized at 0.45 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, 2026 was $10.20 per share.

***Restricted Stock Units***

The 2025 Omnibus Incentive Plan also allows for the grants of restricted shares and restricted stock units. During the year ended April 30, 2026, the Company granted restricted stock units which vest under three methods:

- Three-year service period restricted unit grants which vest one-third on each of the first, second and third anniversaries of the date of grant. The fair value of these restricted stock units is determined based upon the Company's stock price on the date of grant and expensed over the service period.

- Performance-based restricted stock unit grants that vest after one year only if the Company has achieved curtained performance objectives as defined and approved by the Company's Board of Directors. The fair value of the performance awards is determined based on the Company's stock price at the date of grant and expensed over the performance period based on the probability of achieving the performance objectives. If such targets are not met or service is not rendered for the requisite service period, no compensation cost is recognized, and any recognized compensation cost in prior periods will be reversed.

- Market-based restricted stock units that have combined market conditions and service conditions for vesting, for which the Company uses the Monte Carlo valuation model to value equity awards (as of the date of grant). Compensation cost is not adjusted if the market condition is not met, as long as the requisite service is provided.

*Time Based Restricted Stock Units*

Restricted stock unit activity for the year ended April 30, 2026 is as follows:

| | Number of restricted units | Weighted average grant date fair value |
|---|---|---|
| **Outstanding at April 30, 2025** | — | $ — |
| Granted | 2,655,737 | 17.56 |
| Forfeited | (155,779) | 16.95 |
| **Outstanding at April 30, 2026** | **2,499,958** | **$ 17.60** |

As of April 30, 2026, there was $34,052 of total unrecognized compensation cost related to unvested restricted stock units that is expected to be recognized over a weighted-average period of approximately 2.38 years. As of April 30, 2026, none of the restricted stock units were vested.

*Performance Based Restricted Stock Units*

During the year ended April 30, 2026, the Company granted 434,702 performance-based restricted stock units that vest upon achieving curtained performance objectives. Achievement of these performance objectives was deemed probable during the three months ended July 31, 2025. The weighted average grant date fair value is $16.04.

As of April 30, 2026, there was no unrecognized compensation cost related to unvested performance-based restricted stock units. As of April 30, 2026, none of the performance-based restricted stock units were vested.

*Market Based Restricted Stock Units*

During the year ended April 30, 2026, the Company granted 217,351 market-based restricted stock units that vest upon achieving both market conditions and service conditions.

The Company estimated the fair value of the market-based restricted stock units granted using a Monte Carlo simulation model with the following assumptions:

| | April 30, 2026 |
|---|---|
| Expected volatility | 54.6% |
| Expected term | 1.76 years |
| Risk free rate | 3.91% |
| Fair value of underlying common stock | $ 17.30 |
| Weighted average grant-date fair value per share | $ 20.25 |

As of April 30, 2026, there was $2,741 of total unrecognized compensation cost related to unvested market-based restricted stock units that is expected to be recognized over a weighted-average period of approximately 1.21 years. As of April 30, 2026, none of the market-based restricted stock units were vested.

***Employee Stock Purchase Plan***

Under the 2025 Employee Stock Purchase Plan (the "ESPP"), participants are permitted to purchase shares of Common Shares, up to the IRS allowable limit of $25,000 in any calendar year and no more than 1,000 shares on any purchase date, through contributions (in the form of payroll deductions or otherwise to the extent permitted by the administrator of the ESPP) of up to 15% of their eligible compensation. The ESPP provides for offering periods not to exceed 27-months, and the Company anticipates each offering period to consist of one or more six-month purchase periods. Participants are permitted to purchase shares of the Company's Common Shares at 85% of the lower of the fair market value of the Company's Common Shares on the first trading day of an offering period or on the last trading date in each purchase period in the applicable offering period. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares. Participation ends automatically upon termination of employment with the Company. No purchases were made during the year ended April 30, 2026.

***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, | |
|---|---|---|
| | **2026** | **2025** |
| Research and development | $ 3,601 | $ 1,964 |
| Selling, general and administrative | 30,043 | 22,307 |
| Total share-based compensation expense | $ 33,644 | $ 24,271 |

**13. Income Taxes**

The components of loss before income taxes are as follows:

| | **2026** | **2025** |
|---|---|---|
| U.S. Operations | $ (116,148) | $ (105,417) |
| Foreign Operations | (15,171) | (8,262) |
| Total | $ (131,318) | $ (113,679) |

In 2025, the Company completed its restructuring in connection with its initial public offering. The Company's parent company is based in Bermuda and is a resident for Irish tax purposes. Its subsidiaries are 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.

As a result of the restructuring completed in connection with the initial public offering, 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, 2026 and 2025, the Company provided a full valuation allowance against its net deferred tax assets that we believe, based on the weight of available evidence, are not more likely than not to be realized.

Income tax expense for the year ended April 30, 2026 differs from the amount of income tax determined by applying the applicable Irish statutory tax rate to pretax income as a result of the following differences. For purposes of the reconciliation between the provision (benefit) for income taxes at the statutory rate and the effective tax rate, an Irish 12.5% rate is applied to pretax income as a result of the following for the year ended April 30, 2026:

| | Year Ended April 30, 2026 | |
|---|---|---|
| | **Amount** | **Percentage** |
| **Irish Statutory Tax Rate** | $ (16,415) | 12.5% |
| **Foreign Tax Effects** | | |
| US | (9,873) | 7.5% |
| State Tax Provision (net of Federal Benefit) | (2,871) | 2.2% |
| Other | 503 | (0.4%) |
| **Non-deductible Expenses** | | |
| Stock-Based Compensation | 6,656 | (5.1%) |
| Other | 696 | (0.5%) |
| **Tax Credits** | | |
| R&D Credit | (395) | 0.3% |
| **Other** | (155) | 0.1% |
| **Change in Valuation Allowance** | 22,148 | (16.9%) |
| | $ 294 | (0.2%) |

As previously disclosed for the year ended April 30, 2025, prior to the adoption of ASU 2023-09, income tax expense differs from the amount of income tax determined by applying the applicable U.S. statutory federal income tax rate to pretax income as a result of the following differences:

| | **2025** |
|---|---|
| Tax provision (benefit) at statutory rate | $ (28,420) |
| Foreign Rate Differential | 4,719 |
| State Tax Provision (net of Federal Benefit) | (4,110) |
| Non-deductible Expenses | 3,561 |
| R&D Credit | (402) |
| Other | - |
| Change in Valuation Allowance | 24,787 |
| | $ 135 |

Significant components of the deferred tax assets and liabilities are as follows:

| | 2026 | 2025 |
|---|---|---|
| **Deferred Tax Assets** | | |
| Loss Carryforwards | $ 80,953 | $ 52,281 |
| Interest Carryforward | 6,661 | 7,211 |
| Accrued Expenses | 1,563 | 4,553 |
| Operating Lease Liability | 716 | 539 |
| Inventory Basis Differences | 308 | 224 |
| R&D Credit Carryforward | 5,912 | 5,517 |
| Intangible Asset | 35,375 | 35,375 |
| Stock Based Compensation | 6,156 | 4,998 |
| | 137,644 | 110,698 |
| Less: Valuation allowance for deferred tax assets | (125,962) | (103,815) |
| Net deferred tax assets | $ 11,682 | $ 6,883 |

| | 2026 | 2025 |
|---|---|---|
| **Deferred Tax Liabilities** | | |
| Property and Equipment | $ (10,658) | $ (6,233) |
| Prepaid Expenses | (591) | (533) |
| Right-Of-Use Asset | (541) | (257) |
| Other | (198) | — |
| Total Deferred Tax Liabilities | (11,988) | (7,023) |
| Net deferred tax assets (liabilities) | $ (306) | $ (140) |

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 for the year ended April 30, 2026 are as follows:

| | 2026 | Expiration Years |
|---|---|---|
| Net operating losses, federal (Pre-TCJA) | — | |
| Net operating losses, federal (Post-TCJA) | 322,006 | Indefinite |
| Net operating losses, state | 97,540 | Various |
| Tax credits, federal | 6,336 | 2039 - 2043 |
| Tax credits, state | — | |
| Net operating losses, foreign | 43,657 | Indefinite |
| Tax Credits, foreign | — | |

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:

| | 2026 |
|---|---|
| Unrecognized Tax Benefit - Beginning of Year | $ 819 |
| Additions - current year | 44 |
| Additions - prior year | — |
| Decreases - prior year | — |
| Unrecognized Tax Benefit - End of Year | $ 863 |

All of the unrecognized tax benefits as of April 30, 2026 are accounted for as a reduction in our deferred tax assets. Due to the valuation allowance, none of the $863 of unrecognized tax benefits would affect our effective tax rate, if recognized. We do not believe it is reasonably possible that our unrecognized tax benefits will significantly change in the next twelve months. We recognize 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, 2026 or April 30, 2025. We do not expect any significant change in our 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, 2026, there are no penalties or accrued interest recorded in the financial statements.

**14. Commitments and Contingencies**

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. From time to time, the Company may become involved in litigation relating to claims arising from the ordinary course of business.

The Company enters into indemnification agreements with its officers and directors, and the Company's bye-laws include similar indemnification obligations to its officers and directors. To date, there have been no claims under any indemnification provisions, and therefore there is no accrual of such amounts as of April 30, 2026 and 2025. 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, 2026 and 2025, matching and discretionary contributions by the Company totaled $2,240 and $1,660, 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 Company's equity offerings 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 consolidated balance sheets and consolidated statements of changes in redeemable preferred stock and shareholders' equity

(deficit) represents the number of shares legally outstanding as of the latest 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 to purchase Common Shares. 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, 2026 or 2025, 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.

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, 2026 and 2025:

| | Year Ended April 30, | |
|---|---|---|
| | **2026** | **2025** |
| **Numerator:** | | |
| Net loss attributable to Kestra Medical Technologies, Ltd. | $ (131,612) | $ (113,814) |
| Undeclared preferred dividends | — | (12,321) |
| Net loss attributable to common shareholders | $ (131,612) | $ (126,135) |
| **Denominator:** | | |
| Weighted average shares of common share outstanding - basic and diluted | 54,184,698 | 24,583,745 |
| **Net loss per share attributable to common shareholders - basic and diluted** | $ (2.43) | $ (5.13) |

The following potentially dilutive securities outstanding have been excluded from the computations of weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares):

| | As of April 30, | |
|---|---|---|
| | **2026** | **2025** |
| Stock options | 4,504,508 | 4,649,100 |
| Restricted stock units | 2,499,958 | — |
| Performance-based restricted stock units | 434,702 | — |
| Market-based restricted stock units | 434,702 | — |
| Restricted stock | 25,640 | 32,485 |
| Warrants to purchase Common Shares | 109,069 | 434,916 |
| Employee Stock Purchase Plan | 68,142 | — |
| **Total** | 8,076,721 | 5,116,501 |

**17. Subsequent Event**

On July 10, 2026, Kestra Medical Technologies, Inc. (the "Borrower"), a wholly-owned subsidiary of the Company, and other credit parties thereto (the "Credit Parties"), entered into a loan agreement (the "Loan Agreement") with BPCR Limited Partnership and BioPharma Credit Investments V (Master) LP (each, a "Lender") and BioPharma Credit PLC, as collateral agent. The Loan Agreement provides for a five-year senior secured term loan facility of up to $200.0 million, divided into four tranches: (i) a committed Tranche A Loan in an aggregate principal amount of $75.0 million (the "Tranche A Loan") which was funded on July 10, 2026 (the "Tranche A Closing Date"); (ii) a committed Tranche B Loan in an aggregate principal of $25.0 million (the "Tranche B Loan") which may be requested, subject to certain limited conditions, at the Borrower's option through July 31, 2027; (iii) a committed Tranche C Loan in an aggregate principal amount of $50.0 million (the "Tranche C Loan") which is available to the Borrower upon reaching a trailing twelve-month revenue of $150.0 million and which may be requested on or prior to June 30, 2028 and (iv) an uncommitted Tranche D Loan for acquisitions at the Company's option in aggregate principal amount of $50.0 million (the "Tranche D Loan" and collectively with the Tranche A Loan, the Tranche B Loan, and the Tranche C Loan, the "Term Loans"), subject to certain limited conditions and upon approval of the Lenders, on such date mutually agreed upon between the Lenders and the Borrower.

The Borrower's net proceeds from the Tranche A Loan were approximately $20.0 million, after deducting estimated debt issuance costs, fees and expenses, and repaying the Borrower's obligations under Term Loan 2024 on July 10, 2026. The remaining proceeds will be used to fund the Company's general corporate and working capital requirements.

The Term Loans mature on July 10, 2031 (the "Maturity Date"). The Term Loans bear interest as a variable rate per annum equal to a 5.50% plus three-month Secured Overnight Financing Rate ("SOFR") with a SOFR floor of 3.25%. Interest is due and payable on the last day of each quarter, with payment beginning in the calendar quarter immediately following July 10, 2026. The Loan Agreement requires the Borrower to pay an amount equal to 1.75% of the Lenders' total committed amount to fund the Term Loans, payable with respect to each Term Loan on the funding date of such Term Loan. The Term Loans provide for 48 months of interest-only payments and amortizes in four equal quarterly installments beginning in the second fiscal quarter of 2030 and continuing through the Maturity Date. The Term Loans may be voluntarily prepaid in whole (but not in part), and are subject to make-whole, prepayment premium and exit fees, and must be prepaid upon a Change in Control (as defined in the Loan Agreement). The Borrower is required to maintain a minimum liquidity of at least $20.0 million in cash and cash equivalents at all times.

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